Life Sciences and Biotechnology: The Transatlantic Divide

Life sciences and biotechnology[1] have seen a rapid expansion over the last few years. Scientific advances in genetics and molecular biology and their combination with chemical engineering and new information technologies have begun to transform the industrial landscape of the transatlantic economy. These advances are having a lasting impact on a variety of economic sectors, including healthcare, pharmaceuticals, industrial processing and agro-production. Indeed, many analysts are now talking about an emerging bio-economy that will be of increasing global economic significance in the future.

The United States and the European Union have been amongst the leading players in the field of biotechnology. While the commercial application of biotechnology and life sciences originally started in the US in the 1980s, European companies have slowly begun to catch up with the US over the last few years. However, the profile of the biotechnology sector in both continents remains radically different, as a result of different regulatory systems and public attitudes. The impact of the current financial crisis, moreover, is likely to differ for biotechnology companies on both sides of the Atlantic.

This brief will focus on the different industrial profile and political differences that characterize life sciences and biotechnology in the United States and Europe. Are these differences likely to lead to renewed regulatory and trade conflicts across the Atlantic, or will the future yield to a more integrated transatlantic "bio-economy"?

Biotechnology in Europe and the United States

The EU's biotechnology sector developed later than in the US, and therefore has not reached the same level of maturity and profitability. In Europe, biotechnology first took off in the UK, where academic life sciences were quick to develop commercial applications, and the UK's financial sector was able to provide the venture capital needed for their development. The UK's initial success was followed by Germany, where the development of the biotechnology sector was largely the result of publicly funded competitions. Today, the majority of Europe's biotechnology firms are located in Germany, the UK, France, Switzerland and the Scandinavian countries.

According to a 2005 survey, there are more than 2,100 biotechnology companies in Europe, employing some 96,500 workers.[2] Due to the high research intensity of the industry, a large percentage of these workers (44%) are directly involved in R&D activities and are therefore of great importance for sustaining Europe's knowledge base. Most of these companies are small and medium-sized enterprises (SMEs) that are only a few years old and employ no more than a handful of people. While it has been estimated that the biotechnology industry makes a contribution of around 1.5% to Europe gross-

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value added (GVA)[3], the sector indirectly also influences developments in a variety of other industries, including healthcare, pharmaceuticals, industrial processing and agro-production. The uptake of biotechnology differs considerable across these sectors.

Most European biotech companies focus on healthcare and some 9% of pharmaceuticals launched over the 1996-2005 period have been biopharmaceuticals. However, overall the EU has a relatively weak position in biopharmaceuticals, with only 15% of world wide production, compared to the US (54%) and Switzerland (10%).[4] The same holds true for agro-biotechnology, which has received the majority of public attention and criticism. While the EU has now put in place a new regulatory system and has approved several genetically-modified (GM) crops for cultivation, public skepticism has meant that the uptake has been slow. Today, only a handful of EU countries are cultivating GM crops. Amongst these, Spain is the largest with around 100,000 hectares under cultivation, compared to 62.5 million hectares under cultivation in the US.[5] EU companies are considerably more advanced when it comes to industrial biotechnology and especially the use of biocatalysis and fermentation that are used in the chemical industry. Here EU companies are global leaders. The development of bio-ethanol has also been also been an important area for European biotechnology companies, due to European Commission plans to increase the EU-wide share of bio-fuels to 10% by 2020.

Leading Biotechnology Companies in Comparison[6]

Country	Com-panies	R&D Investment/ company	Biotechnology R&D Investment			Employees	R&D Investment/ employee	Market Capitalisation
			2005	AGR 2004/2005	AAGR 2002-2005			
	#	€K	€m	%	%	#	€K	€m
EU-27	57	21 186	1 208	11.1	7.4	25 312	47.7	17 125
CH	4	154 855	619	-0.8	13.9	6 491	95.4	7 903
JP	2	141 445	283	12.9	0.2	8 915	31.7	4 518
US	44	159 541	7 020	23.2	12.1	70 033	100.2	182 792
Other	4	50 428	202	26.0	8.1	7 364	27.4	6 866

Overall, the EU's biotechnology industry – except for certain sectors – still lags behind that of the United States. In the US, life sciences and biotechnology have grown robustly for a long time and have found an enthusiastic uptake. While the number of biotech companies in the US and EU is similar, the US biotechnology industry employs more than twice as many people as the EU (around 180,000). This is mainly the result of the greater maturity of US companies and the more advanced process of market consolidation. US companies also generate much larger revenues and spent almost twice as much on R&D as their European competitors. Much of this can be explained by the fact that it is easier for US companies to raise money from the financial markets – especially in the form of venture capital and through equity and debt financing. While European companies will become more competitive as they mature, they are going to be held back by their limited ability to access venture capital and other sources of funding.

Despite these considerable constraints, EU companies are faring well when it comes to the filing of patents, and seem to have largely caught up with the US. In 2002, EU

companies accounted for 34.5% of all biotechnology patent applications filed at the European Patents Office (EPO), compared with 39.9% for the US.[7] In 2006 the ratio was reversed, when EU companies filed 45.1% of patent applications to the EPO, compared with 25.7% for the US.[8] Nevertheless, the continuing large gap in R&D spending bodes ill for EU companies. Thus, with around €100,000 R&D investments per employee, US companies spend twice as much as European companies. Moreover, public funding in the US is considerably more generous. According to a 2005 survey, public funding in 32 European countries amounted to $4.1 billion, compared to $23.2 billion for the US.[9]

Snapshot: EU and US Biotechnology Industries[10]

At end 2003, Europe's biotechnology industry	At end 2003, US biotechnology industry
Had 1976 companies	Comprised 1830 companies (2002: 1891)
Employed approximately over 94,000 people, including 35,000 in R&D	Employed approximately 172,400 people (2002: 168,000)
Spent about €6 billion in R&D	Spent €16.4 billion on R&D
Had 450 compounds in clinical development or awaiting approval	Had over 1110 new drugs in clinical development or awaiting approval (2002: 1164)
Generated nearly €19 billion revenue	Generated nearly €42 billion of revenue (2002: nearly €40 billion)
Raised €750 million in Venture Capital (raised over €940 million in 2004)	Raised €2.1 billion in Venture Capital in 2003 and over €2.9 billion in 2004
Raised a total of €1.49 billion through equity in 2003 and €1.6 billion in 2004	Sold an additional €5 billion worth of equity – largely through the public markets in 2003 and another €4 billion in 2004
Raised nearly €1 billion in debt financing in 2003 and over €1 billion in 2004	Raised a further €4.3 billion of debt in both 2003 and 2004
Formed 132 new companies	Formed 83 new companies

Public Opinion and Regulatory Differences

In the past, much attention has been given to the different regulatory approaches the EU and the US have applied when it comes to the area of biotechnology. Here, much of the focus has been on the transatlantic dispute over genetically-modified (GM) crops.[11] Indeed, European public opinion remains largely hostile to GM food. A 2005 Eurobarometer poll indicated that 58% of European respondents opposed GM food while 42% endorsed it. However, European public opinion has been much less hostile when it comes to commercial application of biotechnology in other areas. Over 70% of respondents supported industrial biotechnology, including bio-fuels and pharmaceuticals. And a majority of 52% stated that they thought that biotechnology will improve their lives. Overall, therefore, it seems that European public opinion has slowly warmed to the increased use of biotechnology in everyday life.

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This slow change in public opinion has been reflected in the regulatory approach taken by the European Commission. The EU's new regulatory framework allows for the approval of GM crops and has done so in several cases. However, EU conditions for approval of new GM varieties remain much tougher than in the US, and EU member states maintain a considerable say in the approval process. As a result, member states have frequently budged to public pressure and prevented the approval of new GM varieties. Still, on the whole the European Commission has become more supportive of biotechnology. As early as 2002, the European Commission adopted a strategy to promote the use of life sciences and biotechnology in Europe. A mid-term review conducted in 2007 promised further Commission action in order to encourage the wide-spread use of biotechnology in Europe and to create a Knowledge-Based Bio-Economy (KBEE).[12]

Despite the gradual realization that the EU needs to make a greater effort to encourage the use of biotechnology, the industry remains constrained by three specific factors: the EU's fragmented patent systems, which make approval more difficult; the lack of risk capital on a comparable level to the US; and a lack of cooperation between universities and businesses – a cooperation that is more established in the US. It seems unlikely that this will change in the short term. Moreover, US public opinion and regulatory approaches will remain more business-friendly for the foreseeable future. GM varieties are now dominant in many US crops, and public opinion continues to endorse the wide-spread use of biotechnology for the production of pharmaceuticals and foodstuff.

The Impact of the Financial Crisis

The impact of the recent global financial crisis on the biotechnology sector is likely to differ between the EU and the US. Overall, European biotechnology companies are faced with a considerably greater problem. Many European companies are much younger and less profitable than their US counterparts. That means that for the time being they are more dependent on credit – especially since it often takes a long lead-time for biotechnology innovations to become commercially viable. As a result many analysts expect that the current credit crunch, if it continues, will lead to a culling of European biotech companies. According to some estimates, one of five European biotech companies will risk bankruptcy unless alternative sources of funding are forthcoming. According to a survey by Alcimed, European companies will need some $2.6 billion in funding in order to maintain their current level of operations and innovation.[13] However, for the time being, emergency funding remains largely focused on the financial sector and traditional industries, such as the car industry. In this situation it seems unlikely that additional funding for the biotechnology sector will be forthcoming.

In the US, the situation is slightly different. Although the US biotechnology industry has traditionally been more reliant on venture capital and equity funding, it can be expected that the financial crisis will have a less dramatic effect. Due to the industry's greater maturity, US companies overall are more profitable and not as reliant on credit. While the credit crunch is therefore likely to affect company creation in the US, it is unlikely to lead to the bankruptcy of a large amount of US biotech companies. Moreover, the new US

administration is expected to provide a considerable boost to the scientific community. Indeed, President Obama has already lifted the restrictions on federal funding for human embryonic stem cell research that had been imposed by his predecessor. The US economic stimulus is also expected to deliver large additional funding for scientific research, which should at least partially replace the funding traditionally provided by the financial sector. As a result, the US biotechnology industry is likely to make it better through the crisis than its European competitors.

Conclusion

There remain large differences in the use and application of life sciences and biotechnology in Europe and the United States. While Europe has lost some of its former inhibitions when it comes to biotechnology and its industry has slowly begun to catch up with the US, differences remain when it comes to public perceptions and the regulatory environment – especially with regards to GM crops. In the short run, it seems likely that the financial crisis will exacerbate transatlantic differences. Europe's biotechnology industry is likely to suffer more under the credit crunch and fall further behind the US. Moreover, the US seems better able to channel its economic stimulus into research-oriented industries, providing its biotechnology sector with further advantages. While future trade disputes over GM crops cannot be ruled out, they seem unlikely for as long as the new US administration is bent on a more constructive relationship with European countries. More likely, future disputes will arise over the international regulatory framework for biotechnology products. With its biotech industry on a sound footing, the US is in an advantageous position to dominate the debate.

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[1] According to the OECD, biotechnology is defined as "the application of science and technology to living organisms as well as parts, products and models thereof, to alter living or nonliving materials for the production of knowledge, goods and services."
[2] Critical I (2005), Biotechnology in Europe: 2005 Comparative Study, BioVision: Lyon
[3] European Commission (2007), Consequences, Opportunities and Challenges of Modern Biotechnology for Europe, JRC Reference Report, EUR 22728
[4] European Commission (2007), Competitiveness of the European Biotechnology Industry, Working Document
[5] Clive James (2008), 2008 ISAAA Report on Global Status of Biotech/GM Crops, International Service for the Acquisition Of Agribiotech Applications (ISAAA)
[6] European Commission (2007), Biotechnology in Europe: Patents and R&D Investment, 100/2007
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[8] European Commission (2007), Life Sciences & Biotechnology for Europe, April 2007
[9] BioPolis (2007), Inventory and analysis of national public policies that stimulate biotechnology research, its exploitation and commercialization by industry in Europe in the period 2002–2005, June 2007
[10] Critical I (2005), Biotechnology in Europe: 2005 Comparative Study, BioVision: Lyon
[11] See EUCE Briefing paper "The EU-US Dispute over GMOs: Risk Perception and the Quest for Regulatory Dominance": http://www.unc.edu/depts/europe/business_media/busbrief0705-GMOs.htm
[12] European Commission (2007), Communication on the mid term review of the Strategy on Life Sciences and Biotechnology, SEC(2007) 441
[13] Ben Hirschler (2009), Fifth of European Biotechnology Companies could fail in 2009, Reuters March 16, 2009

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