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## **IDENTIFICATION OF EXTERNAL CRITICAL SUCCESS FACTORS IN BIOTECHNOLOGY FIRMS**

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### **ABSTRACT**

Biotechnology is expected to change production methods, the products themselves and the structure of the industries in the new economies. Hopefully, countries in the Middle-East, Latin America, Asia and Africa have already recognized the importance of biotechnology's promise. In this sense, the importance of externalities which might affect the success or failure of these companies becomes an issue of paramount importance. In the present study, we will try to identify the main external factors which could lead in the success of biotechnology firms in Iran. To do so, the research follows a qualitative research design to answer this main question. Based on our findings, critical success factors are categorized in the following categories: General Environment (GE), Political Position (PP), Economic Position (EP), and Market Position (MP).

**Keywords:** Biotechnology, External Success Factors, Iran

## 1. INTRODUCTION

Despite high interest in developing the biotechnology industry as the growth engine of the future national economy in developed and developing countries, few empirical studies have been used to scrutinize critical success factors in the biotechnology sector in countries with industry in early development stages. In this study, we review the relevant literature, and start our investigation from a developing country of interest, i.e. Iran. But, to investigate the topic in a better manner, we should firstly define biotechnology. Biotechnology was defined in 1919 by Karl Ereky<sup>1</sup>, in order to describe methods and techniques which produce substances from raw materials with the aid of living organisms (FÁRI AND; KRALOVÁNSZKY, 2006).

A standard definition of biotechnology was proposed and agreed upon in the Convention on Biological Diversity in 1992, which argues: "any technological application that uses biological systems, living organisms or derivatives thereof, to make or modify products and processes for specific use" (YOUNG, 1986). This definition was agreed by 168 member nations, and accepted by the Food and Agriculture Organization of the United Nations (FAO) and the World Health Organization (WHO) as well (MAHBOUDI et al, 2012).

Keeping pace with the growing importance of biotechnology and its potential to address some of our urgent needs such as those in food and health care industries, a spurious and somewhat bogus debate on biotechnology business has been started in Iran. The last decade has also seen a significant growth in importance of biotechnology firms in numbers of establishments and also in employment. This research concentrates on identification of external success factors in biotechnology business in Iran. Then, the main question is: "what are the critical external success factors of biotechnology firms in Iran?" In order to answer this research question, we follow a qualitative approach which includes interview sessions. In order to do so, first of all we review the theoretical background of this area and then we will discuss the methodology. Afterwards, the findings of our study are presented and the paper concludes.

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<sup>1</sup> a Hungarian engineer

## **2. LITERATURE REVIEW**

Today, the pharmaceuticals, biotechnology, medical devices, and diagnostics form the backbone of a growing and rapidly integrating life science industry complex (LSIC) estimated to be worth a trillion dollars in sales. There is every indication that the importance of this set of science based industries will grow very significantly in the future. Indeed a number of prestigious reports speak of the emergence of a bio-economy by 2020 or 2030 (MROCZKOWSKI, 2010). In recent decades, Iranian policymakers tried to facilitate the infrastructure movement in the area of biotechnology. In 2004, a long-term plan for the national biotechnology policy was prepared in which different aspects of biotechnology have been defined in terms of education, research, production, and international relations. In recent times, the Ministry of Health and Medical Education has allocated a considerable grant especially for biotechnology in all Iranian universities. This special grant reveals the great importance of biotechnology in the current 5-year plan of national development. It should be noted that the research activity and importance of biotechnology had a strong impact on the progress of this field in the country. A recent trend toward the export of biotechnology products manufactured by private companies has started. It is noteworthy that some Iranian biotech products have been exported to Europe, South America, India, Egypt and Pakistan (MAHBOUDI, 2005; LARIJANI; ZAHEDI, 2007; JOSHI, 2013).

Critical success factors have been defined as “those few critical areas where things must go right for the business to flourish” (ROCKHART, 1979). Critical success factors are particularly useful to practitioners as they provide clear guidance on where to focus attention (SHANKS et al, 2000). Critical success factors and performance indicators provide the biotechnology industry with a foundation on which to grow and manage risks. There is a huge demand in the industry to define the success factors that dictate what makes a company successful. This need is driven by the reality that in order to attract capital to promote industry growth, investors require predictable indices (VANDERBYL; KOBELAK, 2007).

New biotechnology firms often set up in regions that have innovative firms, government laboratories and universities, which attract them to enter (NIOSI; BAS, 2001). A number of emerging economies increasingly expend resources to improve national innovative capabilities and create knowledge economies through the

development of biotechnology industries. Standard measures and ways of tracking biotechnology industry progress, such as those used by the OECD, were designed for developed economies (MROCZKOWSKI; ELMS, 2009).

In future, biotechnology will become an even more global industry and new entrants from emerging economies will continue to make efforts to become players. Emerging market governments and private sector leaders are aware of the strategic importance of the bioeconomy for the future and of the opportunities that the rapid international outsourcing of R & D may bring. A number of emerging economy governments have launched national "catch up" policies of rapid biotechnology development, including Singapore, Taiwan, Brazil, and South Korea (MROCZKOWSKI; ELMS, 2009). Iranian government also launched a variety of policies to develop biotechnology industry. The main institutes involved in the biotechnology sector of the country are as follows:

- National Institute for Genetic Engineering and Biotechnology,
- Pasteur Institute of Iran,
- Razi Institute for Vaccine development,
- Universities (Sharif University, Tarbiat Modares University, Tehran University of Medical Sciences, Mashhad University of Medical Sciences, Gorgan University of Medical Sciences, Zanjan University of Medical Sciences, Hamadan University of Medical Sciences, Shiraz University of Medical Sciences, Semnan University of Medical Sciences, Tehran University, Tabriz University of Medical Sciences, Shahid Beheshti University of Medical Sciences, and Islamic Azad University),
- Persian Gulf Biotechnology Research center,
- Agriculture Biotechnology Research Center,
- Royan Research Centers, and
- Avacinna Research Centers.

The principal policies in biotechnology sector of the country include: National Biotechnology Committee at Ministry of Science, Research and Technology; National Strategic plan of Biotechnology; Biotechnology Committees at Ministry of Industry

and Mine, Ministry of Health, Ministry of Agricultural Jihad, Department of Environment protection. Moreover, the main priorities of Iranian biotechnology sector are:

- Molecular detection of infectious and genetic diseases
- Production of Recombinant medicines and vaccines
- Bioremediation
- Bioinformatics, Biosafety and Bioethics
- Transgenic plants Resistance to Biotic and Abiotic Stress
- Human Genome Diversity
- Bioleaching of Copper
- Oil desulphurization
- Privatization of Biotechnology Industry

The advancement of biotechnology as a successful industry, confronts many challenges related to research and development, creation of investment capital, technology transfer and technology absorption, patentability and intellectual property, affordability in pricing, regulatory issues and public confidence (MAHBOUDI et al, 2012). Based on the scientific research and reports, biotechnology techniques can solve several potential problems. But what is the opinion of ordinary people about these types of changes? Just a decade ago, the awareness of biotechnology was very low in most countries. For example, surveys indicated that only about one-third of consumers in the USA have heard or read much about biotechnology. In 1995, similar results obtained from Japan, France and UK (Hoban, 1997). Although during recent years, increased media coverage led to a significant increase in public awareness but not public knowledge (SHEIKHHA et al., 2006)

In sum, an entrepreneur planning to establish a biotechnology firm in Iran has to overcome a lot of different barriers. Partly, those are typical bureaucratic barriers making entrepreneurship difficult in general. However, there are also specific barriers related to spin-offs initiatives. On top of that there are special difficulties specific to the sector of biotechnology. Therefore, in this paper, we reviewed the literature and tried to identify the external critical success factors for biotechnology business in Iran.

### **3. METHODOLOGY**

The multiple case study research approach is used in this research. Case studies are used to study phenomena within their real world context (YIN, 1989), and may be used to build theory as well (EISENHARDT, 1989). In this study, a process model and a set of critical success factors were synthesized from the literature and provided a framework based on which interview protocols were developed and the multiple case study data is presented. The unit of analysis in the study is the management teams of the firms of our study. Multiple case study data was collected by two researchers, using interviews of approximately one and a half hours duration and based on the same interview protocol. Interviews were conducted with several different stakeholders within each of the companies. Other data was collected from project documentation and other company literature (DARKE, 1998). Data were collected in 2011-2012, based on the interviews from managing boards of 30 biotechnology firms in Iran.

### **4. RESULTS**

#### **4.1 General Environment (GE)**

Here, general environment is defined as "environment which parameters are relevant to all systems or organizations" (CVILIKAS et al, 2007; SALAMZADEH et al., 2011). More specifically, by general environment we mean those elements which are peripheral to biotechnology firms, and are not included in other three categories. The main elements are as follows:

- **Motivating environment:**

Motivating environment is of crucial importance in the success of biotechnology firms. The purpose of a motivating environment is to encourage every member of a biotechnology firm to motivate himself/herself to contribute his best effort to the job at all times (KAMERY, 2004). Based on our findings, a motivating environment is a critical success factor for biotechnology firms, as it helps these firms in handling their activities and paves the way for their success.

- **Culture:**

Culture is regarded as an emancipating way of approaching organizational phenomena, and as a metaphor for revitalizing organizational theory. Culture

consists of the patterns of meanings that link these manifestations together, sometimes in harmony, sometimes in bitter conflicts between groups, and sometimes in webs of ambiguity, paradox, and contradiction (MARTIN, 1992; SOOREH et al., 2011). An appropriate culture will make biotechnology firms more able to succeed in running their business. In contrast, an inappropriate culture might lead in the failure of biotechnology firms.

- Role models:

A role model is someone whose values, attributes, or accomplishments are admired, but the role but the role model may have no personal connection to his or her admirer (BECK; LAUDICINA, 2001). Role models can still be an effective means of imparting professional values, attitudes, and behaviors in biotechnology firms. These individuals could pave the way for the success of biotechnology firms as they are considered as the unwritten rules of the game.

#### **4.2 Political Position (PP):**

The political position is defined by the general legislative system of the society and designed legal considerations (SVENSSON, 1986). By political position, one might determine the ease of performance by biotechnology firms. Among these elements, the followings are of paramount importance for biotechnology firms.

- Rules and regulations:

Rules and regulations governing access and exchange of human biological samples are complex and depend upon the nature of the material, national legislation, the position of the countries, etc. (REYMOND, 2002; FARSI et al., 2013). Motivating rules and regulations could lead in a clear regulatory system which is a fertile ground to improve biotechnology business. Also, these could hamper the fluent and fluid activity of biotechnology firms.

- General support:

Products of biotechnology research may not be predicted and broad general support is needed (GREIF; MERZ, 2007). Otherwise, if general support is not available, the success of biotechnology firms might be unclear. General support is a vital factor in the success of biotechnology firms, as it could increase or decrease the degree of success for biotechnology firms.



- Political stability:

Political stability and the certainty and enforceability of property rights are two important issues for biotechnology firms (PERSAUD, 2001). In more stable countries, biotechnology firms could act more freely, while in less stable countries, the success of biotechnology firms is a function of bans, embargos, freedom, etc.

#### **4.3 Economic Position (EP):**

The economic position is defined by the general economic system of the society and economic realities, which can be improved by reducing disposal and liability costs, conserving resources, and improving an organization's public image (CARTER et al, 2000). Among these elements, the followings are considered as the most important ones:

- Liquidity:

The shareholdings of biotechnology firms are mainly composed of persons involved in biotechnology. The liquidity of such firms, when they are listed, may be reduced compared to other sectors that are easier to understand for a large public of investors (MANGEMATIN et al, 2003; LEVITAS; MCFADYEN, 2009).

- FDI:

Although foreign direct investment (FDI) cannot be regarded as a substitute for domestic capital, there is growing evidence that the firm can grow by tapping foreign investors (MALO; NORUS, 2009). These FDIs could lead in more improvements in both technology and techniques. As biotechnology is a high-tech industry, it highly relies on investments. This investment could be domestic or kind of FDI. In both cases, the investment will grow the pace of technology improvement and guarantee the success of biotechnology firms.

- Investment:

In the early stages of development, biotechnology firms miss no opportunity to signal the abilities of their scientists as well as the science they are undertaking. Especially, the scientists can also serve as bait to the investment community (AUDRETSCH; STEPHAN, 1996; TANHA et al., 2011). Growth of biotechnology is a function of investment in these firms.

#### 4.4 Market Position (MP):

The market position is defined by the market success and the strength of the market position in comparison to the competition (LECHLER, 2001). To some scholars market position is defined in terms of one firm's share of the total market and its relation to competitors in the industry (STEVENS et al, 1998). In this research, the following elements are the most important ones for biotechnology firms:

- Marketing and sales:

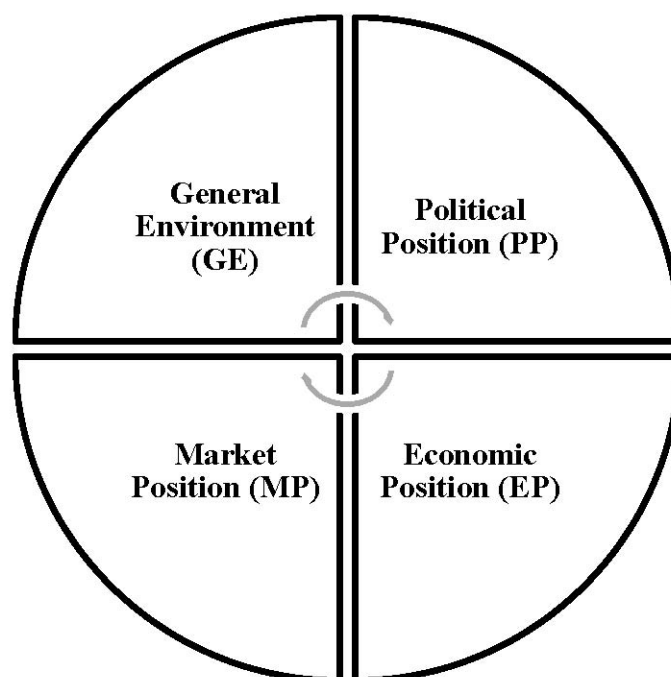
The commercialization of biotechnology is characterized by extensive cooperative arrangements. In comparison with not-fully integrated firms, the transaction value decreases if the fully integrated licensor has their own marketing and sales activities (KOLLMER; DOWLING, 2004).

- Rivalry:

Seemingly, product competition in biotech involves less rivalry (Powell, 1996), and more specialization. But, in these industries, the competitive landscape and the rules of competitive rivalry change constantly (GEORGE et al, 2002).

The following framework illustrates the external critical success factors for biotechnology firms.

Figure 1: External Critical Success Factors in Biotechnology Firms



## 5. CONCLUSION

The development of biotechnology is making rapid progress and the importance of biotechnology is growing. Nowadays, both developed and developing countries are competing in becoming pioneers in new areas of biotechnology. Therefore, gaining knowledge about the critical success factors is becoming of paramount importance in this domain. In this paper, we concentrated on Iranian biotechnology firms and investigated their success factors. But, a different point of view in this research deals with external factors which could be considered as the main institutional elements. Based on the findings, critical success factors are categorized in the following categories: General Environment (GE), Political Position (PP), Economic Position (EP), and Market Position (MP). General Environment (GE) is defined as "environment which parameters are relevant to all systems or organizations" (CVILIKAS et al, 2007) which includes: Motivating environment, Culture, and Role models. Political Position (PP) is defined by the general legislative system of the society and designed legal considerations (SVENSSON, 1986), and include: Rules and regulations, General support, and Political stability. Economic Position (EP) is defined by the general economic system of the society and economic realities, which can be improved by reducing disposal and liability costs, conserving resources, and improving an organization's public image (CARTER et al, 2000), and includes: Liquidity, FDI, and Investment. Market Position (MP) is defined by the market success and the strength of the market position in comparison to the competition (LECHLER, 2001), which includes: Marketing and sales, and Rivalry.

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