

## BIOTECHNOLOGY COMMERCIALISATION IN EUROPE

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**Abstract:** European biotechnology was mapped for research and commercialisation from various information sources. Social and economical benefits from technology transfer in biotechnology are clearly visible in those European countries where proper attention is given to bioscience entrepreneurship education alongside with scientific base creation and spin-off development. Successful bioscience commercialisation is a result of a coordinated support of research and specific commercialisation programmes leading to spin-off establishment and industry partnership.

**Key words:** commercialisation, biotechnology, technology transfer, spin-off

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### 1. Introduction

Europe is considered a continent where education and research are undoubtedly strongly supported. Biotechnology has deep roots in extensive European life science research and globally competitive results. However, the phase of commercialisation of biotechnology research and development is a different matter. The USA has accumulated and maintained a large absolute advantage in innovative biotechnology activities compare to the rest of the developed world (ALLANSDOTTIR *et al.*, 2002). Europe began investing into life sciences commercialisation later than US and made a great effort to become the principal world competitor in biotechnology business (HODGSON, 2006; DUCHENE *et al.*, 2007; BEUZEKOM and ARUNDEL, 2009).

There are many studies being published whether universities and research institutions should accept the role of active players for commercialisation activities or stay in the traditional role of an educator and fundamental research base (MULDUR *et al.*, 2003). Universities were traditionally funded by public money, ensuring a certain amount of neutrality and independence (DOWNIE and HERDER, 2007). For those universities and research institutions that decided to become entrepreneurial more than a decade ago, the results are evident in financial resources from licensing, royalties and other economic provisions flowing back to research and development (SIEGEL *et al.*, 2007). These make prestigious universities modern institutions and, consequently, have an advantage at the competitive global market. Spin-off companies are increasing seen as a favoured route for commercialisation of university intellectual property. Thus research spin-offs are companies what have been created in order to commercialise intellectual property arising out of a research where staff are transferred from the research institution to a new firm. Intellectual property from the institution is licensed to the founding intellectual property of the firm (THORNBURN, 2000;

JARRETT, 2007). The success of the biotechnology commercialisation depends on an array of interwoven factors, not the least of which is the protection, preservation and promotion of public trust in the science, the scientists and the regulators (CHALMERS and NICOL, 2004; SAVAGE, 2006). The idea of entrepreneurial research institutions and new firms creation disseminates and yet further research and development is necessary (ROTHAERMEL *et al.*, 2007; MROCZKOWSKI, 2009).

The European Commission can play a major role in fostering innovations in the life sciences sector, through its Framework Programmes for Research and Technological Development, as well as through other policy initiatives implementing a coherent EU strategy for biotechnology and life sciences (KÜTT *et al.*, 2003). The European Council and the European Parliament have recognised the importance of life sciences and biotechnology, and the European Commission has put forward an action plan to address the challenges and opportunities involved. This 'Strategy on life sciences and biotechnology', adopted by the European Commission in 2002, proposed a 30 point action plan involving the Commission, the other European Institutions and other stakeholders and it runs until 2010 (European Commission, 2007).

In this article, we map biotechnology commercialisation in Europe and summarize the papers and reports on this topic in European countries. In the concluding section, we discuss some organizational and societal issues that arise from past experience and gained knowledge in biotechnology commercialisation.

## 2. History and present status

Biotechnology commercialisation began in Europe at the end of 1980s, more than a decade later than in USA. The first to stir up the market appeared United Kingdom followed by Germany, France and Switzerland. Some of the smaller European countries, particularly Ireland, Denmark, The Netherlands and the Scandinavians countries, are also focused on biotechnology (ALLANSDOTTIR *et al.*, 2002).

### *United Kingdom*

United Kingdom (UK) leads Europe in biotechnology, although it is still some way behind the United States (SAINSBURY, 1999; DECTERA *et al.*, 2007). Almost a quarter of all European biotechnology companies are located in the UK. Despite the maturity of UK biotechnology, R&D institutions seeking to license intellectual property or use it as the basis for a new life science venture still face several challenges in finding the relevant expertise and creating a fertile environment to facilitate start-up activity (SEARLE *et al.*, 2003). In 2003, there were 455 firms involved in biotechnology in UK. These spent in public-private partnership \$ 2008.4 million on R&D and employed 22405 fulltime equivalent employees, 59% of which were working in the healthcare sector (van BEUZEKOM and ARUNDEL, 2006; SMITH and BAGCHI-SEN, 2006).

### *Germany*

Although the European biotechnology industry is large and growing larger, individual countries represent very different stages of biotechnology growth and

venture capital progress. Germany provides a good example of how directed changes in governmental policy and commitment can lead to flourishing biotechnology and venture capital industries. Before the 1990s, Germany had an extensive research base but little interest in commercialising its results. In 1996, the German Minister for science and technology launched the BioRegio contest to promote the commercialisation of biotechnology. BioRegio was a government initiative that promoted the development of biotechnology 'clusters', with the winning 'model' regions receiving \$25 million over five years. At the same time, Germany set up a program called "Risk capital for small technology companies" investing into new biotechnology enterprises (HOWELL *et al.*, 2003). In 2004, there were 607 firms involved in biotechnology or biotechnology-related businesses and 24134 biotech-active employees, of which 11958 (50%) were employed by core biotech firms and 10995 (46%) by large life science firms (van BEUZEKOM and ARUNDEL, 2006).

#### *France*

The financial, fiscal, and research landscape for innovation and biotechnology has dramatically improved in France between 2001 and 2006. France became an attractive country for research, innovation, and the rise up of innovative small and middle enterprise. The "Young Innovative Company" status was conceived in France and already benefits more than 300 of the country's biotechnology companies and their shareholders. Proposal 'Excellence Valo' aims at creating a favourable environment for technology transfer and the emergence of start-up projects in research organisation (notably universities) thanks to a France-wide competition designed to spread good technology transfer practices and better funding to technology transfer teams throughout France (CARMAGNOL, 2007). According to the French biotechnology association and the industry representative France Biotech, the sector has been buoyed by venture capital investments throughout the first half of 2008, particularly pump-priming rounds, with investment of EUR 87mil. (COSTA and CARMAGOL, 2008). In 2003, 755 firms undertook biotechnology R&D in France, which represented 11% of all firms undertaking R&D, and spent \$ 1342.0 million on biotechnology R&D in private-public partnership, which represented 5.6% of total business enterprise R&D spending (van BEUZEKOM and ARUNDEL, 2006).

#### *Switzerland*

Out of a total of 693 European biotechnology products in the development pipelines of listed companies, 97 come from Switzerland (ALEXAKIS, 2007). This second-place ranking in Europe shows the country's innovative capabilities. With 137 enterprises and 81 suppliers, Switzerland boasts the world's highest per capita biotechnology density. In 2006, the Swiss biotechnology industry generated a turnover of more than 6 milliard CHF and had a workforce of over 14 300 employees. The basis for this ongoing success is the intensified collaboration and exchange of knowledge within a network of institutes, universities and private businesses. Switzerland, with over 40 venture capital firms and private equity funds, as well as various science parks and incubators, is a very inviting environment for innovative start-up companies.

### *Denmark*

Danish biotechnology not only outperforms its European counterparts but is on the rise. In 2006, companies raised unprecedented amounts of venture capital, pried open the window for initial public offerings and tempted investors with follow-up offerings (GIOVANNETTI and JAGGI, 2007). The Danish biotech industry has developed at a rapid pace over the past ten years. In the late 1990s, there were around 30 businesses in Denmark, the number rose to 117 in 2004, whereas in 2007 it was 82 active biotech companies. Geographically, 77 percent of the companies are located in the Danish part of the cluster Medicon Valley (MORAN, 2006). A new report from Ernst & Young shows that Denmark ranks third in Europe in terms of number of biotech products under development (SORENSEN *et al.*, 2008).

### *Scandinavian states*

The Research Council of Norway supported biotechnology, biology, biomedicine and functional genomics research in total funding in 2003 close to EUR 70 million (JOHNE, 2004). In the business sector, had the highest R&D expenditures on biotechnology (public-private partnership \$11.2 million), followed by the chemical sector (public-private partnership \$10.2 million). In 2003, 1440 biotechnology researchers worked in the higher education and institute sector; about half of these were women.

Scandinavia has a strong life science and healthcare industry (BRAZIL, 2008). MedCoast Scandinavia is a Norwegian/Swedish network organization with the aim to strength and develops the biomedical sector in the Göteborg-Oslo region. It includes 400 biomedical companies with 10 000 employees, every year about 20 start-ups are and the biotech venture capital investment about EUR 50 million annually (Oxford Research, 2004).

### *Belgium*

In 2006, there were over 140 biotechnology companies operating in Belgium, 7% of all such companies in Europe and two are elite companies (Tab. 2). Belgian biotechnology companies accounted for 16% of European turnover and almost 10% of R&D expenditure (Belgian Federal Government, 2008).

### *Ireland*

Irish biotechnology sector is strongly supported by state funding. Because commercialising technology is vital to achieve sustainable growth this aim, state agency Enterprise Ireland has established expert commercialisation teams working across the academic-industry interface in three key technology areas: life sciences and food, informatics and industrial technologies. Proof of concept funding is available to individuals or small groups who wish to demonstrate that their ideas have originality and true commercial potential. Commercialisation of research and development funding aims to bring a new product idea or business venture from third level educational institutions to market. These funding encourages knowledge based campus companies and academic entrepreneurs and to the year 2004 created 49 spin-off

companies. The bio-incubators at Trinity College Dublin and National University of Ireland in Galway, funded by Enterprise Ireland in 2004, already house a number of spin-off companies (Enterprise Ireland, 2008).

### **3. Biotechnology and life sciences clusters**

There are sixteen biotechnology and life sciences clusters in Europe. For a number of years now the area where Denmark and Sweden meet, Copenhagen Capacity and Region Skane, has been branded 'Medicon Valley'. This area is a life science cluster of research and development, as well as being home to a number of other institutions important for R&D, including several universities and contract research organisations (BRAZIL, 2008). The trinational BioValley is a unique, global, cross-border life sciences cluster, has one of the world's highest densities of life science activities, is one of the biggest life science clusters in Europe, has a strong scientific basis: more than 600 companies including big pharma, medtech and start-up companies, four renowned universities Basel, Freiburg, Mulhouse and Strasbourg (DANIEL *et al.*, 2006).

#### *Central and Eastern Europe*

The two main features of the restructuring are increased autonomy for scientists and the beginnings of competitive research funding. In some countries in Central and Eastern Europe, high proportion of research funding is still allocated as block grants to institutes and/or universities. However, these funds may be allocated to institutes dedicated to a specific area of research, e.g. molecular biology.

None of the countries reach the EU-25 average for gross domestic expenditure on R&D as a percentage of GDP, which was 1.86% in 2004; most are significantly below this figure (ENZING, 2007). The agencies that fund research are normally separated from those that fund its commercialisation through support to applied research, technology development, industrial research grants, university-industry research collaboration and measures to encourage the creation of small firms.

Applied research and development was carried out in industrial research institutes under specific ministries and was completely separate from the enterprises and there was little in-house industrial R&D. The Czech and Slovak Republic differ from this general pattern and over half of R&D was performed in the business sector. Only four countries have attempted to implement this priority by allocating funds to biotech-specific research programmes – Bulgaria, Hungary, Lithuania and Slovak Republic.

There is limited data on commercialisation in NMS and AMS and this probably reflects the early stage of development of biotechnology in these countries. For instance, there is no data on venture capital investment in biotechnology firms or on initial public offerings (firms floated on stock markets). Growth in publications output over time, particularly the capacity to sustain and increase growth of publications, provides a basis to cluster countries with similar performance into three groups:

Group 1: the Czech Republic, Estonia, Hungary and Slovenia are closing the gap with the EU-25.

Group 2: Cyprus, Croatia, Poland and Slovak Republic are making progress.

Group 3: Bulgaria, Latvia, Lithuania, Malta, Romania and Turkey have weak performance.

#### **4. Measuring biotechnology commercialisation**

The socio-economic impact of biotechnology has become very important for policy makers, industry, and consumers. A broad range of indicators measures commercial orientation of the various countries in biotechnology: patents and scientific publications, number of spin-off companies, distribution of employees and venture capital investment.

##### *Patents and scientific publications*

Commercialisation begins with science. Evidence suggests that public expenditure on biotechnology research has been increasing steeply in recent years. Several European countries have declared the fostering of biotechnology to be a key priority in their science and technology policies. For example, Ireland dedicated a substantial sum of 635 million euro to promoting excellence in scientific research in strategic areas such as biotechnology and information and communication technologies (MULDUR *et al.*, 2003).

In order to obtain a general impression of the commercial orientation of European countries in biotechnology, authors of the report BioPolis related the patent output as a measure for technology generation and commercial interest to the scientific publications output, which could be considered as a measure for scientific activities (ENZING, 2007). In 2003 almost similar numbers of patent applications are observed from Europe and the United States while in the preceding years a clear lead of the United States could be detected.

Biotechnology seems to gain more importance in smaller high-performing countries, such as Sweden, Finland, Denmark, Iceland or Switzerland (MULDUR, 2003). These countries also perform best according to measure of relative scientific output in biotechnology and show the highest relative growth rates. Performance in terms of technology generation as measured by patent applications on a per-capita basis also reveals a broad variety among European countries. Top performing countries in the most recent years are Iceland, Denmark and Switzerland (Muldur, 2003).

##### *Biotechnological industry – companies and employees*

As number of biotechnology companies indicates a quality level of biotechnology commercialisation, Report Critical I in the year 2006 compares the biotechnology sectors across some eighteen European nations and the United States (HODGSON, 2006). The survey for 2006 report Critical I gathered data from 4 154 companies, of which 2 163 were in Europe and 1 991 in the USA. European companies are younger and tend to be smaller. While the Healthcare sector in Europe accounts for just over a third of companies, it employs 50 000 people, approximately 52% of the European biotechnology workforce (Fig. 1).

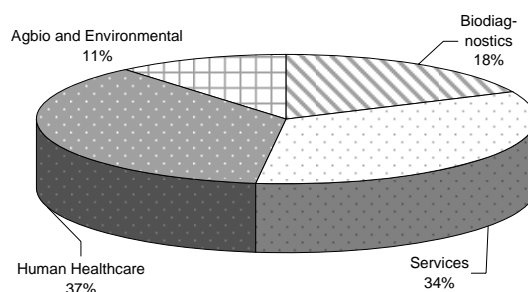


Fig. 1. Distribution of biotechnology companies in Europe by sector (HODGSON, 2006).

*Venture capital in biotechnology*

Measuring commercialisation of biotechnology in terms of venture capital investment reveals an increasing flow of venture capital into almost all countries considered since the mid 1990s (Tab. 1).

Tab. 1. A snapshot of the EU biotech sector data collected from dedicated biotech companies (HODGSON, 2006).

Indicator	Europe	US
Number of companies	2 330	1 991
Number of new companies formed	131	78
Number of employees	98 500	190 500
R & D expenditure (in mld €)	7.6	21
Revenue (in mld €)	21.5	41.5
Venture capital raised (in mld €)	1.02	3.2
Equity raised (in mld €)	3.65	11.3
Debt raised (in mld €)	0.81	7.4

Interestingly, for most countries where data is available (Denmark, Austria, United Kingdom, Sweden and Finland), we observe a continuous growth over years 1995-2004. The past few years marked a recovery period for the European biotechnology sector. Looking at 2006, it appears that it is now on the right track of sustained progress (Tab. 2). A record year of financing, with 4.7 milliard euros raised with 45 percent increase demonstrates the robustness and growing strength of the European biotechnology sector (DUCHENE, 2007). Although venture capital funding did not increase at similar rates, the amount of private equity raised by European companies set an all-time record, passing 1.5 milliard euro for the first time ever. With 722 million euros in proceeds from 32 initial public offerings a stable trend in European public company financing appears to be emerging (Ernst & Young Report, 2008).

Tab. 2. Top venture funding in Europe (HODGSON, 2006).

Name	Country	Round	Amount raised (in mil EUR)
Movetis	Belgium	First Round	49
Chroma Therapeutics	UK	Third Round	44
Cerenis Therapeutics	France	Second Round	43
Nabryva Therapeutics	Austria	First Round	42
Ablynx	Belgium	Fourth Round	40
Palau Pharma	Spain	First Round	40
Santaris Pharma	Denmark	Fourth Round	40
NowImmune	Switzerland	Second Round	37
Chiasma	Israel	Second Round	35
ESBA Tech	Switzerland	Third Round	32
Neuropharma	Spain	Second Round	32
Genextra	Italy	Second Round	30

## 5. Conclusions

There is no doubt that biotechnology is the key technology of modern economies. Biotechnology industry is built upon excellent science and market demand. If adequate attention is given to creation of scientific base and consequently commercialisation, economic rewards are beneficial for the academic and business community. The results are clearly visible in old member states of European Union where combination of biotechnology specific and generic policy instruments have been adopted since end of 1990s (SAINSBURY, 1999). The analysis confirmed the trend towards commercialisation even in those countries that fell behind the European average. The new member states and accession countries of European Union suffer from lack of public resources to invest into research in general. Fragmented and uncoordinated support of biotechnology research makes it difficult for any commercialisation at all. Government science and technology policy, significant factors that can often explain the biotechnology performance, are restructuring to make the support system more effective (ENZING, 2007).

European biotechnology companies are part of a smaller industry due to lower amounts of capital available, and therefore take longer to raise capital (HODGSON 2006). They face slow growth beyond the start-up stage than those in US and remain sub-critical size. A recent study showed that there are close to 1 400 technology transfer offices in Europe (European Commission, 2009). Many started as industry liaison offices and also developed services to encourage commercialisation of research results. Over time, many of these have developed specialised staff and services for assessing disclosed inventions, patenting, licensing, and developing and funding spin-offs, but also for actively approaching firms for contract based arrangements.



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