Original Article

Tracking progress: Two approaches to biotechnology development – Cases from Central Europe

Received (in revised form): 29th January 2009

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ABSTRACT **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. In this paper we review critically a recent report funded by the European Union which also assesses biotechnology industry development in the new member states of Central Europe. Going beyond the report we identify additional characteristics important for an evaluation of nascent biotechnology industries and apply them to Hungary and Poland. Our analysis reveals that the two countries are pursuing different approaches to biotechnology industry development with Hungary following a relatively well-funded national strategy of launching a biotechnology sector specialised in innovative drug discovery whereas Poland has adopted a more hands-off approach. Developing appropriate measures and tools to monitor the potential and progress of an emerging biotechnology industry can help avoid expensive and wasteful policy failures and also provide investors with more reliable information on which to base their decisions. However, those measures should take into account the differing policy objectives and national strategies pursued by different countries.**

Journal of Commercial Biotechnology (2009) **15,** 227–235. doi:10.1057/jcb.2009.4; published online 7 April 2009

Keywords: innovation; emerging economies; clusters; knowledge economy; biotechnology

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INTRODUCTION

While the United States remains the undisputed leader in the biotechnology industry, Europe and increasingly the emerging economies are playing hard to catch up. The European Union (EU), as part of its Lisbon Strategy of improving competitiveness, views biotechnology as a critical pillar of the knowledge economy of the future.[1] Although the growing biotechnology potential of Asian economies is receiving a lot of attention, little is known about biotechnology industry development in the emerging economies of Central Europe many of which have become new EU members. In this paper we critically review a recent EU-funded report assessing biotechnology industry development in new EU member states of Central Europe. Going beyond the report we identify additional characteristics important for an evaluation of nascent biotechnology industries and apply them to Hungary and Poland. We then discuss the implications of our analysis for future research leading to more valid ways of tracking the progress of emerging economies towards creating viable biotechnology industry sectors.

THE BIOPOLIS REPORT

The EU recently funded a complex assessment of 'national public policies that stimulate biotechnology research, its exploitation and commercialization by industry in Europe'. This report entitled 'Biopolis' also includes the new member states of Central Europe and accession countries.[2] The report relies on the concept of national innovation systems as those responsible for enabling biotechnology development and acknowledges that promotion of biotechnology has been on the agenda of the EU for many years; yet the 'national and institutional settings differ' as does performance. The results of the Biopolis study are country rankings: first in terms of policies that create a knowledge base for biotechnology and second in terms of policies that support knowledge transfer and commercialisation.[2] The report also looks at 14 indicators of biotechnology industry 'national performance', such as numbers of companies, patent applications, venture capital, field trials, biomedicines and several others.[2]

A separate section of the Biopolis report using somewhat simplified criteria for ranking deals with new EU members and accession states. It groups these countries into three clusters 'with similar performance in biotechnology'. The criteria include: gross domestic expenditures on R&D, economic sectors relevant to biotech, policy coordination in the areas of science and technology, funding for biotechnology research and 'policy-directed research instruments'. As additional indicators of country performance Biopolis uses: cumulative publications, coordination of FP6 projects and biotechnology patents per million cap. The total budget for biotechnology is an indicator of country commitment to the field as presented in Figure 1.

The report looks at the number of policy-directed research instruments by type. Countries with higher funding levels, more diverse policy instruments and tighter policy coordination score higher in the rankings. The numbers of policy-directed research instruments by type for the lead cluster countries are presented in Table 1.
The report places emphasis on policies that target commercialisation and biotechnology

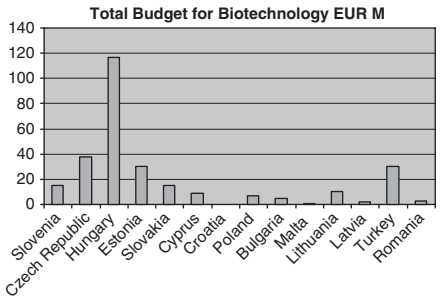

Figure 1: Biotechnology budgets in new EU member states and accession countries. *Source*: BioPolis Final Report March 2007.[2]

Table 1: Number of policy-directed research instruments by type for lead cluster countries

Country	*Generic R&D*	*Biotech-specific R&D*	*Commercialisation gen. (B-S)*	*Others*
Cluster 1				
Slovenia	3	—	2	2
Czech republic	5	—	2	—
Hungary	2	3	3(2)	1

Source: BioPolis Final Report March 2007.[2]

specifically as opposed to 'generic' policies of R&D support.

In the summary analysis that cumulates all the criteria used, Slovenia, Hungary and the Czech Republic plus Estonia emerge as the 'leading' cluster of new EU member states. Poland, Slovakia, Croatia and Cyprus are grouped in the second cluster, with the remaining countries in the third cluster.

The Biopolis study (Section 8 'New member states and accession countries') is perhaps the first comprehensive attempt to assess the biotechnology potential of new EU member states. However, it suffers from several weaknesses and in our view does not provide a sufficiently deep assessment. The study was not based on field work and does not include any detailed or even general case studies, but rather relies only on numbers provided by government agencies. Whereas the report does provide useful information about some of the policies and institutional frameworks within which biotechnology research occurs, some of the actual numbers such as those on 'total budget for biotechnology' have been disputed and need to be verified. The criteria used to evaluate biotechnology performance are restricted to: cumulative publication pMC, number of partners and coordinators in FP6pMC and biotechnology patents pMC. The use of pMC data can lead to the exaggeration of the achievements of small states at the expense of big ones. There is no attempt in the report to measure biotechnology company revenues, venture capital funding, employment, and so on. In our framework presented later on in this paper we make an attempt to include more company characteristics than the Biopolis study did; we have also undertaken in-country research to verify some of its numbers and conclusions related to biotechnology research funding and organisation as well as to company performance. We also consider some of the barriers to development that biotechnology faces. Our study covers only two countries: one from tier one of Biopolis: *Hungary* and one from tier 2: *Poland*. We selected the two countries because Hungary is representative of small countries with ambitions to create a niche biotechnology sector, whereas Poland with its much larger internal market and more diversified economy represents countries that do not have a focused strategy of biotechnology development. National policy objectives are not the same. Although there are important lessons to be learned from the experience of developed economies, there is no 'standard way' to develop biotechnology. Conditions prevailing in each of the Central European countries are different and differ even more with those in, say, Singapore and China.

In our study we first assembled some quantitative measures representing the enablers of biotechnology (which we termed predictors) and also some that could be treated as leading/early indicators of performance (measures of progress). We selected criteria useful for comparisons across countries. In preparing our country profiles we also relied on qualitative information which we obtained through in-country interviews with company managers, business association leaders, consultants and government experts. We also made use of local language sources not available in English.

Table 2: Predictors and measures of biotechnology success: Poland and Hungary compared

Country	Predictors							Measures of progress		
	GDP (2005, $PPP)	*Pop. (2005, million)*	*WEF GCI rank (2005)*	*Gov't funding (euro)*	*VC funding (2005)*	*Industry spending*	*Researchers in natural sciences*	*# Biotechnology companies*	*# Biotechnology employees in biotechnology companies*	*Biotechnology industry*
Hungary	163 billion[4]	9.9[4]	35	34 million[5] (2006)	8 million[6]	100 million[5] (2005)	7537[7] of which 1400 are in biotechnology (est)	50[5]	1192[5] Out of which 370 in R&D	56 million[5]
Poland	505 billion[4]	38.5[4]	43	34.6 million (2007)[8]	217 million[6]	8.2 million[9] (2007)[8]	16 162 of which 2833 are in biotechnology in 111 institutes	20[8]	1172[9] Out of which 232 in R&D	$92.97 million[10]

Such an approach allowed us to compare some of the critical success factors and barriers to biotechnology development in the two countries. Our results provide a deeper understanding of biotechnology development in those two countries than what Biopolis offers and also suggests more comprehensive ways of assessing biotechnology progress in the region and in other emerging economies.

BIOTECHNOLOGY DEVELOPMENT: POLAND AND HUNGARY COMPARED

Typical measures of biotechnology performance in developed economies include product pipeline characteristics, market cap of companies, number of IPOs, and so on.[3] Those measures cannot be applied to nascent biotechnology sectors. We selected the following measures as those on which data were the most reliable and available for Hungary and Poland:

Predictors of Biotechnology Success:

- Gross Domestic Product
- Population (a measure of local demand)
- World Economic Forum Global Competitiveness Ranking (a measure of ease of development and innovation)
- Government Biotechnology Funding
- Venture Capital Biotechnology Funding
- Biotechnology Industry Spending
- # Researchers

Measures of Biotechnology Progress:

- # of Biotechnology Companies
- # of Biotechnology Employees
- Biotechnology Industry Turnover

Data on each of these variables are presented in Table 2 (with further comment on each of the measures in the notes).

Hungary[5]

The Hungarian Biotechnology Association is the most active and sophisticated of similar associations in the region. For example, this

association worked closely with the Hungarian government to develop the Hungarian Innovation Act of 2004, an Act which identifies research and development as the source of economic development, and encourages the establishment of new innovative companies in Hungary.
The National Biotech Strategy 2005–2010 anticipates the formation of 100–200 new biotechnology companies (of which approximately 80 viable and established ones should remain in business by 2010), 2–5 new large foreign direct investment in R&D by multinational pharma or biotechnology companies, several thousands of high value-added jobs with highly skilled and well-paid employees, positive effects throughout the Hungarian economy through life sciences and other high-tech industries, and global recognition of Hungary as an emerging biotechnology country.

The main sector of the Hungarian biotechnology industry appears to be human, but agricultural and environmental biotechnology centres have emerged to a lesser degree (though no clear statistics on company diversity are yet available).

As noted, Hungary is relatively successful within the region in terms of number of core biotechnology companies (50), but there is also a population of biotechnology-related companies as shown in Figure 2. This is reflected as well in biotechnology employee numbers: while there are 822 core biotechnology employees (see Figure 3), there are 3500–4000 broader biotechnology-related employees. Five Hungarian companies have established representative office in the United States for the purpose of selling products and services to US customers. Seventy per cent of Hungarian biotechnology revenues already come from international markets.

Most biotechnology companies are located around the major university clusters, and the majority of the new companies established between 2005 and 2006 were university spin-offs relying on the laboratories and IT infrastructure provided by academic research

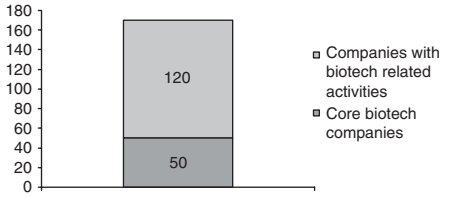

Figure 2: Number of biotechnology companies in Hungary.
Source: Hungarian Biotechnology Association, 2008. Available at http://www.hungarianbiotech.org/html_eng/index.htm.

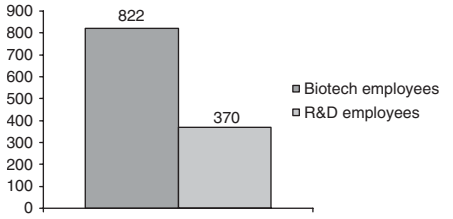

Figure 3: Employment in Hungarian biotechnology companies.
Source: Hungarian Biotechnology Association, 2008. Available at http://www.hungarianbiotech.org/html_eng/index.htm.

institutions. Biotech-specific infrastructure is still underdeveloped, which is why about half of the companies rent space on some cooperational basis in academic or university research institutions. The rest of the companies set up their R&D facilities in technology parks. Sixty-one per cent of biotechnology companies are located in the largest cluster, Budapest.

Hungary's experience suggests the importance of history. Early in the twentieth century, Hungary already had a relatively well-developed pharmaceutical industry – Richter Gideon (one of the 44 companies currently listed on the Budapest Stock Exchange) was established in 1901, Alka Chinoin in 1910 (privatised and sold to Sanofi in 1991), Biogal in 1912 (privatised and acquired by Teva), Phylaxia in 1912 (later called 'Human'), EGIS in 1913 (another of the few companies listed today on the Budapest Stock Exchange) and Alkaloida

in 1927 – and following WWII, Hungary was designated as the main pharmaceutical producer for the Warsaw Pact countries. In addition to Sanofi, multiple multinationals have made recent investments in the pharmaceutical industry in Hungary: for example, a US$100 million vaccine plant in Gödöllö. This experience with pharma provides Hungary with a broad base of pharma-trained staff as asset for the biotechnology industry.

Poland

The Polish pharmaceutical industry was less significant to its economy than in the Hungarian case with most firms manufacturing generics. However, Poland did have a large and relatively well-developed network of medical schools and hospitals with a good track record as a competitive international destination for preclinical and clinical trials. Its academic pharmacology and life sciences are of good quality. However, Polish academe had few traditions of entrepreneurship and distanced itself from business. This together with rather belated attempts at reforming scientific institutions has delayed biotechnology progress in the country.

None of the previously available reports on Polish biotechnology present an accurate, comprehensive and up-to-date picture. The OECD profile of Polish biotechnology companies based on very incomplete results of a survey underestimates the number of biotechnology companies by 35 per cent. (The report has no data on Hungary.) The Biopolis report referred to earlier, which like the OECD data, is based on a mail survey only (no on-site field work), has highly inaccurate data on Polish biotechnology spending. As was pointed out earlier, it also does not contain information on biotechnology companies. The Biocon Valley report on Poland published in 2005 has quite a lot of useful information, but does not use the rigorous definition of biotechnology (as recommended by the OECD) and therefore likely overestimates the size of the Polish biotechnology sector as well as the number of core biotechnology companies.[10]

The section on Polish biotechnology below is based on the latest statistics provided by the Polish Ministry of Science. The numbers and information have been verified by one of the authors of this paper through on-site interviews with company representatives, consultants and academics. The company count is based on a narrow and rigorous OECD definition of a core biotechnology company and on data approved officially in the summer of 2007 by the interagency committee of experts appointed by the Polish Ministry of Science.

Unlike Hungary, Poland has not formally made biotechnology a government policy priority. The government has created an interagency task force under the auspices of the Ministry of Science to present recommendations to the government regarding the development of the bioeconomy in Poland.[11] Poland has also been slower than Hungary to develop policies that encourage innovation and academic entrepreneurship. Only in the last year or so are more substantial funds being made available to academic spin-offs.

In terms of potential in the Natural Sciences, Poland has 16 162 active scientists of whom 2833 are employed in biotechnology fields in 111 different institutions (85 units are affiliated with universities, 14 are self-standing institutes and 12 are part of the Polish Academy of Science). The government task force estimates that Polish spending on biotechnology research in 2005 amounted to 42.8 million euro of which 34.6 million euro was government spending and 8.2 million euro was private sector spending. According to this figure, spending on biotechnology research constituted approximately 4 per cent of all spending on R&D by the government. Of the government monies spent between 2002 and 2006, about 50 per cent was

spent on medical biotech, 30 per cent on agriculture biotechnology and 15 per cent on industrial biotechnology research.[11] These numbers suggest that although Poland has approximately twice the number of scientists in biotechnology fields as Hungary, Hungary's public spending is at about the same level as Poland's. However, Hungary's private sector spending on R&D is much higher than Poland's. Relative to country size, Poland's spending on biotechnology R&D and commercialisation is more restrictive than Hungary's.

Unsurprisingly, Hungary has more dedicated biotechnology companies than Poland. According to the latest count, there are approximately 20 companies in Poland that meet the narrow definition of a core biotechnology company (Figure 4). Total employment in those companies is 1172 of which 232 persons are directly employed in R&D (Figure 5). Interestingly the 50 Hungarian companies employ a total of 1192 employees of which 370 are in R&D – a higher proportion than in Poland.

Hungary has more dedicated biotechnology companies as well as somewhat more companies that are active in biotechnology-related fields than Poland. Nevertheless, biotechnology industry turnover in Poland is almost twice that of Hungary and Poland attracts more than twice the venture capital (see Table 2). In spite of the significant barriers to academic entrepreneurship, Poland has been able to create a number of successful companies. Owing to lack of financing in the past, the vast majority of Polish companies are revenue-producing companies. They are producers of biosimilar drugs, vaccines, biotechnology services or products. Their R&D is often financed from the resulting cash flows. Poland has several quite large biotechnology companies: Bioton employs over 600 persons with production of insulin and antibiotics which sell in international markets (annual sales exceed $100 million) Biomed, a vaccine producer employs 270. Celon Pharma, a successful biosimilars

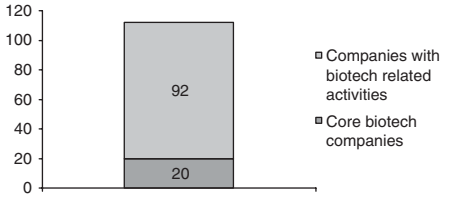

Figure 4: Number of biotechnology companies in Poland.
Source: Bio-tech consulting (2007), and own research. Available at http://www.biotechnologia.pl.

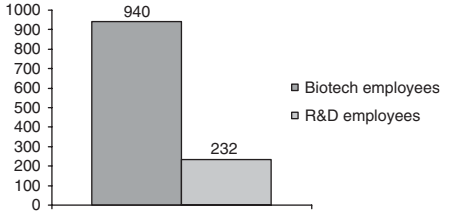

Figure 5: Employment in Polish biotechnology companies.
Source: Bio-tech consulting (2007), Biocom Valley, 2005. Biocon Valley, 2005. 'Life Sciences & Biotech in Poland', Available at www.biotechnologia.com-pl.

and drug development company has over 100 employees and turnover of 35 million PLN. The remaining Polish biotechnology companies are small academic spin-offs which typically employ less than 20 persons. Although all Polish dedicated biotechnology companies perform their own R&D, only 20 per cent of the companies could be classified as drug development companies – the remaining representing a mix of diagnostic, service or biotechnology product companies in diverse fields ranging from agro-biotechnology to bioinformatics.

Hungary has no big national biotechnology companies but has a greater number of drug development companies which have more money and scientists undertaking R&D than Poland. Hungarian companies are also more international and export-oriented than most Polish companies and are beginning to attract some international investments aimed at drug discovery.

Polish biotechnology companies are quite dispersed geographically between Warsaw, Poznan, Gdansk, Łodz and Krakow. Krakow has an active plan to create a life sciences cluster based on the scientific potential of its universities and research institutes, but it is not yet clear how many new companies it will be able to attract.

In evaluating Polish biotech, it should be added that the country graduates 1300 persons in various biotechnology fields annually and has recently instituted a variety of venture capital funds specifically designed to support academic spin-offs and high-tech start-ups. Polish biotechnology consultants thus expect that between 3 and 5 new biotechnology start-ups will be created in coming years. Nevertheless, relative to the potential of the country's scientific base and the size of its economy (GDP of $242 billion), the biotechnology sector is relatively underdeveloped. For example, South Africa with a smaller GDP than Poland and similar levels of public spending on biotechnology research ($43 million) has 47 core biotechnology companies and three bioparks under development. Thailand which has a smaller GDP than Poland, but also similar levels of public spending on biotechnology research has created 70 core biotechnology companies and has two sizeable bioparks.[12]

CONCLUSIONS AND AREAS FOR FUTURE RESEARCH

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,[13] Taiwan,[14] Brazil[15] and South Korea.[16] Some of those governments have committed substantial resources to that end (for example, both Singapore and Taiwan have committed over $1.5 billion in government funds to support biotechnology), whereas others have adopted more of a hands-off approach.

The most successful biotechnology industry in the world – that of the United States – evolved over a period of more than two decades starting with large outlays of federal funding in support of basic scientific research.[16] Private sector investment aimed at commercialising the results of the basic research gradually took over the lead role and today is by far the dominant driver of the American biotechnology industry.[17,18] This model of biotechnology development however is not replicable outside the United States and many developed European countries still use public sources for the majority of funding of their biotechnology.[19] Some of the major emerging economies so far appear to be relying on public spending not only to boost the enablers of an innovation economy but are also using public spending to accelerate the emergence phase of the biotechnology industry – for example by providing incentives for private firms to move into designated bioparks.[12]

The standard measures used by such agencies as the OECD or Ernst & Young for tracking progress of biotechnology were developed for advanced economies and, as we have shown in this paper, are not very helpful in the case of biotechnology industries in nascent stages.

Having the right measures and tools to monitor the potential and success of an emerging biotechnology industry is important. Effective tracking methodologies can help avoid expensive and wasteful policy failures and also provide investors with more reliable information on which to base their decisions.

Moreover, our comparative study of Poland and Hungary suggests that no single set of measures may be appropriate for all emerging economies, as the goals of their strategies

and approaches are different. Small countries with small domestic markets such as Hungary may decide to specialise in niche areas of innovation-based drug discovery relying on attracting international R&D partnerships and investments. Countries with larger domestic markets may want to see a more diversified biotechnology industry that will act in synergy with such economic sectors as agriculture, food processing or energy and may be reluctant to spend substantial resources supporting expensive biopharmaceutical R&D.

In the former case the measures of success will include R&D expenditures and drug pipelines, in the latter biotechnology product revenues will be more important.

More research is needed on comparative biotechnology development in emerging economies. Such research should look at both public sector spending and multinational company investments in emerging biotechnology sectors (establishment of R&D centres, R&D outsourcing, collaborative agreements, acquisitions, venture capital funding). Such research should enable us to eventually develop theoretical frameworks of the stages of biotechnology development with emphasis on the dynamic of the relative roles of public and private funding, and establishing crucial 'turning points' representing real progress on the road to a competitive biotechnology industry.

ACKNOWLEDGEMENTS

This article was made possible through support from a Kogod school of Business research grant.

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