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The Barriers to Growth of Biotechnology Companies in Emerging Economies; Regional Case Study Analysis

Abstract:
This paper presents the key results emerging from the case study analysis carried out in SME biotechnology companies located in Lodz Region (Central Poland). The research was carried out in the form of face to face in depth interview with the key people representing biotechnology companies operating in the region. This research is a part of the larger project titled the "Conditions and Perspectives for Development of Biotechnology Companies in Poland".
The main findings of the research indicate the significant diversification between the barriers to growth of well established companies and the new business start-ups and university spin-offs. These differences in general are in line with typical variation of barriers to growth of business units along their cycle of development. In the case of newly established business units the most important barriers are associated with financial limitations and underdevelopment of financial institutions. The overall high capital intensity associated with long period of capital investment in the field of biotechnology are not recognised by financial institutions. Respondents stressed the lack of the competences of financial institutions and simplistic, underdeveloped and inappropriate approach to new business ventures' assessment. Excessive level of protection of intellectual property rights and its overall counter-productivity was also highlighted by the respondents. Well-established business units stress the importance of human barriers and barriers associated with the economic policy of the state and legal regulations. Especially associated with accounting regulations applicable to business R&D projects and the regulations associated with the administration of publicly funded research projects coordinated by the business units. Recent regulations shift the distribution of risk and in a process are discouraging for business units considering significant research and development projects. The respondents representing well-established business units also stressed the importance of market barrier associated with the inhibited level of acceptance of new innovative products originating from domestic companies.

Key words: biotechnology firms, growth, barriers, emerging economies, innovation, technological change.
JEL Classification: O1, O3, O4, D24

1. Introduction

Biotechnology encapsulates the substantial economic potential, supported by inputs from genomic research, biotechnology is a major force for progress and economic development in many countries. Biotechnology represents an important ingredient of knowledge based economy, economy where knowledge has become perhaps the most important factor determining the standard of living. This above average innovative potential of biotechnology in the realities of many emerging economies is not reflected by the economic activity of the business units. The existence of various barriers associated with shortage of resources including capital resources, advanced human skills and expertise, coupled with underdevelopment of various institutions and facilities in emerging economies inhibits an ample utilisation of various economic and business opportunities that modern biotechnology is offering. Increasing competition and changing nature of business risk in biotechnology industry creates the situation when at the present time the expertise is even more important because there is no room for making mistakes as it was "in early days" (Ernst & Young 2008).

Biotechnology represents the field of science that is related to vast advances in research and development and innovations of significant micro and macroeconomic potential. Even so called traditional biotechnology encapsulates substantial potential, that nowadays is significantly enriched by inputs from new areas like for instance genomic research. Biotechnology is a major force that supports economic development in many advanced countries. Numerous high profile reports forecast the advent of so called bio-economy between 2020 and 2030. The OECD (OECD 2009) report indicates that the commercialisation and application of new advanced biotechnologies by 2030 will contribute to 80 % of pharmaceutical and diagnostic, 35% of chemical and will account for up to 50% of agricultural output. The authors of this report suggest that the application of biotechnology will be far more widely spread in industry and agriculture than biologic and biopharmaceutical applications that are been utilised in contemporary biotechnology. What is even more important from the presented paper's point of view, it is expected that increase of the contribution of biotechnology to the economy is expected to be even greater in the case of emerging economies in comparison with the well-developed ones.

The level of development of biotechnological business ventures in Poland does not reflect the country's aspirations and the potential of research and educational base in the country. Therefore the identification and specification of the main barriers affecting the growth of biotechnology companies seem to be an issue of particular importance also from the perspective of other emerging economies, that might experience the similar conditions and business environment. The recently published OECD report Looking to 2060: A Global Vision of Long-Term Growth (OECD 2012) forecasts somehow moderate growth perspectives for polish economy, therefore the need for creating the more supportive environment for the knowledge intensive sectors of the economy is even stronger.

This in general terms above average potential of biotechnology in the realities of many emerging economies is not reflected in economic activity of business units. The shortage of resources and other specific barriers that biotechnology entrepreneurs are facing in emerging economies, including shortage of capital resources, lack of expertise and specific advanced human skills, certain institutional barriers, inhibit an ample participation in various economic and business opportunities that modern biotechnology is offering. In such a complex environment and in a face of the global economic slowdown the need for adequate supportive policies to sustain biotechnology innovation and investment is even stronger (Ernst & Young 2010).

2. Biotechnology Sector in Poland; an Overview

The sector of polish biotechnology firms is relatively small, currently there are around 60 to 70[1] biotechnology and over 140 pharmaceutical companies operating in Poland (see table 1 for details and international comparisons). According to The Report on Polish Biotech and Pharma (2012) despite the fact that the number of biotechnology business ventures in Poland is fairly limited the sector is recently growing, over half of the companies have been established in the last 5 years.

Table 1: Biotechnology Companies in the 14 New Member States and Candidate Countries

	Biotechnology - Therapeutics	Biotechnology / R&D Services	Biotechnology - other
Hungary	12	55	10
Poland	5	33	14
Czech Republic	0	29	10
Estonia	1	26	3
Turkey	2	10	5
Slovak	1	6	4
Slovenia	1	4	3
Romania	2	4	2
Lithuania	2	2	3
Latvia	1	4	1
Cyprus	1	1	
Croatia	2		
Malta		1	
Bulgaria		1	

Source: Report on Polish Biotech and Pharma (2012), www.biotech-pharma.pl and www.biotechgate.com

Biotechnology firms in Poland have a focus on healthcare but also on industrial-environmental applications. The industry is still in its infancy and revenues are modest. According to OECD Biotechnology Statistics 2009 there are 11 biotechnology R&D firms in Poland[2] and the overall picture of polish biotech sector is not particularly promising, suggesting rather stagnation than a significant progress. The majority of dedicated biotechnology firms employ less than 50 employees, all the dedicated biotechnology firms in Poland are small units. The share of firms with less than 50 employees ranges from 62% in the Philippines to 100% in Poland, with an average by country of 81%. Over the period between 2005 and 2007 the number of dedicated biotechnology firms in Poland remained the same, while over the same period of time the number of all biotechnology firms in New Zealand changed from 87 to 135, in Spain between 2004 and 2006 changed from 280 to 659. The business R&D expenditure of polish biotechnology companies is very low by

[1] Various reports suggest different figures

[2] Authors of the report suggest that the research probably underestimate of the true number.

international standards (OECD 2009). Despite the relatively low overall biotechnology R&D expenditure, the government sector in Poland undertakes the largest share of biotechnology R&D (43%). These figures together with low compound annual growth rates and low total biotechnology R&D expenditures in the business sector, might suggest stagnation and strongly unfavourable conditions for creation and growth of biotechnology business ventures in Poland. The low business R&D investment in Poland is in a sense typical also to other catching up economies. For instance in China the average business R&D investment in new drugs is roughly 10 times smaller in relative terms than in Japan and USA (Zhe and Xinghua 2011).

Biotechnology companies in Poland are relatively evenly distributed among major academic and business centres in Poland. Mainly in Warsaw (13), Krakow (11), Wroclaw (10), Gdansk together with Gdynia (10), Poznan (9), Lodz (9) and other cities (6). The innovative activities of Polish biotechnology firms focus mainly on new cosmetics, drugs for metabolic disorders, oncology drugs, food supplements and immunology drugs.

Table 2. The main groups of innovative products to be implemented by the Polish biotech companies in 2012 – 2017

Group of products	Share
New cosmetics	23%
Metabolic drugs	21%
Oncology drugs	16%
Food supplements	12%
Immunology drugs	8%
API (active pharmaceutical ingredients)	5%
Neurodegenerative drugs	5%
Molecular biology tools	3%
Other	7%

Source: Report on Polish Biotech and Pharma (2012), www.biotech-pharma.pl and www.biotechgate.com

Research and development projects of the biotech and pharma industry are conducted in over 100 scientific institutions. Most on-going research and development projects in Poland (over 70% of all biotechnology R&D projects) concern the development of innovative products, which can be applied in health care.

Table 3. Type of current biotechnology R&D projects in Poland

Type of project	Share
Drugs	38%
Medical materials	18%
Diagnostic kits	15%
Molecular biology tools	9%
Other	20%

Source: Report on Polish Biotech and Pharma (2012), www.biotech-pharma.pl and www.biotechgate.com

According to the authors of the Report: „Perspectives and directions of Polish biotechnology till 2013" (Bielecki 2005) the following areas of industrial biotechnology have the real and outstanding chances to develop in Poland in the near future:.

- Biofuels
- Enzymes production,
- Biomaterials / Biopolymers,
- Bio catalysis in synthetic organic chemistry,
- Bio refineries,
- Environmental biotechnology

The main existing industrial biotechnology installations in Poland include in the field of energy sector - the biodiesel sector – the first industrial installation has been already working but not for the Polish market. Further industrial installations are being constructed. In the field of biomaterials and biopolymers the main developments include bacterial cellulose that has excellent wound dressing capabilities and is a potential carrier of medicinal substances. Bio catalysis has been already successfully used in many industries (i.e. textile industry, detergent industry, food industry, feed industry, fermentation industry, brewing industry, pulp and paper industry, leather industry). In the field of environmental biotechnology the recent advances include application of molecular biology techniques in environmental biotechnology, detection of micro-pollutants and chiral compounds and development of efficient methods for their removal (pharmaceutics, endocrine disruptors, etc.), development of biotechnological hybrid methods, e.g. coupling biological processes with advanced oxidation processes, application of membrane techniques in environmental biotechnology (Bielecki 2005).

Conditions for development and perspectives of biotechnology sector in selected emerging economies are specified by the SWOT analysis of industrial biotechnology in Croatia, Czech Republic and Poland (see table 4 for details).

Table 4: SWOT analysis of industrial biotechnology in Croatia, Czech Republic and Poland. Summary of the Roundtables on Industrial Biotechnology

Croatia	**Czech Republic**	**Poland**
Strengths - Very long tradition in chemistry, biotech and engineering - Good level of scientists - « competition between research bodies »	**Strengths** - Traditional biotechnology (fermentation) - Pharma generics - Biotech machinery (but not very high level/quality machineries) - Good level of research and education	**Strengths** - Diversified research areas covered by research institutions - Knowledge and skills of Polish biotechnologists - High quality education - Raw materials base (developed agricultural sector) - Environment (diversity and low level of degradation)
Weaknesses - Lack of R&D from private sector - Lack of scientific students (lots still choose humanities)	**Weaknesses** - Lack of white biotech research - Lack of SMEs - Transfer of technology/research	**Weaknesses** - Lack of financing support (not enough VC) - Low demand for new high technologies from Polish industry

- No operative strategy for IB at government level - Lack of awareness about IB potential (Gov. Level, industry, citizens) - Budget for research is fragmented - Very low level of funding in applied research - Lack of up to date infrastructures	to industry (problem of innovation)	- Inadequate or unused research infrastructure - Lack of information flow mechanisms among groups dealing with IB - Small participation of applied research sector to IB - Inadequate support of IB by State authorities - Shortage of adequately educated managers to support the commercialization of biotechnological products
Opportunities - New government action plan for R&D - Funds are available in the EU accession instrument - Technology transfer and Innovation Centre	**Opportunities** - Pressure of "green processes", that will need cleaner technologies and processes (ex: REACH) - Algae & Waste treatment - Biofuels - Biomaterials - Food crisis (cf. GMO agriculture)	**Opportunities** - Development of science in chosen IB areas (action plan) - High educational level and attitude of students - Changes in law regulations connected to scientific research aimed at protecting and stimulation of research activities - Political declarations of improvement of mechanisms supporting investments in new technologies - Support to the development of industrial clusters by local and State authorities - Low labour costs (including research personnel costs) - Development of sectors connected with IB development
Threats - Competition between universities/institutes - Lack of communication and cooperation between academia and industry - Lack of political commitment	**Threats** - Food crisis (access to raw materials)	**Threats** - Ever decreasing and insufficient financing of scientific research - Lack of investments in research and new technologies connected with IB in enterprises - Foreign entities' competition which is often aimed at taking over Polish entities - Emigration of young, educated personnel

Source: Prepared on the basis of summaries of Roundtable Discussions on Industrial Biotechnology in Croatia, Czech Republic and Poland carried out under Bio-based Economy initiative.

The main recommendations for policy makers, that emerge from round table discussions carried out in the above mentioned countries include improvement in the field of matching between academia and industry needs, filling-in the gap between R&D and market, easier access to market - facilitate smoother bio-products entrance on the market, better policies to ensure conditions to promote Knowledge-Based Bio-Economy (KBBE) - the sector estimated to be worth more than € 1.5 trillion per year.

3. Barriers to growth of high-tech business ventures and the key success factors

The technology based companies encounter various barriers in the process of their development. Various studies conducted by independent institutions in Poland in the field of the barriers to growth of innovative companies in Poland point out the following main barriers [ ]:

- High cost of innovation and R&D projects,
- Insufficient financial resources within the companies,
- Difficult access to financial resources from external sources,

Less important barriers include:

- Difficulties in finding a business partner,
- Lack of information regarding new technologies and volume of demand for innovations,
- Low entrepreneurs' awareness of alternative means for capital rising,

Other specified barriers include:

- Incompatibility of technological solutions developed by R&D institutions to real life commercial applications,
- Underdeveloped infrastructure for commercialisation of effects of R&D activities,
- Low interest of research and development institutions in fostering cooperation with business units.

One can therefore identify, in the light of available research evidence, three groups of factors that may inhibit innovative activities and growth potential of high-tech ventures in Poland.

- Economic factors, i.e.: raising finances, cost and risks of innovative business ventures, risk of research and development activities and general business risk, tax issues and tax credits,
- Factors associated with knowledge accumulation, obtaining qualified personnel, access to innovation, availability of partners,
- Market factors, the volume of demand for innovation, business partners impact and pressure.

With regard to the issue of development of biotechnology ventures in Poland, the key success factors might be identified. They allow to identify the primary similarities and important distinctive features that differentiate innovative biotechnology companies in Poland with their counterparts in the West. The key success factors include (Mroczkowski 2010):

1. The combination of specialized biotechnology and business knowledge of market, commercial value of discovery and of competitive risk. This unique combination of competences in business and in science is vital for the development of a vision leading to the right selection of goals and directions for the research and development effort and also for attracting investors.
2. Successful acquiring and motivating of employees, recruiting talent at the national level and in creating motivational packages which will not only attract the most gifted persons, but will offer them on-going competitive with academia advancement

opportunities while giving them incentives to gain business experience in areas crucial to the firm's progress.

3. Professional management of partnerships that includes three competences of the manager: (1) awareness of the importance to crate partnerships, (2) ability to find the right partner, (3) on-going openness and capability of extracting the full benefits from a working partnership.
4. The ability of taking advantage of ever growing national and international forms of financing of innovative enterprises. In order to overcome the financial barrier companies are forced to pursue two parallel forms of activity, one aiming at securing income, the other related to R&D and breakthrough innovations. It is expected that as the sector matures this parallel model will become less important.
5. Organisational learning and inherent dynamic capability are perceived as the most critical factors of success at all the stages of the development of the firm. The continuous learning pertains to management and all personnel.

4. Barriers to growth of biotechnology companies; evidence from case studies

This section of the paper is based on case study analysis of small and middle size biotechnology companies located in Lodz Region (Central Poland), the survey has been carried out as the pilot study within a larger research project. Findings presented underneath are based on in-depth interviews carried out with managing directors and CEOs of small and medium sized biotechnology companies. The research sample includes both well-established business units and biotech business start-ups including university start-ups. Respondents were asked about various aspects of their business activities with the emphasis on condition and perspectives for development and barriers to growth of their companies. They were also asked to rank the importance of the identified barriers divided into categories specified underneath.

Prior to in depth interviews barriers to growth were divided into several categories based on recognised in literature methodology (Piasecki 1997), specified categories include:

1. The Market Barrier – associated with limited demand for products and services and other market issues,
2. The Financial Barrier – associated with limited access to the sources of funding,
3. The State Policy Barrier – associated with legal regulations, tax policy and licences,
4. The Human Barrier – associated with inadequate qualifications of work force and lack of possibilities to gain them,
5. The Property Barrier – associated with limited property (real estate) base both in qualitative and quantitative terms,
6. The Infrastructural Barrier – associated with insufficient development of technical and organisational infrastructure,
7. The Managerial Barrier – associated with weaknesses in the area of management,
8. The Psychological Barrier – including resistance to risk and lack of support from families, lack of entrepreneurial spirit,
9. The Corruption Barrier – associated with dishonest competition and corruption.

The most important barriers to growth of biotechnology companies identified on the basis of case study analysis include:

The Market Barrier

Technology based firms are in general facing the dilemma whether to on its own build the distribution network or to look for the business partner in the field of sales. The

importance of this factor is even greater in the case of the breakthrough technologies and products that potential customers are not familiar with. The novelty and originality of the product make the marketing effort even more uncertain and complicated. This in turn forces the company trying to sell innovative products on its own to allocate scars resources to marketing - including selling and distribution activities. In the respondents' opinions the existing distribution and sales firms show very limited interest in cooperation with biotechnology SME's especially in the field of marketing of new advanced products. The sales and distribution companies consider that type of business engagement as risky, inefficient and incurring additional excessive costs, that they are not ready to accept. In turn biotechnology SME's are trying to sell products on their own, what negatively affects their growth potential. It utilises limited resources and due to the lack of marketing and sales expertise, potential negatively affects the growth opportunities of biotechnology firms. This issue, identified in the process of the presented case study research, seems to have a significant potential for future scientific pursuits and its seems, on the basis of the results of the research, that some sort of specific public measures targeted to overcome the above specified market failures might be appropriated in order to unveil the true potential of biotechnology based business units in emerging economies and help to overcome the specific growth barriers they are facing. Specific instruments and policy measures would help the technology based entrepreneurs to concentrate on their core competences and help to allocate in the optimal way the unique human and intellectual capital, that is at their disposal, instead of engaging in the sales activities that they are most likely not familiar with and not especially keen on engaging into.

Another barrier to growth of biotechnology business ventures, that has been revealed in the course of the research is in a sense the mixture of market and regulation barriers. For the real breakthrough biotechnology (especially in the field of pharmacy) in order to gain a chance to enter the market the massive regulation barrier has to be overcome. This has to be done well in advance in order to properly manage the various aspects and phases of the innovation process. The study revealed the barrier associated with the substantial lack of competences available in the market. The respondents were stressing the significant shortage of patent attorneys and other law and regulation specialists in the above specified field. The market offer in that field, partly due to fairly limited market size, seems to be vastly underdeveloped both in quantitative and qualitative terms. Respondents claim that this issue constitutes a real barrier to growth especially in the field of true breakthrough pharmacy and healthcare biotechnologies. The issues like the index of approved substances and patent clarity ought to be known at the very early stage of the innovation process and business development. Especially the start-up university spin-off entrepreneurs need to know these things well in advance. The lack of experience in that field is of paramount importance for the development of advanced biotechnology business ventures, well targeted public measures to help to overcome specific market failures, seem to be indispensable in order to resolve this issue and create the more favourable environment for the development of true high tech new biotechnology business ventures. The quality of available business training and consultancy doesn't meet the specific and refined expectations of biotechnology entrepreneurs, this may suggest that the methods and priorities of EU funds allocation leaves much to be desired and more appropriate methods of public funds allocation need to be implemented at both EU, national and regional level, in order to foster the growth of biotechnology firms in emerging economies.

The Financial Barrier

In the case of financial barrier to the growth of biotechnology firms the two fold situation emerges. In the case of business start-ups and university spin-offs the financial barrier is considered by the respondents as the most important barrier affecting the growth of biotechnology companies in Poland. Biotechnology entrepreneurs consider the capitalization of venture capital funds and the scale of its activities as insufficient from the point of view of the needs of biotechnology industry, even at its early stage of development. Respondents stress that the biotechnology sector is not only exceptionally capital intensive but also requires relatively longer investment horizon. The typical pay-back period in the case of biotechnology research and development based business ventures and projects exceeds pay-back periods in other high-tech sector, on top of this as the firms grow the needs for external capital become even more substantial. Respondents claim that there is a noticeable lack of competences on the site of financial markets and institutions. Respondents underline that especially the projects and proposals of entities related to dedicated biotechnology are essentially outside the area of interest of financial institutions, or in the rare cases when it is not so, the project appraisal activities are based on external experts who quite often are accidental and represent limited understanding of the nature of the particular problem. The business model of financial and especially venture capital institutions is generally immature as far as project appraisal procedures and techniques are concerned. Respondents claim that venture capitalists use inadequate and simplistic 0 and 1 approach. In case that the company has already any product in the market the investment risk is assumed as low almost from the beginning. In the case when a company hasn't got any product in the market the risk is generally assumed as inacceptable, regardless the type of product this company is working on. As one of the respondents put it "in case that the venture capitalists have for instance, three project proposals, they most likely select the one that pretends in the best way that it is already in the market". In the opinion of biotechnology entrepreneurs the financial institutions are incapable of accessing properly the potential of biotechnology ventures.

The cases study research reviled an interesting strategy, that the biotechnology entrepreneurs developed in order to increase the likelihood of attracting the venture capital. Biotechnology entrepreneurs, who in fact work on truly new technologies and it is expected that it is going to take several years for the technologies to develop and the products to be ready to enter the market, in order to gain venture capital financing in a sense pretend that they are already in the market with their other products. In the process quite often the significant share of company resources and potential is allocated to rather trivial products that are already present in the market, like the food supplements for instance, and other products without, for instance, specified health claims. In the process company is capable of pretending that it is already in the market and quite often for an incompetent venture capitalist or other financial analyst it is in many cases almost identical with the truly innovative product and the potential of that kind of product is often overestimated by the financial market. Therefore certain market imperfections are possible to identify in that respect. At the same time the expectations and priorities of financial institutions are so, that the company that has the pre-money characteristic without the positive cash flow is typically treated by venture capitalists as representing a "zero potential". At the same time any, even marginal product, that reaches the sales in the range of i.e. 100 000 Euro pre year at the low profit margin, represents a sufficient basis for credible valuation on the basis of widely accepted and utilised by financial institutions models and techniques. These methods are quite often based on simplistic trend extrapolation techniques and methods of valuation based on discounted cash flow (DCF) techniques. It therefore seems to be advisable, in order to improve the process of capital allocation (to the benefits of both venture capitalists, business ventures and economy as a

whole) and in order to increase the likelihood of adequate project selection, that the typical discounted cash flow method ought to be enriched with project success probability factor and alternative business scenarios with specified probability of success. The respondents claim the in practice the situation is often even more unfavourable for biotech entrepreneurs, since in real business situations venture capitalists are not even interested in application of typical discounted cash flow method (without probability factor). Venture capitalists often, in the process of business negotiations are not surpassingly taking advantage of their outstanding bargaining power (due to unfavourable supply-demand market conditions and the overall inadequate capital supply in the economy) and impose the evaluation methods based on the actual costs and investment that the company covered so far. These methods are almost totally neglecting the intellectual capital and intangible assets. The business propositions are often put in this way, when the company has already spent say 250 000 Euro, the venture capitalist offers 250 000 Euro and expects 50% of company shares in return (while the real value of the business venture might be several millions of Euro or more). The research showed that in the entrepreneurs opinion the financial investors operating in the country do not have the clear vision of how to exit equity investment. This is partly due to the lack of experience and perhaps more importantly due to a number of unfavourable objective conditions. The objective shortage of the next stage investors in the country is probably, in the respondents opinion, one of the single most important factors. On the macroeconomic level the current stage of the national economy seems to be an important factor. Poland according to the international standards has not quite reached the innovative stage of the economic development. According to the Global Competitiveness Report 2011-2012 (2011) the country's economy is still in transition between efficiency stage of economy development and innovation stage. As the result the investors might have in general other, than risky and unpredictable innovation and technology based options, mainly efficiency oriented investment options available for them in the current state of the economy. The shortage of second stage investors hinders the capital circulation process and poses significance barrier to the development of biotechnology ventures. This might, in turn result with the limited interest towards investment in risky and unpredictable technology based business ventures, that they are not familiar with, like in the case of biotechnology. The dynamic and efficient circulation of equity capital in the economy is an important factor supporting the development of the new technology based firms. First stage investors (including the start-up entrepreneurs) should sell the company at or around the moment of product (i.e. medicine) registration are at the beginning of the first stage of clinical trials. Despite critical comments expressed by respondents towards financial institutions in general, one has to remember that biotechnology high tech business ventures and especially Pharmaceutical R&D are extremely risky fields of activity. Only around 10% of drugs entering development finally reach the market, and only 20% of marketed drugs recover their investment (Klaus, Joachim, et al., 2009).

The State Policy Barrier

As far as the state policy barrier is concerned respondents were stressing the lack of real financial, especially tax, incentives for undertaking research and development projects. In their opinion the situation has even deteriorated over recent years. The unrealistic state policy in the field of organisation and administration of publicly funded research and development projects was highlighted. According to recently introduced regulations the business units must act as the coordinator of research consortium of publicly funded R&D project and therefore take the full responsibility for the results of the project. This regulation and lack of flexible approach was strongly criticized by the respondents, since the company is often obliged to

cooperate with research partners (i.e. research institution; university or institute), that it's not particularly familiar with and in practical terms it's very difficult to take the full responsibility for the results of the partner's research and development work. This regulation has been recently introduced in order to strengthen the position of business units within the research consortium and in a sense ensure more market oriented publicly funded R&D activities, but in the respondents opinions it entails significant limitations for joint research and development undertakings. Respondents suggest the alteration of present regulations via the introduction of "external institutional coordinator-consultant" that assists the company in their R&D effort and somehow coordinates projects, acting in between business unit and research institution and helps to mitigates the R&D risk associated with the project coordination and execution. In recent years the coordination of the joint R&D projects, from the formal point of view, is becoming more complicated, availability of credible and comprehensive information regarding various aspects of project administration is critical for successful R&D ventures and proper risk management. Therefore the introduction of (perhaps not obligatory) "Institutional Joint Research Project Coordinator" will secure and provide source of credible and comprehensive information regarding various formal aspects of project execution and will help to mitigate the overall risk and cost (via reduction of i.e. alternative and transaction cost) of joint, business and academia R&D projects.

Further to the considerations specified above the certain subcategory of state policy barrier has been identified. This barrier does not particularly refer to the state's national level. In the first place it applies to both EU level and overall international regulations. The legal framework for business biotechnology ventures in EU is in the respondents' opinions overregulated and excessively complicated. They suggest that this is the result of deliberate activities of large multinational corporations aiming at limiting the market competition and through purposely creating specific regulatory barriers that the biotechnology SMEs, especially start-ups originating from emerging markets find in many cases impossible to overcome. The more pro-competition and pro-entrepreneurship oriented regulatory framework might stay behind the recent successes of i.e. Indian biotechnology and heath sector. The apparently excessive EU regulatory environment in the field of biotechnology and perhaps other high technology sectors should be the subject of deeper consideration at the EU level especially in the face of the current economic slowdown in Europe. The unfavourable legal conditions, due to excessive regulation and excessive protection of intellectual property rights, for the development of new technology ventures in Europe at least to certain extent explain the reason for relative success of biotechnology and health care business ventures in India and China. The respondents stress that problem of patent trolls in biotechnology is becoming gradually more important cost factor. They strongly stress the overall counter productivity of intellectual property rights protection system on one hand for the development of new technologies and on the other for the general public interest exemplified by the slowdown of the development process of new innovative products, i.e. medicines. Respondents claim that there is a need for the comprehensive discussion and the creation of the general models for development at the international level. This to the large extent has to do with the distribution of wealth between the rich and the perhaps significantly less rich and reflects the very important aspect of barriers to growth of technology oriented business units in emerging economies. The current situation is in general so that highly developed large economies dominate and are in the position to impose institutional solution that reflect the needs of their economies and at the same time are inappropriate and harmful for developing and emerging economies from the point of view of their growth opportunities. Respondents claim that certain economies, mainly BRIC countries are trying to implement solutions more

appropriate for their economies, while Poland and other emerging economies without the proper consideration accept solutions imposed by well-developed large economies unreasonably assuming that their conditions for development of high technology business ventures are closer to those of well-developed large economies, what in fact seems definitely not to be the case in the reality.

At the national and regional level the public measures targeted specifically to overcome the above specified barriers and conditions might include the rearrangement of university programs and curricula. In the respondents opinion the biotechnology students to the larger extent ought to be made aware of the various legal aspects of technology based business activities, if they are supposed to stand a chance in the real biotechnology business environment. The process of creation of legal framework at the national level, although the superior regulations do not leave much room for manoeuvre, also in the respondents opinions leaves much to be desired. In the respondents opinion the law at the level of the national state is in general created in the way hat "never" takes into account conditions and specific character of the new technology based firms and high tech sector in general, that is in Poland at the early stage of development and needs to be supported and taken care of, rather than controlled and excessively and unfavourably regulated (i.e. in terms of accounting regulations for business R&D costs clearance). On top of this there is a significant shortage of public attention and understanding of the conditions and specific character of the high-tech sector. Even public media seem to neglect this issue, perhaps due to the lack of public understanding and awareness, what results with low audience interest. The recent vibrant discussions about protection of intellectual property rights and ACTA in particular omit the important aspect of high tech business venturing and present the problem as it would only refer to artists and perhaps computer software issues. Another aspect of protection of intellectual property rights refers to the issue of excessive protection of intellectual property rights in academia and the subject of division of these rights between university itself and researchers developing the particular technology. The current model in the respondents' opinion is strongly unfavourable for the development of high tech in general and especially biotechnology business ventures. There are various models resolving the issue of distribution of intellectual property rights between university as an institution and the researchers as individuals. The Swedish model where the researcher is automatically gaining the rights to the intellectual property might be perhaps considered as in a sense far reaching, but it at least shows the significant room for the manoeuvre in that respect even within EU standards. This issue obviously reflects the significant and socially controversial aspect of the distribution of wealth but one has to answer the question of priorities and in fact the true social interest. Is rally, the build-up of intellectual property rights at universities, truly in line with the well understood public interest, or quite contrary the dynamic creation of various new high technology business ventures and creation of high profile employment opportunities backed with overall development of the economy at the both regional and national level are in fact in the best understood public and social interest. It seems that at universities and other public R&D institutions the more pro-entrepreneurial models of intellectual property rights division between institutions and individuals should be undertaken in order to efficiently capitalise on the existing domestic research and development base for the well understood social and public interest. Various models are potentially available in that respect, including the model that incorporate a certain conditional delayed pay back mechanism.

The Human Barrier

The assessment of the quality of work force available in the market, especially the quality of university graduates, varies between the representatives of new business start-ups

and well established companies. In the light of the results of the research the significance of the human barrier is especially noticeable in the case of the well-established business units where the significance of the generation gap is likely to play an important role as a factor affecting the growth potential of biotechnology firms. The key people in well established companies know each-other and cooperate with each-other for longer period of time and due the problem of aging the significant problem of work force continuity emerges, especially in the case of key people. The problem of aging and lack of continuity in well-established biotechnology SMEs also poses a threat for the future competitiveness of the biotechnology firms from the point of view of social capital issue (Dana, L-P, Light, I 2012). The social capital is particularly important in the high technology sector. The elimination of generation gap is crucial for the long term competitiveness of biotech SMEs in that respect, since once the present key people retire, the social capital accumulated by the existing biotech firms is in the real danger of being lost or diminished.

In the opinion of persons managing well established biotechnology business ventures the quality of university graduates weakens, they claim that young people have unrealistic expectations and not much to offer. On contrary the representatives of the new business start-ups claim that human barrier ether doesn't exist or is definitely of minor importance in the case of high tech biotechnology business ventures. Start-up entrepreneurs stress that the lack of competences in practice doesn't exist in the case of business units. In their opinion human barrier does exist in the case of public administration, in the government and among politicians. In their opinion these groups entirely don't understand the importance of new technology development for the economic well-being of the country. In the respondents opinion even representatives of financial institutions begin to understand the importance of new technology development.

The Infrastructural and Property Barrier

Respondents claim that there is a limited and complicated access to the suitable laboratory and production infrastructure where the standard required by high tech biotechnology ventures is available. Although there are older solutions and infrastructure available in the region, but the process of upgrading these solutions to the contemporary standards is often in practice impossible or cost ineffective. The process of development of infrastructure and premises by SMEs, from the very beginning is in respondents' opinion very difficult and sometimes impossible especially when the market status of the business unit is not yet sufficiently defined. Due to the transformation of the economy there is a noticeable lack of continuity. The existing premises and infrastructure is insufficient and inadequate and the creation of the infrastructure from the beginning is very difficult or impossible. Respondents stress that especially for SMEs it is extremely difficult to secure infrastructural conditions and fulfil all the formal requirements. The significance of property and infrastructural barrier results also from the overall limited supply of second hand industrial buildings, originating from i.e. companies that went bankrupt or changed the area of activities. This factor strongly differentiates the conditions for development for biotechnology SMEs in emerging economies from the conditions for creation and growth for technology oriented business units in developed economies. Respondents claim that in practice there are two solutions addressing this issue, large companies might create the campuses for small business units and start-ups (i.e. the case of Bayer) or significant investment of public money is needed. There is, not only in the region, a noticeable lack of readiness of large multinational companies to engage in that kind of activities, therefore the need for public measures and initiatives in that respect is even stronger in the less developed economies than in the

developed ones. Respondents stress that in comparison with well-developed economies, there is a significant shortage of quality consulting services in that respect. In the well developed economies it is relatively easy to find the necessary expertise and advice related to infrastructure and property related issues. The property and infrastructure barrier result from the overall technical backwardness of economy and industry, high-tech entrepreneurs originating from academia are not in the position to resolve these issues, since they are lacking in necessary experience in solving specific business problems i.e. related to capacity sharing. The creation of the Regional Science Park obviously just recently helps to the improve situation, but the distant, from academia, location of the science park leaves in respondents opinion much to be desired. The best practices suggest that it is beneficial both from academia and business point of view that technology oriented companies are located within the university campus area. In the respondents opinion universities located in the region hasn't been capable to realise the comprehensive benefits resulting from the fact that technology based business units are operating inside the university campus area. This partly was the case due to the lack of experience of business being located inside the university campus area[3]. The experience derived from science parks located in developed countries suggest that effective are only high-tech incubators and science parks located inside the university campus (i.e. Aston Science Park, Birmingham UK). The science parks located outside university require additional scarce resources and time to become fully functional. In the respondents opinion the Regional Science Park has also not yet reached even partly the required critical mass in order to become functional.

The Managerial and Psychological Barrier

The managerial barrier seems to be twofold, managers originating from industry have either experience from the past economic system which is not applicable for the contemporary challenges, or have the experience of acting on a small scale. In the respondents opinion academic entrepreneurs quite often, experience in general a kind of mental block, "they are afraid of being too ambitious, afraid not to go too far, not to exaggerate". In the opinion of university based entrepreneurs Polish scientists and academic entrepreneurs in the process, are focusing on "safe and niche subjects, subjects where one is not supposed to receive the Nobel Prize, but one is in the position to be the best in the world in the particular niche subject". This defensive approach might partly result from complicated, not only distant, historical experience, which taught that the primary aim is the survival not the real development. On the other hand this approach might in fact partly result from quite realistic reasons. The technology based entrepreneurs are afraid to face confrontation with the best and look for niches where they have better chances to survive, but do not stand the chance to achieve anything truly spectacular with outstanding market potential. If they decide to do so they will most likely face the confrontation with the best and the biggest, which is extremely difficult. This somehow realistic approach, of focusing on niches and avoiding the excessive risk, might be the result of the objectively limited availability of capital associated with the overall level of the development of economy (The Global Competitiveness Report 2011-2012, 2011). Nevertheless the purely mental issues might play an important role in that respect, as the factors limiting the growth potential of technology based business ventures.

[3] Due to perhaps mainly mental and partly objective legal obstacles the truly close cooperation of the science park with academia proved to be impossible, as the result of which the city authorities created the science park and the only benefit resulting from potentially close proximity between technology based business and academia, comes at most only from the location in the same city.

In the respondents opinions another management – mainly mental based - barriers includes limited ability to cooperate and share the information for mutual benefits. This results with artificially complicated negotiation strategies. Respondents claim that the business partners put a lot of effort to present their business position in the not clear and understandable manner. There is a noticeable lack of good patterns of business communication and negotiations, as one respondent named it "talks are very movie-like and imprecise". A lot of often redundant dialogs and talks, somehow compensate limited amount of true business relations and transactions. This in turn incurs additional transaction costs and stretch anyway fairly limited resources.

All these managerial barriers are becoming in a sense stronger in the case of technology based units originating from academia, as one respondent put it "combining business and academia is still in practice like acting against the system and outside the system, everybody must prove that he or she is not a criminal". The above specified conditions may in practice make the communication process even more complicated and strengthen the above identified communication distortions and problems.

The Corruption Barrier

In the field of corruption barrier respondents were stressing issues associated with unjust competition, especially dumping practices undertaken by large foreign companies. Small and middle sized domestic companies, especially the ones with very limited product range, have very little, if any strategic option to respond to dumping practices undertaken by large especially multinational companies. In the opinion of respondents national state authorities do very little, if any, to make large foreign and multinational companies refrain from undertaking unjust competition practices. One of the respondents even described this situation as the state authorities are being "either blind folded or just pretending to be blind folded" in the face of unjust competition practices of large corporations. It seems that more strict state regulations and actions of public authorities have to be introduced in order to protect just market competition and equal treatment of business units.

To certain extent similar situation might be recognised in the field of product certification for market admission. One of the respondents stressed somehow strange and not transparent behaviour of public authorities in this respect, when internationally recognised company delivering high quality products was not capable of passing through the certification process allowing them to sell high quality products in EU, while at the same time another manufacturer of similar product managed to obtained the certificate allowing to sell it in the EU market, despite the fact that its products represented significantly lower level of quality and somehow questionable overall reputation. This particular situation resulted with significant problems for the respondent's company, since they cooperated with the high quality product's manufacturer not only on business, but also on scientific basis and as the result of, hard to understand, decisions of public authorities, they are now forced to buy components from lower quality supplier which entails certain manufacturing problems and inhibits potential for scientific cooperation, since the lower quality supplier is only interested in pure buy-sell relations.

5. Summary and conclusions

The intensity, both in qualitative and quantitative terms of biotech business in Poland doesn't reflect the countries potential and aspirations. The study revealed, that the biotechnology companies taking part in the research are facing diversified barriers to their growth. The most important barriers indicated by the case study participants include: financial barrier, the state policy barrier and the market barrier. In general main barriers for development reflect the stage of development of companies. The financial barrier is considered as the most important barrier in the case of business start-ups, whereas the state policy barrier was especially underlined by the representatives of well-established business ventures. Well established business ventures also stress market barriers associated with the limited acceptance of innovative products. New business start-ups highlight in the first place financial barriers associated with lack of start-up capital. Start-ups and university spin-offs, that are based on advanced novelties perceive market barrier as the moderate factor determining the growth potential of their companies. At this stage of development other factors and barriers seem to be predominant.

On top of barriers specific to business start-ups and well established business ventures the study allows to identify certain common barriers, that the domestic biotechnology SME are facing regardless of their life cycle stage of development. The respondents in this respect were stressing the lack of interest of public authorities and their lack of understanding of specific issues related to technology oriented business ventures.

Respondents taking part in the case study research generally realistically recognise the overall economic potential of the biotechnology sector in general and their biotechnology ventures. Nevertheless they identify and stress various important barriers and obstacles that in practice limit and hinder the growth potential of biotechnology business units operating in the region. The number of barriers to growth, that business ventures are facing is in many cases quite predominant, so that the development of persuasive and realistic business strategies aiming at overcoming these negative conditions seem to be beyond realistically defined capabilities of business units. Fostering the development of biotech companies require the application of a mixture of interconnected initiatives and polices. The up to date story of biotech firms operating in the region is not particularly impressive, and in the face of the growing international competition the margin of error is becoming even smaller especially at the time of global economic slowdown.

No single factor or barrier to growth of biotechnology firms identified in the research seems to be predominant and fully explain the moderate growth rate of biotechnology companies in the region. In order to create and secure more favourable conditions for development of biotechnology companies in the region the comprehensive set of measures ought to be implemented. Since complex conditions require comprehensive actions, measures and polices. The situation requires various interconnected and parallel measures helping to gradually create more favourable overall climate for the development and growth of biotech companies in Poland. The overall development of the country's economy will probably create more favourable conditions for the development of various high-tech ventures, including biotechnology ones.

On the basis of regional cases study analysis and in the light of opinions expressed by top people managing the high technology business ventures in the region, one can conclude that the conditions for development of biotechnology ventures and barriers, that they are facing constitute rather nor supporting and promising business environment. The overall picture suggest at best rather continuity instead of significant progress and opening for new business opportunities.

In the light of the research the young people and university graduates unfortunately do not seem to be a significant asset and resource determining the creation and development of new high tech business ventures. The reason for that might be perhaps two fold. On one hand university graduates in the respondents opinion are less enthusiastic, they do not represent sufficient level of entrepreneurial spirit and potential coupled with excessive financial expectations, on the other the overall business environment is not favourable and supportive for new biotechnology business start-ups due to, in the first place growing standards and entry barriers, lack of mezzanine financing and excessive and counterproductive patent law and excessive protection of intellectual property laws. The overall specifics of biotechnology business venturing is its particularly long horizon, what might discourage young people from more serious engagement in biotechnology business ventures. The research revealed the substantial need for redefinition of existing and the development of new public policies addressing the barriers, that the high-tech biotechnology ventures are facing along their growth path. This issue should be the subject of comprehensive future research.

Mental barriers and inhibited acceptance of innovation infer the innovative growth potential of domestic innovative biotechnology companies, since the end users in many cases (even business end users) seem to surprisingly neglect the higher productivity of new products and are bound to their well-known routine. It seems that market in certain emerging economies does not expect and is not to certain extent ready to accept the real significant innovation in the field if biotechnology coming from small and middle size domestic companies. Significant innovations and real market breakthroughs are rather expected from foreign business entities and especially large multinationals from developed countries, that in a sense are entitled to set new standards and change the paradigm not necessarily in the large scale context. One can argue, that the failure and difficulties in introducing by domestic SMEs new innovative biotechnology products in the market might result from lack of experience, inappropriate business strategies, capital shortages and questionable competitive advantage of the offered new products, nevertheless a kind of specific obstacle limiting the growth potential of biotechnology firms, associated with the above described limited acceptance of true innovative products coming from domestic biotechnology firms, was identified in the course of the research. It is advisable that the domestic SME biotechnology companies should take into account the possible existence of this specific market and mental barrier and incorporate it into their more realistic business strategies.

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