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Biotechnology commercialization in Vysegrad Pact countries

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Review

Abstract

The transformation to bioeconomy is a challenging task for developed countries and even more for emerging economies of Central and Eastern Europe. New life sciences clusters emerge and new players from public and private sector appear on the international biotechnology scene. Universities are conscious of the adversities in their future strategy and it is up them how quickly they adapt and how they withstand the competitive universities. Further, it is up to regional and national policies to launch programmes to enhance and 'sell' science. It is obvious that Vysegrad Pact countries are fully aware of the life science and biotechnology commercialization, conditions and consequences of these processes. In the BioPolis project, vertical policy instruments (biotechnology specific) and horizontal policy instruments (generic or not biotechnology specific) are included. Vysegrad Pact countries transform from centrally planned to market economies and at the same time from traditional to knowledge-based, even bio-economy as seen in developed countries. It is observed that those countries performing best in the commercialization of biotechnology were a strong commitment to supporting basic scientific research. Lack of incentives and missing bridges between industry and academia are institutional and network failures. Government bodies should consider the definition and implementation of public initiatives to meet the specific needs of spin-off companies in the maturation phase. The paper follows and summarizes indicators of biotechnology commercialization in four European countries of Slovakia, Hungary, Poland and Czech Republic.

Keywords: biotechnology commercialisation, spin- off, Vysegrad Pact countries

Introduction

Life sciences commercialization is desirable. A modern university or a research institution encourages and supports an entrepreneurial environment where creativity is celebrated. Entrepreneurial R&D organization recognizes the advantages of protecting and commercializing intellectual property and wishes to sensibly and fairly share the benefits among inventors and investors. Thus, most life sciences and biotechnology companies are located around the major universities and have tendency to stay close even in the later stage of business development (Eriksson and Rajamäki 2009). The main world driver in biotechnology commercialization are undoubtedly USA, however Europe and Asian-Pacific region accelerated their commercialization activities in the past decade with comparable results (Nagle, et al. 2003, Liu and Schmid 2009).

New EU member states took the path of biotechnology commercialization and build their biotechnology sector on experience from chemical, pharmaceutical and food industries adding experience and skills of biotechnology industry from abroad (Lacasa, Reiss and Senker 2004). We discuss the approach of Vysegrad Pact countries (Slovakia, Hungary, Poland and Czech Republic) in biotechnology commercialization mapping their progress according to publicly displayed results and indicators (Enzing and Reiss 2008).

Vysegrad Pact Countries

Slovakia, Hungary, Poland and Czech Republic gone through an economic transformation since 1989 and in May 2004 joined the European Union. They made considerable transitional progress since then, although constrains of the past centrally planned economies slowed down systematic attempts in R&D sector. The financing of research transforms from bulk to project financing and invites private sources into exploitation of R&D results. As the countries did not yet harmonized on their science and technology statistics with OECD standards, there is not enough official data to reliably compare biotechnology development (Enzing 2007). For example, there is no systematic survey on biotechnology commercialization under governmental auspices in Slovakia. In addition, there is no data available on the amount of venture capital invested in biotechnology for Vysegrad Pact countries. BioPolis report from 2007 indicates numbers of biotech firms in each country according to local estimates. Consequently, there is not enough data on venture capital investment in biotechnology firms or on initial public offerings. Only Hungarian data were introduced in EuropaBio Report

Critical I in 2004 and only Polish data are enclosed in OECD Biotech Statistics Report in 2006 (Hodgson 2006, van Beuzekom 2006).

Slovakia

Slovakia has a long history of chemical and pharmaceutical industries. They take 15% of all industrial production and 23,1% of all export employing more than 35 000 persons. Slovak Association of Research Based Pharmaceutical Companies records 22 members and Association of Chemical and Pharmaceutical Industry of the Slovak Republic 53 members (Association of Chemical and Pharmaceutical Industry of the Slovak Republic 2007). Although this pool represents a solid base for existing and new university-industry alliances, no official data on strategic partnerships and their evaluation are published.

According to three sources (BioPolis, Inventory and analysis of national public policies that stimulate research in biotechnology, its exploitation and commercialisation by industry in Europe and the National Report of the Slovak Republic BioPolis for the period 2002–2005) most biotechnology organizations are located in Bratislava region. Three universities are active in the field of biotechnology and several Slovak Academy of Sciences institutes are doing research on biotechnology. The number of firms active in biotechnology is rather limited. Large biotechnology companies are Fermas, Imuna Pharm Holding, Azoter, Biotika and LIKO Bratislava. Axxon, Danube Clone, Slovgen and Genexpress, Arbor, UNIS and Arboretum are examples of small Slovak companies in the field of biotechnology. AlphaBio EcoService and Bursa are examples of Slovak biotech companies in the field of ecological engineering (van der Molen and Enzing 2007).

Industrial biotechnology is very limited in Slovakia today although the country has a very long tradition in biotechnology research and a good level of education in the field. In the same time, the Slovak Republic is the only new Member State where industrial biotechnology actors are gathered together in a national association with the objective to further develops this sector at national level (Polakovic 2008).

Slovakia is the first country of Vysegrad Pact reaching euro implementation. EU Structural Funds will enormously support the present infrastructure of R&D and innovation activities. The Ministry of Education of the Slovak Republic founded the Agency of the Ministry of Education of the Slovak Republic for the Structural Funds of EU on January 1, 2007 and its main objective is to provide assistance for the implementation process of EU Structural Funds, in the program period 2007 – 2013. European Regional Development Fund

allocated for the Operational Programme Education more than 617 million EUR and for the Operational Programme Research and Development 1,209 miliard EUR for the implementation period 2007-2013 (Slovak Research and Development Agency 2008).

The Ministry of Education of the Slovak Republic, Slovak Centre of Scientific and Technical Information and its Central Information Portal for Research, Development and Innovation publishes official data on numbers of R&D institution from 2008 (Holubova 2007). There is 155 legal and personal entities divided into life sciences (44 entities), technical sciences (82 entities), medical sciences (14 entities) and agrofood (15 entities) in 2007. Expenses on R&D reached 282,63 million EUR what is 0,46% GDP (Infostat 2007).

Tab. 1 Number of biotechnology firms (OECD, 2009)

Country	**All biotech firms**	**Dedicated biotech R&D firms**
Slovakia	27	13
Hungary	not available	not available
Czech Republic	82	52
Poland	11	not available

Slovakia does not have a national policy for the support of biotechnology. In 2007, government adopted the National Science and Technology Policy which aims at increasing direct R&D support to 1,8% of GDP in 2015 and where biotechnology and industrial biotechnology is a one of twelve priorities. Two state grant agencies Slovak Research and Development Agency (Agentúra na podporu výskumu a vývoja APVV) and Slovak Scientific Grant Agency (Vedecká grantová agentúra VEGA) funded research projects on a response mode basis, including a number in the field of biotechnology. On the basis of the data available it can be concluded that, through the medium of biotech-specific instruments and non-policy funding, at least 5,3 million EUR has been spent on biotechnology research: almost half (2,4 million EUR) through BITCET and the other half (2,9 million EUR) through non-policy-directed funding by VEGA and APVV.

The largest growth rates in the number of biotechnology publications between the periods 1994-1996 and 2002-2004 were in the following four subfields: plant, food, industrial and environmental biotechnology. In terms of biotech patent applications per biotech publications, the output of the Slovak Republic improved slightly over a ten-year period (from 14 for 1994-1996 to 29 for 2002-2004). According to 6th Framework Programme Project

"Small and medium enterprises go life Sciences, there was 30-40 companies focused on life sciences research, development and production. The latest OECD report cites 27 R&D biotech firms in 2006 holding onto OECD definition of biotechnology company (Fig. 1, Tab. 1).

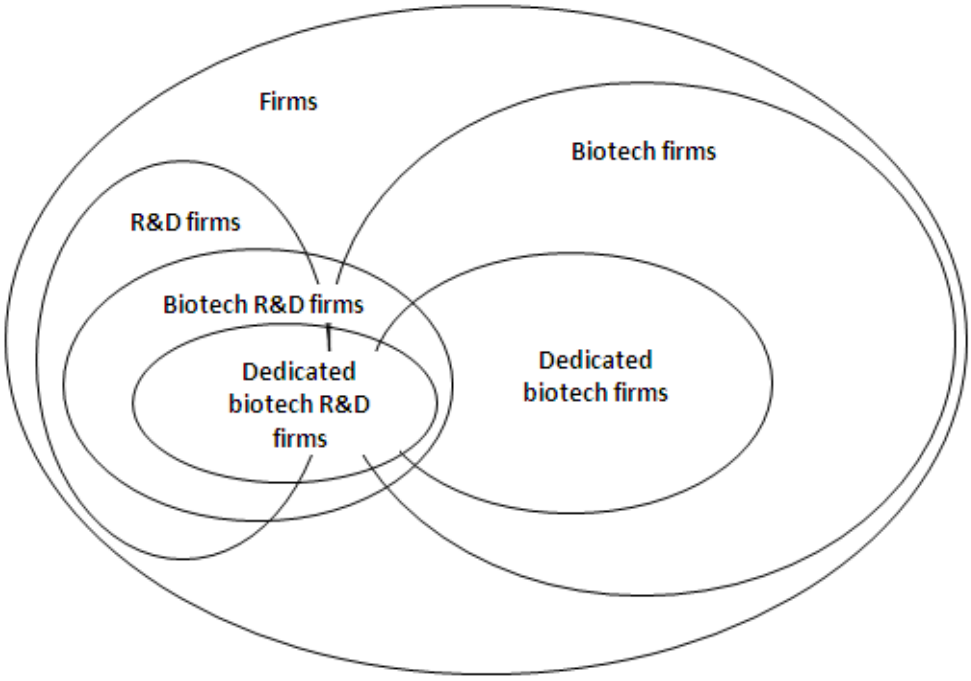

Fig. 1 Scheme of sampling frame for definition of a biotechnology firm (B. A. van Beuzekom 2009).

Measuring commercialization, the Slovak Republic has zero biotechnology Initial Public Offerings and no venture capital invested in biotechnology companies. In the sources used for the performance analysis, there are no data available on the Slovak Republic's number of biotechnology companies except OECD (Tab. 2). In many European countries big pharmaceutical companies intensively create partnership with small biotechnology companies or chemical plants undertake biotransformation. However, only a couple of companies in Slovakia include biotechnology processes in the production programmes. Although there are no official data on number and performance analysis,

Tab. 2 Total biotechnology R&D expenditures in the business sector in public-private partnership in 2006 in mil. USD (OECD, 2009)

Country	mil USD
Slovakia	13
Hungary	not available
Czech Republic	83
Poland	0.32

a few biotechnology spinoffs are known e.g. Biorealis, Geneton or Scientica. Other sources (Slovak Association for Industrial Biotechnology) mention that more than 20 biotech companies exist in the Slovak Republic, however sector distribution is not available.

Hungary

Since 2000 biotechnology has been a clearly priority within science and technology policies in Hungary. In 2004, there was 16 companies with 394 employees, 196 in R&D with revenues 38 million EUR (Hodgson 2006). Hungarian Biotechnology Association has almost 90 members.

On the basis of a national report on biotechnology conducted in 1998-99, in order to define the research and development priorities within this sector, the Hungarian government launched in 1999 the Biotechnology 2000 programme (Biotechnology 2000 Programme, 2003), which lasted until 2002 (Rafols 2007). The aim of the programme was to enhance the knowledge base for research and development in the field o biotechnology, to increase the competitiveness of companies and to develop new methods and services. The programme gave subsidies to successful applicants to encourage the introduction of newly developed, advanced, high-value and competitive biotechnology products. Biotechnology 2000 set the following priority areas: food safety, phytotechnology, bioconversion, bioremediation, application of biotechnology to environmental issues, biotechnology in animal breeding, biomedicine, biopharmacology, and bioinformaticsgenomics. Between 2000 and 2002, 18M EUR were spent on this programme.

The Asboth Oszkar programme aims to set up of technological platforms and innovation clusters in the following high-tech industries: health, biotechnology, agriculture-based renewable energy-resources. The funding is for a maximum of 48 months. The applicants are consortia formed by businesses, universities and other private research organizations as well as industrial lobbying bodies active in innovation. The total budget was

about 26 million EUR for 4 years. Although the call was not biotechnology-specific it appears that all the clusters have been awarded to biotechnology-related areas, including bioenergetic innovation, therapeutic vaccines, and multidrug resistance reversal drug (treatment for cancer) and covers health (65%) and industrial (35%) biotechnology.

The Bioincubator programme launched in 2005 is a competitive call supporting the creation of incubators for small and medium enterprises in biotechnology. The investment goes to infrastructure and equipment for the creation of the incubator during a two-year period with the commitment to provide services to assist entrepreneurship and innovation activities for a period of at least five years. It awarded about 4M EUR for two incubators in 2005, one in Budapest and another in Debrecen.

Given that the Hungarian R&D governance system underwent a major reform in 2003 which was only fully implemented after 2004 (as shown by the decrease of funding in 2003, compensated for in the following year), no major changes can be expected in the short to medium-term (Havas, Borsi and Papanek 2004). The new funding system, derived directly from taxing industrial activities may provide more funds and focus more on technology transfer activities, as shown for example in the new measures that commenced in March 2006. These changes will hardly be radical, since current policy is not seen as a priority in Hungary according to experts (Duda 2006).

Poland

In 2005, the Ministry of Education and Science ran a biotechnology firm survey including the OECD definition of biotechnology (van Beuzekom and Arundel 2006). There were 13 biotechnology firms in Poland in 2004 classified into six areas of application: bioinformatics, environment, health, agriculture and food processing, industrial biotechnology and non-technical areas of biotechnology. The companies employed 946 persons, of these 12% had biotechnology R&D responsibilities. The firms spent 8.7 million USD on biotechnology, 54% (of which was spent on biotechnology R&D 0.58% of total business enterprise R&D expenditure by all firms in Poland) which was spent on biotechnology R&D and 36% on biotechnology capital (instruments, equipment, land and buildings) (Bernard 2007).

Some reviews have identified approximately 30 biotech companies in Poland, but these reviews do not say how they have defined the biotech companies included in their reviews (D'Este and Costa 2007). In any event, there is general consensus that biotech

commercialization is still rather weak in Poland. This lack, and absence of data for Poland on biotech Initial Public Offerings pMC, or venture capital € per capita allocated to biotech firms makes it impossible to measure biotechnology commercialisation or market conditions. There is no formal policy on biotechnology (Institute for Information on Education of Czech Republic 2005).

Poland is a member of ScanBalt BioRegion, Europe's first Metaregion for Life Science and Biotechnology (Sheridan 2007). According to its last reports, around 200 companies in biotechnology and life sciences exist in Poland and several networks are active in the field of biotechnology and life sciences (Clausen 2006). In 2005 the Polish Ministry of Science and Higher Education funded the biotech research with 768 949 EUR (1,316 million EUR to all life sciences) (Blank, Samuelsson and Frank 2003). They have identified biotechnology as a priority area and, moreover, they have developed comprehensive policy profiles from an innovation system perspective. However, according to the information available on the policy measures launched in the period of 2002–2005, we can identify policy gaps in four areas: the implementation of biotechnology-specific programmes, fostering university-industry collaboration, the development of human resources and the promotion of international networking (McGloughlin 2006). The extent of these gaps varies from country to country (Lacasa 2008).

Czech Republic

The Czech Republic had no biotechnology companies listed on the stock exchange and there was no venture capital invested in Czech biotech firms in the period 1994-2004. Data on the number of Czech biotechnology companies are not available in the source used for the performance analysis. Other sources (www.gate2biotech.com) indicate a total of 63 to 120 biotech companies. Indicators for performance in market conditions (approved biomedicines and field trials) do not record any achievements for the Czech Republic. The Czech Republic had no programmes that specifically stimulate biotechnology activities until 2008 when a National programme on Biotech was created. With few exceptions, biotech companies in the Czech Republic are rather small. Most biotechnology companies are located in the Prague region (33.9%) and South Moravian region (18.9%). The most frequent activity is producer/manufacturer (75% of all companies). Dedicated companies and subsidiaries are also active in R&D. Diversified companies and business units are active in providing services.

The MediPark project of Masaryk University in Brno and the South Moravian region was initiated in 2005. It was financed by a European Investment Bank loan and by the university. The campus supports the creation of incubators and spin-off companies, as well as attracting foreign companies to the region in the fields of biology, medicine and chemistry. Next to the university building, an incubator for biotechnology is available from 2007. It includes a new campus and 15 hectares of space for hosting commercial partners.

Since 2006 CzechInvest provides an overview of biotech activities in the regions and of major biotechnology companies in the Czech Republic. Well-established is the Technology Centre in Prague, which aims at promoting the commercialisation of university-based R&D and development of small life-science businesses.

Conclusion

Biotechnology is expected to be a leading industry in this century, influencing many other industries. New life sciences clusters emerge and new players from public and private sector appear on the international biotechnology scene (Enzing, Van Der Giessen, et al. 2008). Moreover, biotechnology clusters are interesting and important intellectually and for policy deliberation (Cooke 2008). Universities are conscious of the adversities in their future strategy and it is up them how quickly they adapt and how they withstand the competitive universities (York, McCarthy and Darnold 2009). Further, it is up to regional and national policies to launch programmes to enhance and 'sell' science. It is obvious that Vysegrad Pact countries are fully aware of the life science and biotechnology commercialization, conditions and consequences of these processes. In the BioPolis project, vertical policy instruments (biotechnology specific) and horizontal policy instruments (generic or not biotechnology specific) are included. All highly performing countries in commercialisation had both generic and biotech-specific instruments in place (Enzing and Reiss 2008). Vysegrad Pact countries transform from centrally planned to market economies and at the same time from traditional to knowledge-based, even bio-economy as seen in developed countries. The accent on critical mass of R&D may be does not apply to Central and Eastern Europe countries as one cannot replicate the American way of commercialization in this emerging region. Different approach seems to be more applicable way. The innovation and commercialization performance is extremely diverse here and therefore we suggest pointing out the necessity of continuous and steady flow of R&D funding instead. Small countries should focus on fewer priorities and

specialize not only on costly biopharmaceutical research and development. However, it is necessary to move from spontaneous spin-off creation to systematic and sustainable support (Meyers 2009). The success factors except funding life sciences research are funding coaching and spin-off promotion (Allan, et al. 2009).

It is observed that those countries performing best in the commercialization of biotechnology were a strong commitment to supporting basic scientific research (Moses and Cape 1999). The industrial application of biotechnology seems to depend both on the incentives for scientists to develop innovation out of their scientific results and on the awareness of industry about the technological potential of scientific research carried out in academic laboratories. Lack of incentives and missing bridges between industry and academia are institutional and network failures (Bains 2009). Government bodies should consider the definition and implementation of public initiatives to meet the specific needs of spin-off companies in the maturation phase (Booth 2006) (Mroczkowski 2009) (Senker, Enzing and Reiss 2008). The indicators of biotechnology commercialization do not change (W. Bains 2008). Number of biotechnology companies per Million Capita, investment of venture capital in biotechnology related to the size of the population, knowledge base indicators used for performance clustering, etc. will be permanently part of business analysis to mirror the results on the regional, national or global level.

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