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Why Invest in Biotechnology, and How? Britain and Germany Compared

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Executive summary

Using a comparison of policy development in Germany and the UK since 1992, this report attempts to answer the question why governments across the world commit so many resources to biotechnology. As Germany and the UK have the most highly developed biotechnology structures in Europe, as well as distinctive policy structures, they are interesting case studies in their own right. The mechanisms by which policy has been developed in the two countries are evaluated in the light of an overview of the national and regional systems of innovation literature. It is argued that biotechnology represents a unique case because it is intrinsically regional and 'clustered' in nature and hence represents an attractive vehicle for coordinating a number of areas of government industrial policy.

An Anglo-German comparison provides insights into the development of biotechnology policy. First, both countries have favourable knowledge and skills regimes alongside a strong science base. Second, both have large domestic pharmaceutical companies. Finally, the public is seen as having a generally positive attitude towards biopharmaceutical research although in both cases it is more sceptical about agricultural biotechnology. However, the policy structures to support biotechnology in the two countries are quite different. As a relative latecomer Germany has been highly instrumental in market creation strategies at a regional level while the UK has relied much more heavily on a market facilitation approach.

This paper considers policy structures in the two countries in terms of basic expenditure on research and development and examines policies to stimulate private sector involvement, commercialisation and clustering. It constructs a map of policies in the two countries and highlights the strong regional dimension to policy in both countries. It pulls together the literature search and the overview of policy to highlight the key 'critical success framework' in each country.

Using a critical success framework to examine documentary and attitudinal evidence in the two countries, the report examines this evidence in terms of clustering effects at a regional level (large companies, business angel activity, specialised consultancies and venture capital firms) and goes on to examine attitudes towards university–industry links and academic venturing in the area of biotechnology. Both countries demonstrate clearly clustered activities and evidence that clusters are developing outside of established centres. The instrumental market creation approach followed by the German government has been highly successful in creating new technology-based biotechnology firms but in the light of the collapse of the venture capital market has recently been criticised for creating unsustainable businesses. The process of market facilitation is much slower in the UK and the number of start-up businesses is smaller.

It is argued that the networked and clustered structure of German biotechnology has provided both a stimulus to rapid catch-up and a strong research base on which to build the sector in the future. Irrespective of subsequent vagaries in risk capital markets, UK policymakers have some examples of public–private sector partnership in the funding and organisation of science and its commercial application from which lessons could be

learned. In particular, the role of the regions is key as, of course, is substantial and sustained investment in the research itself.

The report concludes by attempting to answer the question 'why bother with biotechnology?' It argues that biotechnology is a central part of any government's science strategy. European policymakers do need to ensure that we do not fall behind the US, either in research or in commercialisation, for the simple reason that a national monopoly in one particular aspect of scientific endeavour would distort future competitiveness as and when commercial biotechnology products become part of everyday life in the way that computers have. Further, the Anglo-German comparison provides evidence that a strong biotechnology policy creates jobs and that this leads to a strong sense of regional renewal around science-based industry. However, the critical stage in a biotechnology company's development is the transition from a research and prototype base largely supported by the public sector to actual commercialisation and sustainable growth. The issue of how to manage this process effectively – both at the level of the individual firm and at the level of policy – is not clearly understood and there is scope for more research in this area.

1 Introduction

Of all the areas of government policy, biotechnology may seem the least obvious as a focus for an Anglo-German comparison. To begin with, the whole area of biotechnology is fraught with ethical difficulties, not least because it is often seen as synonymous with 'Frankenstein' pictures of chickens without feathers, or mice with ears grotesquely sprouting from their backs. Second, although at an individual level people can clearly see the link between genetic research and their own health prospects, other areas of biotechnology, for example agricultural biotechnology, have less obvious benefits for society or the economy. And finally, despite the vast amounts of resources poured into biotechnology across the world, and the fact that biotechnology accounts for 41 per cent of patents worldwide (Rammer, 2002), there is still no long-term 'cure' for cancer, no end to world poverty and hunger, and there are very few profitable biotechnology companies providing employment in their regional or local communities.

To a large extent, much of the policy interest around the world was based on evidence from the United States throughout the 1990s that research-led entrepreneurship would generally lead to increases in productivity and, hence, economic growth. Europe has a productivity gap with the US and studies of innovation would suggest that this could be closed by addressing the 'innovation gap' (Fagerberg, 1987; Freeman, 1995; Lundvall, 1992) and that higher employment and wealth generation would follow (Bygrave *et al.*, 1998).

For most people, however, the interest in biotechnology may still seem perplexing. 'Why,' puzzled a senior UK trade unionist during an interview, 'does the government want to pour money into science? How on earth can a few professors with test tubes and microscopes create jobs?' Given the furore surrounding genetically modified foods, and the highly specialised and skilled types of employment that new biotechnology firms create, this question is quite justified and it is the aim of this paper to address it by means of an Anglo-German comparison.

This comparison is built predominantly on desk-based research. However, substantial use has been made of ongoing research by the author in the area of biotechnology and venture capital generally and entrepreneurship in particular. Interviews were held with key experts in university–industry links and biotechnology as part of the *Global Entrepreneurship Monitor* in the UK. Use was made of the equivalent study in Germany.

2 Why an Anglo-German comparison?

The UK and Germany represent interesting cases within the wider European effort to catch up with United States. They have, respectively, the largest and the second largest biotechnology sectors in Europe. Both have strong regional biotechnology clusters around world-class universities and both countries invest the largest amounts in Europe of private- and public-sector money in biotechnology. Their biotechnology policies at a government level are strongly supportive of establishing and developing robust biotechnology research and, accordingly, have the most policy and infrastructural attributes that are either supportive or strongly supportive of biotechnology (for example, risk capital, public sector support for research and development (R&D) etc.) (Senker and Zwangenberg, 2001).

What makes the comparison especially interesting, however, is the way in which the two countries have moved towards this position during the last decade. Britain's biotechnology sector is well established and has emerged out of high-quality research and strong commercial involvement in that research in and around the Cambridge area in particular. Awareness of the significance of biotechnology as a scientific area was first raised in the 1970s and 1980s by a government-commissioned report and subsequent policy sought to increase general awareness of its potential, particularly among private-sector companies. Over the past five years government policy has worked to extend the cluster-based activity beyond Cambridge to other regions of the UK. Thus, for example, policies like University Challenge and the Higher Education Innovation Fund have attempted to stimulate the flow of seedcorn finance to university research-based spin-outs and to encourage academic entrepreneurship generally and, as a corollary, biotechnology in particular.

By contrast, Germany's biotechnology sector was substantially less developed than UK or US biotechnology at the beginning of the 1990s. Although the capacity to audit trends in biotechnology did exist within the Fraunhofer Society's technology foresight programme, Delphi, research activity was limited to three Gene Research Centres at Cologne, Heidelberg and Munich. Real awareness of the importance of biotechnology as an area of research and commercial activity did not really become widespread until the latter half of the 1980s (Wörner *et al.*, 2001). Historically-based mistrust of biotechnology – because of its association with genetic manipulation – and legal restrictions on R&D in this area contributed significantly to its relatively backward stage of development in comparison to the UK in the early 1990s (Harding, 1999; 2001). With the amendment of the Genetic Engineering Act in 1993 the legal barriers to biotechnology research were removed. The subsequent government-led BioRegio programme was set up in 1995 and has arguably been a central driver behind the development of a systematic and positive approach to biotechnology research and commercialisation. It was supported by a strong commitment at the policy level to increasing funds for basic research in biotechnology.

While the two countries provide examples of two different approaches to the development of biotechnology, there are also marked similarities; for example:

- Both have favourable knowledge and skills regimes and strong science bases with an active emphasis on technology transfer between the research base and commercial application.
- Both have strong multinationals operating in the pharmaceuticals and chemicals areas.
- In both countries the public is generally positive about biopharmaceutical research and development, although more wary of the application of biotechnology techniques such as genetic modification in the agro-food areas.

(Senker and Zwangenberg, 2001)

Yet in the UK the structures are largely market-led. Policy works to *facilitate* market operations where any gaps are apparent, for example in funding or in research and development. In Germany, by contrast, biotechnology as a legitimate area of scientific investigation and of commercial enterprise has been developed to a significant extent by policy effort to *create* markets where none existed. This has been done through support for research network development and for biotechnology start-up finance.

Finally, examination of the different policy perspectives provides interesting insights for comparing the countries' approaches to managing their economies. Within the economic literature comparing and contrasting German and UK economic performance there is a tendency to characterise the two economies at different ends of a management spectrum. The UK economy is seen as exemplifying the 'Anglo-Saxon' model of market-based flexibility and radical innovation-led growth, while the much more rigid, structured and ponderous 'Rhineland-Capitalist' model, of which the German economy is viewed as paradigmatic, is reported to be far less successful in creating structures that support and sustain radical innovation-led development (see, for example, Soskice, 1996). Entrepreneurship is generally a test case of this polemic approach: it might, by definition, be expected to be more dominant and more widespread as an expression of labour market activity in a more market-based economy. Bio-entrepreneurship as a particular case is interesting as both radical innovation and regulatory flexibility, especially in labour markets, are required in order for it to be able to thrive.

Against this background, then, Germany would seem to be at a disadvantage. Its labour market inflexibility is well documented (Funk, 2000; 2001) and, arguably, manifests itself in the persistently high levels of unemployment that the economy is currently experiencing. Further, some economists have noted that the German economy has a tendency to produce incremental innovations rather than the radical paradigm-shifting innovations that characterise the US or the UK economy (Soskice, 1996; Casper, 2000; Hall and Soskice, 2001). Because of these two structural weaknesses Germany would appear to have a comparative disadvantage in biotechnology innovation.

However, the evidence does not support this hypothesis. In 1995 German policymakers set themselves the target of overtaking the UK as the leading country in Europe for biotechnology start-ups. By 2001 it had achieved this with 332 core entrepreneurial life science companies (ELISCOs) (www.BioM.de) compared to the UK's 250 (www.dti.gov.uk). And, although the UK's bioscience[1] sector, including all biotechnology companies,

[1] 'Bioscience' is here taken to include the entire arena of life science research where biotechnology is the commercial exploitation of this research.

remains larger in terms of longer-established firms and total turnover, the absolute size of the German industry in terms of the number of firms is marginally bigger: 465 compared to the UK's 450. German biotechnology now accounts for the third highest number of patents per employee in the world after the US and Japan. And finally, in terms of levels of total entrepreneurial activity (TEA) and, indeed, attitudes towards entrepreneurship, Germany and the UK are remarkably similar (Reynolds *et al.*, 2002; Harding, 2002a; Bergmann and Sternberg, 2002).

Much of the development in Germany is still embryonic: for example, the country has a much larger number of start-up companies established for less than three years, whereas in the UK the biotechnology sector is more established. However, the sheer pace with which Germany has caught up in terms of biotechnology research and entrepreneurship warrants further investigation in its own right: it arguably represents an extension of the base of the 'business system' to incorporate this type of activity and, hence, to allow its industrial structures to adapt (Casper, 2000).

3 Why support biotechnology?

3.1 The financing gap

Within the context of the whole European biotechnology sector, the UK and Germany are big players, with the largest and second largest number of firms in the sector respectively. However, in comparison with the more advanced biotechnology sector in the US, the European market is still substantially underdeveloped, heavily reliant on independent start-up firms and with a relative underrepresentation of university spin-outs. The risk capital market is still weak, with less that 3 per cent of total venture capital investment across the whole of Europe going to biotechnology ventures and less than 1 per cent going towards biotechnology in the UK.[2]

The financing gap for biotechnology is illustrated in Table 1. In simple terms, potential investors see biotechnology as risky. Biotechnology is research-intensive and this is expensive. Thus the amounts of money required even to prove that a concept is viable (let alone commercialisable) are very high. It can take anything between ten and twenty years to get to the stage where clinical trials have been completed, and the development of a commercially viable product at the end of this is by no means assured. Indeed, it has been estimated that for every 100 biotechnology research ideas, only one is likely to have any commercial potential at all (Harding and Lissenburgh, 2000). This means that the risks faced by potential investors are high relative to the rate of return within the 'normal' lifespan of a venture capital (VC) investment (where exit is usually planned within three to five years). This manifests itself in a clear underrepresentation in biotechnology financing relative to total equity financing.

Table 1 clearly shows that, as a proportion of total investment, or even of total high-technology investment, biotechnology is a poor relation. Amounts invested in biotechnology across the whole of Europe have remained relatively static since 1996, while total investment has gone up nearly five times, high-tech investment has nearly

Table 1
Financing gap for biotechnology in Europe

	1996	1997	1998	1999	2000	2001
Biotech	2.70	2.60	2.40	2.60	2.90	2.65
Hi-tech	19.60	23.90	27.80	25.60	31.40	28.0
Seed and start-up (% total)	6.5	7.4	11.4	12.9	19.0	15
Total VC funding (€m)	6,788	9,655	14,460	25,116	34,986	24,331

Source: European Venture Capital Association, various

[2] No figures for the US are publicly available.

Table 2
Relative structures for venture capital in Germany and Britain

Country	Investment focus of lower level investors	% at each stage (2001)		% total in technology (2000)
Germany	Biotechnology and information & communication technology	Early stage Expansion Management buy-outs/-ins	26 22 50	46.8 (but 99% of all early stage is in technology businesses)
UK	General investments and cyclical services, increasing general technology focus	Seed/early stage Expansion Management buy-outs/-ins	12 32 56	19.3
EU average	Consumer products and services, manufacturing and industrial production	Seed/early Replacement Expansion Management buy-outs/-ins	15 4 35 40	31.4

Source: updated from Harding, 2000

doubled and seed and start-up investment for all sectors has almost trebled. The European Venture Capital Association (EVCA) reports that between 2000 and 2001 total investment in biotechnology rose in Germany but fell in the UK. Across the whole of Europe the trend for biotechnology investments was downwards, although the level of investment still remains slightly higher than in 1999.

Table 2 examines the relative structures of venture capital in Germany and the UK and compares it to the EU average.

The table shows quite clearly the different foci of the German and the UK venture capital industry. In the UK investments are heavily focused at the large-scale end of the market with management buy-outs (MBOs) and management buy-ins (MBIs) comprising the majority of venture capital funding irrespective of sector. In Germany the seed and early stages of start-up development account for higher levels of investment than in the UK and are substantially higher than the European average. The industrial sectors which attract substantial investment in Germany are biotechnology and information and communication technology (ICT), while in the UK the sectors tend to be much more general and not science-based.

This difference in financing focus is arguably due to the different policy emphases in the two countries (for further discussion of this see Harding, 2001). In Germany enterprise and innovation policy has generally concentrated on stimulating industrial systems and networks by encouraging public–private sector partnerships, technology transfer and private finance capital at a regional level. The BioRegio programme is one example of this, as is the InnoRegio programme that seeks to develop innovation structures for the eastern states. In order to ensure that private-sector investment has gone into biotechnology and ICT, the government has implemented a system of parallel investment through the *Kreditanstalt für Wiederaufbau* (KfW) and the *Deutsche Ausgleichsbank*

(DtA). Under this system any risk capital investment fund prioritising early-stage technology investments can construct a ‘fund of funds’ (broadly, a venture capital fund consisting of more than one independently managed fund) and thereby draw down on a further 25 per cent extra investment from the KfW to provide leverage for private-sector investment. Alongside this, the KfW will also provide up to a 50 per cent guarantee on any investment made by the main ‘fund of funds’; thus the risk to the investor is just 25 per cent of the total amount invested. Clearly this acts as a major stimulus to private-sector investment in riskier sectors and accounts for the higher numbers of investors in biotechnology start-ups.

Indeed, it is this desire to mitigate the risk faced by potential biotechnology investors relative to the returns they might get that underpins much of German government policy towards the financing of biotechnology entrepreneurship. It is clear from Tables 1 and 2 that there is a gap between biotechnology investments and total venture capital investments. What German policy has attempted to do through the KfW and the DtA is to leverage private-sector money into riskier areas of investment by guaranteeing a substantial proportion of any losses that may be made on projects that do not deliver.

That the financing gap is more acute in the UK is also apparent from the data presented here. The reasons for this are complex, rooted in the nature of the private equity market in the UK (which tends to favour larger investments) and extend beyond the scope of this paper (for further detail see Harding, 2000; 2002b). Suffice it to say that research has shown UK investors to be averse to technology investments both in terms of the amounts of money they put in (Murray and Lott, 1995) and in terms of their attitudes towards technology investments (Harding, 2000).

3.2 The knowledge gap

Governments support biotechnology for reasons other than the financing gap. Biotechnology concepts are complex and heavily reliant on multidisciplinary research teams. The research itself is expensive, and ‘critical mass’ needs to be built in terms of research quantity before any of the concepts are likely to become commercialisable. Once an idea with commercial potential is developed, there is still a very long time to full commercialisation and there are many points along the route to market that might end in failure. For example, the public outcry around genetically modified (GM) foods has presented many very large biotechnology companies such as Monsanto with problems in terms of share price and, hence, access to further research funding. Huntingdon Life Sciences is another company that, even when it appeared to be relatively successful, found difficulties in gaining further funding once public opinion swung against it.

This points to the importance of the basic research function within the ‘typical’ biotechnology firm. Until a product is developed, and this can take some time, the company is organised around a concept or a set of concepts that have commercial potential but that require further research in order to progress them further. This requires a strong research base and highly qualified personnel. It also means that a biotechnology company is highly reliant on the research institutions (in particular universities) operating in related fields of research in close proximity.

It is this 'networked' nature of the biotechnology firm that makes it unique and that makes it an attractive vehicle for delivering government policy. The true value of the firm lies in the quality of the research team that 'owns' the initial concept and its national and, critically, international research networks. Often these are groups of scientists from related disciplines who have worked together on research and may not have any developed knowledge of management, or even of presenting their ideas to a lay audience in an approachable manner. They will always require access to a sophisticated research base (including laboratory facilities) and often require access to specialist legal, administrative and financial support as well (Organisation for Economic Co-operation and Development (OECD), 2001; Shohet and Prevezer, 1996).

3.3 Biotechnology as a policy focus

There are clearly some factors associated with biotechnology that warrant public-sector support. In particular, the preceding sections have highlighted a financing gap and a knowledge gap (the 'personal networked' nature of activity) that mean that biotechnology cannot survive alone. This in itself, however, may not justify the large policy emphasis that is being put on biotechnology research in all industrialised economies. In order to examine this, it is necessary to see biotechnology in the context of competitiveness in wider, science-based industries.

Biotechnology as an area of research and commercial activity is derived from the public-sector research base in life sciences on the one hand and the research activities of the chemical and pharmaceutical sectors on the other. Increasingly the pharmaceutical industry is the core sector underpinning R&D in biotechnology. Pharmaceutical companies spend very high proportions of their total turnover on R&D as this is where the competitive advantage in that sector originates (Sharp, 1996).

The research intensity of the sector has increased, with combinatorial chemistry (interdisciplinary chemistry) and molecular biology now working together to develop new diagnostic and drug delivery mechanisms as well as long-term gene-based solutions to diseases or, in the case of agri-environmental biotechnology, crop development. These tools and techniques are developed in-house in large company research laboratories, but the risks associated with the research are high since the need for 'critical mass' in research effort discussed above applies equally to large companies as it does to small. As a result, very new areas of biotechnology research, which are not likely to lead to new products or processes in the immediate future but which may have commercial potential in the future, are often strategically 'outsourced' to smaller research-based companies with strong links to research institutions in the public-sector science base (Sharp, 1996; Gambardella *et al.*, 2000). In order that the pharmaceutical industry within a country remains competitive, it is essential that structures to support this type of activity exist.

Gambardella *et al.* (2000) point to the declining competitiveness of the European pharmaceutical sector and argue that one of the core reasons for this is the underdevelopment of its networks and support infrastructures in the science base relative to the United States. Germany and the UK are leaders in the European market, but there is still a competitive gap between them and the US which is potentially extremely damaging to the future competitiveness of the whole sector. They point to the global mobility of researchers in this area since all belong to international networks of scientists and experts. Increasingly, they argue, local 'innovation clusters' compete with one another at the international level as locations for science-based businesses and it is here that the scale of the US science system, as well as its links with the commercial base, far exceeds that of Europe (Gambardella *et al.,* 2000; see also Cooke, 2001).

Biotechnology is core to competitive success in pharmaceuticals because of this reliance on research outsourcing and excellence in the science base. Biotechnology policy has no single clearly defined area (Webber, 1995); rather it encompasses three major policy areas: university–industry links, regional policy and finance policy.

3.4 University–industry links

The first area is science policy generally and university–industry links in particular. Biotechnology requires a strong basic science research base in the life sciences if concepts or ideas with any commercial potential at all are to be developed. This means that firms tend to cluster in 'knowledge sources' (Cooke, 2002). And, since the research and commercial effort in biotechnology is so internationalised, these 'knowledge sources' compete *and* collaborate with one another nationally and globally.

This 'symbiotic tension' – where research and industry compete for and collaborate in research projects but are ultimately mutually interdependent in the transfer of technology from the science base through to industrial application – is well documented for the German system and regarded as a source of competitive advantage for German innovators (Harding 2000, 2001). Gambardella *et al.* (2000) measure the extent and scope of networks between the public- and the private-sector science base for pharmaceuticals in the US and Europe and argue that the concepts of competition and collaboration in technology transfer are important in understanding competitive advantage in the pharmaceutical industry (see also Senker and Zwangenberg, 2001; Cooke, 2001; Kaufmann and Todtling, 2001; Love and Roper, 2001). Further, the transfer of knowledge in biotechnology is tacit in nature and relies substantially on the relationships between scientists in research institutions and private-sector laboratories, making the spatial concentration in technology transfer at a regional level especially significant in driving the propensity to innovate (Zeller, 2001; Kaufmann and Todtling, 2001).

What policymakers in Europe generally and in Germany and the UK in particular should be aiming to stimulate in the biotechnology sector, therefore, is the development of strong university–industry research networks in the interests of enhancing their attractiveness as locations for global R&D, either by large companies or as the home of international research-based firms. This is the source of national comparative advantage in technology transfer. Studies of biotechnology clusters and university–industry links suggest that 'symbiotic tension' is key to understanding the viability, sustainability and competitiveness of the biotechnology sector. It is this process that enhances the development of vibrant university–industry links nationally and hence facilitates the location of international R&D in one country as opposed to another. It is no longer possible to regard the national and the global innovation system or network as independent of one another (Archibugi *et al.*, 1999) since research is internationally mobile and will locate around specialised centres of excellence. Policy has to ensure that research specialisation is enhanced by strong university–industry networks and linkages if it is to create attractive locations for global biotechnology R&D.

3.5 Regional policy

There is a substantial body of literature to suggest that, in a world where R&D is internationally mobile, competitive innovation advantage is generated at the regional rather than at the national level (Cooke *et al.*, 1997; Edquist; 1997; Cantwell and Iammarino, 2000; Sachsenian, 1997; Harding, 1999). This is because technological specialisation that is so critical to the symbiotic tension within technology transfer is best developed at a regional level. Regional universities have scientific specialisation within specific areas and resources to support that focus; any spin-out companies from university research are likely to be within the areas of scientific excellence developed within the university and large companies are more likely to locate and, hence, to transfer knowledge where such excellence exists. Learning and adaptation to changing market and technological conditions are more likely to be effective and sustainable at a regional level since tacit knowledge transfers more easily between actors in close spatial proximity and with clear links to the cumulative skills and attributes of the regional labour market (Dodgson, 2001; Cooke *et al.*, 1997; Porter, 1998, 2002). As expertise starts to build, specialist financiers, accountants and lawyers set up to support the science base and any start-up businesses are provided with appropriate and readily accessible advice and consultancy. The evolution of this type of regional 'industrial system' is argued to go some way to explaining the development of Silicon Valley and Route 128 in the US (Sachsenian, 1997).

The attractiveness of the 'cluster' approach (Porter, 1998) to policymakers is clear, especially for biotechnology. Since biotechnology research and commercial activity is interdependent with scientific and commercial networks, since tacit knowledge transfer is behind the symbiotic tension at the heart of competitive success in this industry and since firms cluster close to knowledge sources, it makes sense to operationalise biotechnology policy at a regional level. Universities, as stated above, are 'magnets' of biotechnology activity, but a true innovation system for biotechnology at a regional level is created for biotechnology through the combination of research hospitals and 'chains of transactions between scientists, entrepreneurs and various intermediaries including inventors and lawyers' (Cooke, 2002). Only by systematising this set of interactions will regionally generated knowledge add value through the cumulative learning process to create the specialisation that is so important to international competitive advantage in research-led sectors such as biotechnology.

Evidence suggests that such regional 'centres of excellence' or 'clusters' and their intra-regional links (both within a country and globally) are necessary preconditions for creating attractive locations for global biotechnology R&D. Interestingly, the national, regional and sectoral systems of innovation for biotechnology are peculiarly interdependent because of its knowledge-intensive and research-led nature (Senker and Zwangenberg, 2001; Gambardella *et al.*, 2000; Owen-Smith *et al.*, 2002; Malerba, 2002; Freeman, 2002). For policymakers this is a complex message – that regions are important as the point of delivery but that the sources of learning and added value actually rest in the networks that individual researchers have nationally and internationally. In other words, national science policy and regional cluster policy should be mutually reinforcing and formulated to 'promote network building among firms and other actors of a regional innovation system and to interlink these intra-regional networks with national and international knowledge sources' (Koschatsky and Sternberg, 2000).

3.6 Finance policy

Technology-based firms are both more suited to venture capital investment *and* more likely to seek it. They require significant amounts of capital but, because their business is based on an innovation rather than a proven business concept, investments in them are inherently more risky. In theory at least this ought to be the domain of risk-takers and, hence, also the domain of venture capitalists. Yet the figures presented in Tables 1 and 2 above suggest that both Germany and the UK are behind the US in terms of venture capital investments, particularly in biotechnology. This is a clear challenge for policy.

Linking venture capital with bio-innovation through policy is, at best, complicated. Yet, as one German venture capitalist argued, 'Venture capital investments are for technology-based companies. I am a financier, but I have had to learn about (bio)technology – quite simply, this is where the money is.' The reasons for this are as follows:

- *Returns on technology investments are high*. The Bank of England estimates average returns on technology investments to be around 23 per cent (Bank of England, 2001). But one technology investor claimed return rates of 45 per cent in the UK, and rates in the US are certainly higher at 33.7 per cent (www.nvca.com). This return rate is evidence of the high growth and wealth creation potential of technology-based firms as much as evidence of their suitability for venture capital funding. Yet venture capitalists themselves will not be able to take advantage of these potential returns unless they can be encouraged into riskier, technology-based investments.

- *The growth potential these companies have is embedded in the value that they add to their initial concept*. All technology-based companies start with a commercially unproven innovative idea at the seed stage – this is the risk. The growth process is the cumulative 'proof' of the commercial viability of the idea or concept. The value at the end is the return. But, especially in science-based industries like biotechnology, this growth process requires substantial development funding. This funding may be needed over a long period of time – as long as ten years. This is significantly longer than most venture capitalists will invest without a clearly defined exit route. Thus there is a clear role for government support at the seed stage and even at the start-up stage to leverage in informal and formal venture capital.

- *The acquisition of substantial capital investments allows the technology-based firms to attract key scientists and innovators into their business*. The value of the company is embodied in the personnel employed within the organisation. As one Dutch biotechnology fund manager said, 'We don't invest in profit, we invest in value. Biotechnology companies never make a profit but their ideas can be worth millions. One company came to us suggesting that the size of the workforce should be reduced in order to show a working profit. This would have been a disaster as we were investing in the high potential value of their scientists. That's what we can sell on.'

- *It is important therefore that such companies can access easily the high net worth individuals that add value to an innovative concept*. This is primarily a function of the supply of such people from universities, colleges and industry. In turn, it is a function of the capacity of the education and training system, the higher education system and the industrial system to create, develop and, critically, keep these individuals. The role for policy here is in creating an infrastructure that creates such high-value 'human capital' in which venture capital can invest.

- *Finally, in order that the rate of return is fully realised and venture capitalists continue to invest in technology projects, there has to be a good supply of investment opportunities for venture capitalists*. This deal flow stems from universities and colleges through academic entrepreneurs and from indigenous and overseas high-tech companies with research capacity. Governments can do much to stimulate a culture of science- and technology-based entrepreneurship through funding for basic science, significant funding for university–business partnerships, science parks, incubators and programmes to stimulate high-technology investments. Yet there is evidence that there is a weakness in the commercialisation of science from the research base across Europe (Gambardella *et al.*, 2000), but in the UK in particular (Bank of England, 2001).

The biotechnology financing life-cycle is presented in Figure 1.

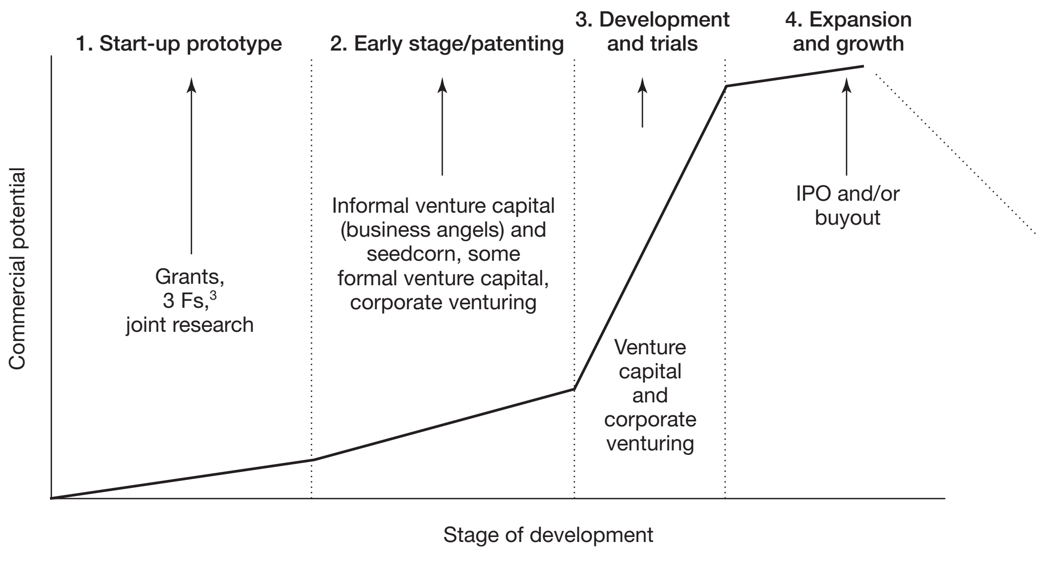

Figure 1
The biotechnology financing life-cycle

[3] 3 Fs is a venture capital term to refer to people who make small investments in start-up businesses: 'friends, family and fools'.

At the seed stage of concept development relatively small amounts of money are required since much of the activity is research-based rather than commercially driven. At this stage the role of public-sector funding of the science base is clearly to provide adequate resources for centres of research excellence to develop.

The second, early stage of development is where the commercial potential of a concept has been proved and a patent registered. Here there is far greater potential for private-sector investors to participate. In the UK, for example, business angels are particularly important in funding biotechnology companies at this stage, while in Germany corporate venturing (where firms fund research in return for an equity stake in the emerging business) is more common. Government guarantees for private-sector investments at this stage can be used to encourage investors to take risks with biotechnology-based businesses.

Corporate venturing and private equity are most important at the third stage of development: development and trials. Here the potential for the value of the company to grow is substantial – not least because the networks and research expertise of the personnel within the company become valuable assets in their own right.

The final stage to initial public offering (IPO) or trade sale (sale to a large pharmaceutical business, for example) is the point at which the venture capitalist or private investor will exit and realise their investment.

Each stage is fraught with risks for the private investor. Biotechnology projects can fail at each stage, either because insufficient research has been conducted or because the concept is not viable. Even after clinical trials (a process which can take up to ten years) there is still a risk that the route to market will be blocked by adverse or inconclusive results. And, as the example of the agri-environmental biotechnology firm Monsanto showed, if a public outcry threatens the acceptability of the product, then investments are not secure even once the company is floated on a stock exchange.

This perceived risk goes some way to explaining the reluctance of the venture capital industry to invest in biotechnology. However, biotechnology is unique, not just in its *modus operandi* but also in the source of value in the business. This value, as stated above, rests in the people in the business. Their research and their networks are assets to potential investors, especially large pharmaceutical companies seeking to spread the risk of financing non-core but strategically important R&D. Policy therefore has to have two strands to its approach to biotechnology financing:

1. To mitigate risks of private-sector investors, either by providing support at the seed and early stages of development or by providing parallel investments for riskier projects
2. To increase awareness of the inherent value in the intangible assets of the bio-business.

4 German and UK policy compared

The previous chapter identified three areas around which biotechnology policy is built: university–industry links (particularly support for basic research and for technology transfer), regional development ('clusters' or 'centres of excellence') and finance. None of these areas are mutually exclusive, however, and – given the multidisciplinary and networked nature of biotechnology itself – it would not be appropriate to construct a single policy for this sector. Further, since the whole area of biotechnology is interwoven with the public understanding of science as well as with strong ethical considerations, any policies tend to cross departmental and legislative boundaries.

To this end, this chapter compares policy formulation, implementation and delivery in terms of three areas:

1. *The legislative, regulatory and policy framework*: this, broadly, includes departmental responsibilities to construct legislation, to regulate biotechnology R&D and commercialisation and to increase awareness and understanding of biotechnology (and ethical considerations around biotechnology) among the wider public. It also includes an analysis of policy initiatives for biotechnology in both countries.

2. *Support for university–industry links*, including the funding of the science base and technology transfer, as well as the institutional structure of the science system that delivers biotechnology research and commercial activity. This includes an examination of academic entrepreneurship.

3. *'Clusters' or 'centres of excellence' at a regional level*: both German and UK policymakers have been strongly influenced by the 'regional systems of innovation' and 'cluster' literature surveyed above that suggests a link between innovation at a regional level and strong national biotechnology performance.

Finance policy in both countries is woven into policies for supporting technology transfer and regional cluster development. Thus this area of policy is not examined in its own right but is instead integrated into the wider discussion and analysis (for further reference, see Harding, 2000; 2002b).

4.1 The legislative, regulatory and policy framework

Nowhere is the complexity of biotechnology more obvious than in the legislative and regulatory framework that underpins policy formulation and delivery. This complexity is apparent in both countries and is illustrated in Table 3.

Table 3 breaks down the framework for biotechnology policy into five areas, legislative responsibility, guidance and advice (including on ethical matters), monitoring (including

Table 3
The biotechnology legislative and regulatory framework in Germany and Britain

	Legislation	Guidance and advice	Monitoring	Access to funding	Research and expert services
Germany	BMU BMVEL[4] BMG	BMU BML BMBF BMG RKI	RKI ZKBS	BMBF BMWi BML BMG Länder DFG	Dedicated government institutes RKI DFG-funded institutes Universities MPG HGF FhG WGL
United Kingdom	DTI Culture HSE DEFRA DoH Home Office European Standards Office	DTI Culture HSE DEFRA DoH Home Office Research Councils Trade Associations	HSE DoH	DTI DoH Home Office Research Councils Wellcome Trust	Culture DETR DoH Home Office Research Councils Universities

regulation, intellectual property and technology/impact assessment), access to funding (for R&D and commercialisation) and research and expert services.

Germany and the UK have one central department broadly responsible for the research and training agendas – the *Bundesministerium für Bildung und Forschung* (BMBF) and the Department of Trade and Industry (DTI) respectively. In both countries the remit of these departments is extensive and covers guidance and advice, access to funding and general policy formulation (see Table 4 below). In addition to this, the DTI is also responsible for biotechnology legislation since the biotechnology directorate and the Office of Science and Technology sit within that department.

Germany's legislative and regulatory framework is far more embedded within a wider departmental structure than in the UK. At the national level 17 different departments or organisations are involved with biotechnology (compared to 11 in the UK). The Federal Ministry for the Environment (*Bundesministerium für Umwelt*, BMU), the Federal Ministry for Consumer Affairs, Food, Agriculture and Forestry (*Bundesministerium für*

[4] Since the 2002 elections the agriculture ministry is called the *Bundesministerium für Verbraucherschutz, Ernährung und Landwirtschaft* (Federal Ministry for Consumer Protection, Food and Agriculture).

Verbraucherschutz, Ernährung und Landwirtschaft, BMVEL) and the Federal Ministry of Health (*Bundesministerium für Gesundheit*, BMG) control legislation, for example, while the BMBF is responsible for policies that enable researchers and small businesses to get guidance and advice on ethical, regulatory and research matters. The Federal Economics Ministry (*Bundesministerium für Wirtschaft*, BMWi) also provides funding for biotechnology. The state (*Länder*) governments also provide research and commercialisation funding, as does the *Kreditanstalt für Wiederaufbau* (KfW)/*Deutsche Ausgleichsbank* (DtA), while research and consultancy is provided by a plethora of establishments within the science base of the German economy, including the Max Planck Institutes, the Fraunhofer Institutes and public- and private-sector research laboratories, universities and research establishments (some of which are dedicated to biotechnology – for example the Gene Centres in Cologne, Heidelberg and Munich). Monitoring and ethical guidance are clear responsibilities of the Robert Koch Institute (RKI) and the Central Advisory Committee for Biological Safety (*Zentrale Kommission für Biologische Sicherheit*, ZKBS) and form part of Germany's wider policy to ensure that technology assessment is fully integrated into any R&D activity (Harding and Harding, 2001).

In the UK departmental responsibility for biotechnology rests with the DTI, the Department of Culture, the Ministry for Agriculture, Fisheries and Food (MAFF), the Department of Health (DoH), the Department for the Environment, Food and Agriculture (DEFRA) and the Home Office. It is only the DTI that has an explicit role towards biotechnology in the form of legislation, funding or regulation; for the other departments biotechnology is integrated into wider policy frameworks. The Health and Safety Executive (HSE) and the European Standards Office play a strong role in monitoring and regulation while the General Medical Council (GMC) has a bioethics committee which assesses the ethical implications of any biotechnology research. R&D is funded by the DTI and the DoH. By far the largest budget is with the DTI since it controls the research council budgets as well. Interestingly, charity funding for research (for example through the Wellcome Trust) forms an important, if small, part of the total funding for biotechnology R&D.

There are three marked differences between the legislative and regulatory structures in Germany and the UK. First, the German framework is to a large extent embedded within its wider science and technology system. This means that the responsibilities for pure (basic or blue-sky) research as opposed to applied or commercial research and development are clearly delineated at the point of delivery (Harding, 2001). Thus, for example, a Max Planck Institute would not be involved in the frontline of commercialisation research since this extends beyond its remit, but the Fraunhofer Institutes may well be. There is a strong 'blue-sky' element within the dedicated '*Blaue Liste*' research institutes such as the *Hermann von Helmholtz Gemeinschaften* and its post-1995 successor in the eastern states, the *Wissenschaftgemeinschaft Gottfried Wilhelm Leibnitz*. All these institutes are predominantly supported by the federal government, but a token 10 per cent of funding comes from the regional states to ensure that long-term public interest projects are fully investigated.

This regional role in the biotechnology framework is a second key difference between the UK and Germany. In the UK the role for regional-level governance and funding for research is not clearly defined, while in Germany a critical part of the remit of state governments is to formulate regionally based science policy to meet regional interests and needs.

The third key difference is in the financing of biotechnology. Again, in Germany, this is embedded within the existing institutional framework of the social market economy, which means a clear delineation between national, regional and local responsibilities in the funding both of public interest research and of commercial activity. Pure research is largely funded by the *Deutsche Forschungsgemeinschaft*, which in 1999 had a total research budget of DM 2,278 million, 36 per cent of which was dedicated to life science research. Alongside this, the KfW and the DtA (now a merged organisation) have responsibility for facilitating loans, mezzanine[5] and equity type finance and work with regional and local banks and venture capital firms to operationalise this. The UK funding system, as depicted in Table 3, is largely for basic research in biotechnology and comes predominantly from the research councils, charitable trusts (around 7 per cent) and from government departments. Where research is applied and likely to lead to commercial exploitation of the science base, finance is through policy initiatives like University Challenge and has a strong private-sector dimension to it.

The spread of biotechnology across so many departments and non-governmental organisations (for example the GMC) is illustrative of a wide dissemination of biotechnology awareness at a policy level. It is interesting to note, however, that although both governments do pay some attention to the importance of raising public awareness and understanding of biotechnology, the extent to which this is explicit within the above framework is limited.

The policy framework to support biotechnology policy in the two countries is shown in Table 4.

Three things are immediately obvious from Table 4. The first is the sheer size of the German effort in the area of biotechnology policy in relation to the UK. Policy has sought to raise the profile of the technology among scientists and businesses alike and, simultaneously, has put in place a framework for informed public debate about the issues in biotechnology research. The second feature of the German system is its heavy reliance on competitions as a way of providing funding for research (basic, applied and technology transfer) and for network-building at the local, regional and national level. Applicants for funding through these routes have to demonstrate a clear and established track record and evidence that they are already following the strategies they propose in their bid for funding. In other words, if a bid is to be successful, the structures and systems for delivery have to be in place and some progress has already to have been made. The final feature of the system is its embeddedness within the overall framework of the German science system. That is, there is a clear delineation between basic scientific and applied research, technology transfer and commercialisation are integrated and, as a logical extension, there is capacity to build clusters relatively easily on the back of existing institutional structures that support competition and collaboration in R&D.

The UK system likewise reflects the intrinsic nature of its science system. It relies heavily on a competitive process for funding of any kind and, similarly, has sought to engage private-sector money on a matched basis at all stages of research and commercialisation beyond pure, or 'basic', research. This is especially the case for any product development work as well as for cluster development. Collaboration in the system comes from specific

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[5] Mezzanine finance is a combination of debt and equity finance and is used to encourage entrepreneurs into formal equity finance.

Table 4
The policy framework in Germany and Britain

	Germany	UK
Basic research	**Deutsche Forschungsgemeinschaft**: research council funding prioritising biotechnology research (14% increase in funding) **Max-Planck Gesellschaft**: national networks of basic research institutes. Research specialisms at regional level. **Blaue Liste Institutes**: regional research institutes with *Länder* funding **Gene Centres** **National initiatives** include specific funding for nanotechnology, proteomics, bioinformatics, German Human Genome project and sustainable bioproduction **BioFuture**: competition to provide young scientists with resource base to develop high-powered research and commercial careers in applied biotech research	**Biotechnology and Biological Sciences Research Council, Medical Research Council** and the **Natural and Environmental Research Council** provide funding for basic science in universities
Applied research	**BioFuture**: also provides support for commercialisation and incentivisation to stay in Germany **Fraunhofer Institutes** work with companies on applying biotechnology research	**Biotechnology Exploitation Platform Challenge** **DTI funding for partnership research**
Technology transfer	**INSTI**: national network of patenting search organisations linked with technology transfer structures like AN-Institutes and Fraunhofer **Kompetenzzentren**: technology transfer centres within the BioRegio structures to facilitate university–industry links Various other programmes including **Innovation-Market, Innovationspartner & Deutsche Wirtschaft**	**Biotechnology Exploitation Platform Challenge**: to encourage universities and businesses to work together **University Challenge**: not specific to biotech but a seed fund for university technology spin-outs
Commerciali-sation	**BioChance**: competitive access to development finance for established start-up biotech firms conducting high-risk R&D	**Bioscience Unit** (DTI) champions commercial exploitation including IPR agreements, regulation and tech transfer **Biotechnology Mentoring and Incubator Challenge Fund** to create high-quality sustainable biotech companies **Trade Partners UK**: to encourage exports in biotechnology
Cluster development	**BioRegio**: competition between *Länder* to develop clusters around biotechnology generally **BioProfile**: competition-based extension finance for BioRegio regions to develop focus/specialisation in dedicated area of research, designed to give new drive to BioRegio initiative	**Public–private sector partnerships** to stimulate biotechnology R&D and commercialisation in the regions following report by Minister for Science in 1999 **University Challenge** to stimulate science and commercial networks through universities
Regulatory Framework	Regulation falls under three categories: **national environmental policy** (BMU), **agricultural biotechnology** (BML) (including animal testing and research) and **health** (BMG) that governs genetic engineering. The **Robert Koch Institute** and **the Central Advisory Committee for Biological Safety** monitor health and safety issues and develop guidelines	Responsibility spread across a number of different government departments and guidance notes are prepared accordingly **Advisory Committees** provide health and safety and ethical advice **Department of Health** has responsibility for medicine licensing
Public under-standing	**Science Live**: 'science touring truck' equipped with research facilities to allow scientists to run experiments where resources might otherwise not exist; also trained personnel to raise profile and understanding of biotechnology; web-based reference centre for bioethics **Safety research and monitoring**	**BIO-WISE**: explaining the commercial potential of biotechnology to businesses **Department of Culture** provides information courses **Public understanding of science** (e.g. through Science Museum)

policies to support partnership (for example the biotechnology exploitation platform) and from broader policies to support university–industry partnership. However, these latter policies, such as University Challenge, the Higher Education Innovation Fund and the Science Enterprise Challenge, are not purely for biotechnology. Public understanding is facilitated through BIO-WISE (although technically the purpose of this initiative is to explain the commercial potential of biotechnology and not to widen public understanding).

4.2 Support for university–industry links

Biotechnology relies heavily on the efficiency and effectiveness of the science base to develop products with any commercial potential at all. The process of biotechnology development which transfers pure science know-how into industrial application (the technology transfer process) is dependent on collaborative and communication channels with business. So if government is to be successful in promoting the industry, it has both to ensure the adequate funding of the science base and, critically, to develop support structures to facilitate the effective transfer of knowledge from basic scientific research into product development.

The first thing to examine, then, is the overall level of science funding in Germany and the UK in order to understand the scale of differences between the two countries. Funding for the science base as a percentage of GDP is given in Table 5. (For comparative purposes the US is included in the next two tables.)

Table 5
Overall levels of science spending in Germany and the UK as a percentage of GDP (US as comparator)

	1993	1994	1995	1996	1997	1998	1999	2000
Germany	2.42	2.32	2.31	2.3	2.31	2.32	2.44	2.46
UK	2.15	2.11	2.02	1.95	1.87	1.83	1.87	–
US	2.62	2.52	2.61	2.66	2.70	2.77	2.64	–

Source: OECD, 2001

Germany spends more as a percentage of GDP than the UK, though not as much as the US. Since Germany has a much larger GDP than the UK, this percentage translates into a higher level of overall expenditure on science, engineering and technology (SET). For example, the UK SET budget expanded by 7.5 per cent to £6,734 million between 1999 and 2000, but Germany still spends more than twice the amount in real terms on its science base than the UK and expanded its funding by 14 per cent over the same period. This is shown in Table 6, which gives Government Budget Allocations for R&D (GBAORD) in current dollar prices for comparative purposes.

Table 6
Total government budget allocations for R&D (million current $)

	1994	1995	1996	1997	1998	1999	2000
Germany	14,952.4	15,696.9	15,879.4	15,595.7	15,625.0	15,991.5	16,224.6
UK	8,058.4	8,628.1	8,942.7	9,055.7	8,603.7	8,879.6	–
US	68,331.0	68,791.0	69,049.0	71,653.0	73,569.0	76,886.0	75,415.0

Source: OECD, 2001

Another point is worthy of note here, namely German reliance on the private and governmental sectors for funding of R&D in comparison to the UK. This is illustrated in Table 7, which shows the sources and modes of funding in the two countries.

Germany's funding for R&D largely comes from government or business. The UK, by contrast, has lower levels of public and private expenditure on R&D. Funding from abroad as well as funding from other UK organisations, often charities, provides a sizeable proportion of total funding. This is particularly important for biotechnology since much of the 'other national sources' category is accounted for by large national medical charities such as the Wellcome Trust.

Actual expenditure on biotechnology is hard to derive on a comparative basis (see also Senker and Zwangenberg, 2001). The reason for this is that, as can be seen from Tables 3 and 4 above, the reach of biotechnology research and application extends far beyond one government department and is interwoven with the structure of the science system itself. However, the German government claimed to spend something in the region of £750m on biotechnology in 2001 across all government departments. In the UK the three

Table 7
Overview of different sources and modes of funding for research and development in selected countries, 1999

	Aus	Can	Fin	Fra	D	J	Sw	UK	US
R&D performer									
Business enterprise	45.1	59.8	71.1	63.1	70.0	70.7	75.1	67.8	75.7
Government	23.4	12.0	11.1	17.9	13.7	9.9	3.4	10.7	7.2
Higher education	29.4	26.9	17.8	17.6	16.3	14.8	21.4	20.0	14.1
Private non-profit	2.1	1.2	0.7	1.5	0.7	4.6	0.1	1.4	2.9
Source of funding									
Business enterprise	39.7	44.7	66.9	53.5	65.1	72.2	67.8	49.4	66.8
Government	47.8	31.2	29.2	37.3	32.3	19.5	24.5	27.9	29.2
Abroad	2.5	16.7	3.0	7.4	2.3	0.4	3.5	17.6	–
Other national sources	4.7	7.4	0.9	1.8	0.3	7.9	4.2	5.1	4.0

Source: OECD and national documentation

Table 8
University–industry policy priorities in Germany and the UK

	Policy priority (2001/2)	Formulation mechanism	Implementation mechanism
Germany	Enhancing efficiency of science system; ICT, biotechnology; health research, sustainable development, physics chemistry and materials sciences, nanotechnology, energy, transport and mobility, space, marine technology	Federal G government, BLK[6] and Science Council **Delphi programme to advise on future scientific trends (through Fraunhofer but also in conjunction with MITI)**	Federal and regional funding initiatives and programmes; foundations and institutional structure Venture capital, InnoRegio and BioRegio programmes
UK	Increased infrastructure funding, research in key technologies, boost to science budget to build on university research; commercialisation of public-sector research	DTI, POST, OST, Chief Scientist, Foresight Programme and Foresight Fund	Government departments, research councils, universities, research and technology organisations in private sector, Faraday Partnerships Programmes and initiatives; venture capital through University Challenge & HEIF, R&D tax credits

Source: Harding and Harding, 2001

research councils with the most explicit remit for funding biotechnology are the Biotechnology and Biological Sciences Research Council, the Natural and Environmental Research Council and the Medical Research Council. Their combined budget is £567.1m, although this is a general budget allocation and is not for biotechnology specifically.

Since it is so difficult to establish exactly how much is being put into biotechnology in the two countries, and since much of the effectiveness of biotechnology as a vehicle for commercial application and hence innovation-led growth rests in the relationship between universities and industry, it makes sense to dwell on this area a little longer. This is broadly 'technology transfer', although the relationships between universities and industry at a local or regional level is core to specialist cluster development as well.

Table 8 examines policy priorities in Germany and the UK in this area.

A number of points that can be drawn out from this table:

1. In Germany funding for teaching and research in higher education establishments comes from regional and national level governments. For example, beyond a token 'core' funding from the national government, teaching is broadly funded by regional governments. However, research is funded by both the regional and the national governments (through the *Deutsche Forschungsgemeinschaft* (DFG) and *Blaue Liste* institutes in the case of national interest research). This means that

[6] *Bund-Länder Kommission für Bildungsplanung und Forschungsförderung*

regional governments can set research funding priorities to reflect regional economic priorities, and that cluster development policies can build on this to develop sectoral specialisms and networks.

2. The UK government has prioritised funding for the science base generally and for biotechnology in particular, and there are more resources available for research in this area. Commercialisation strategies are reliant on the engagement of private-sector businesses through 'matched funding'.

3. Both countries have mechanisms for anticipating technological changes and formulating policies and strategies accordingly. In Germany the mechanism for evaluating biotechnology developments through the Delphi programme is based in the Fraunhofer Society. The UK's Foresight Programme is run through the Office of Science and Technology and is based on committees of scientists and business people who evaluate the commercial potential of technological change as it occurs.

4. At the point of implementation the German policy mechanism reflects the institutional structure and responsibilities of the science system generally. The UK, by contrast, has a much more decentralised delivery system alongside a centralised funding system and is reliant on private-sector partner involvement.

The highly contested research market in the UK makes collaboration more difficult, even in an area where it is essential to collaborate. By contrast, the strongly collaborative nature of German science system makes collaborative science easier, and this may go some way to explaining the speed with which Germany has caught up in terms of patents.

4.3 University–industry links and academic entrepreneurship

Both governments have put much effort into raising the profile of academic entrepreneurship as a driver for technology transfer and commercialisation. Policies are similar in both countries and include strategies to stimulate incubators, science parks, venture capital and, critically, to streamline intellectual property agreements so that universities, researchers and businesses can all profit from research. Evaluating the effectiveness of these types of policy in any rigorous sense is extremely difficult since there is a multitude of different ways in which the relationships between academics, academic entrepreneurs and business are built.

Within the context of this research it was neither necessary nor appropriate to attempt such an evaluation. However the *Global Entrepreneurship Monitor* study (Harding, 2002a) interviews entrepreneurial experts across a number of countries, including Germany and the UK. This study uses an identical methodology to speak to these experts and asks them questions around 'entrepreneurial framework conditions', including R&D transfer, education and training, culture, policy, government programmes and finance. For the purposes of this paper the German and the UK expert surveys have been used to draw out messages on university–industry links generally and biotechnology in particular. The results are shown in Table 9.

Table 9
Attitudes towards university–industry links in Germany and the UK

Entrepreneurial framework condition	Germany	UK
Finance	• Banks seen as not having skills to evaluate research-based business proposals • *Neuer Markt* was important in getting culture of technology-based businesses going • Access to venture capital for university projects good, but this is less the case in the eastern states and there is a perception that the money is 'public' money and therefore not commercial • Development finance for university projects is good	• Persistent risk aversion on behalf of UK investors towards university start-ups • Equity gap for university projects because financiers do not have the skills to evaluate, especially in biotech • Finance is hard to come by unless it matches with a priority area
Government policy	• Too many regulations from government; this is particularly severe for biotechnology businesses	• Regulation, especially in areas of employment law, make growth very hard, especially for science start-ups
Government programmes	• Programmes effective and logical • Incubators work well to transfer technology • Finance measures are used well • Programmes have increased awareness of science venturing • Regional policies excellent – especially BioRegio	• Programmes tend to favour entrepreneurs within universities and not those from outside the university sector • Incubators work well
Education and training	• Lack of business education in schools, especially for the life sciences • There is a strong supply of well-qualified people • Germans prefer not to work across scientific disciplines, which is an issue for biotechnology	• 'Anti-science' culture in schools • Lack of business education throughout the system • Major skills gap in critical scientific areas
R&D transfer	• Patent protection is not always effective and is overly complex especially for biotechnology • It is not easy to find the best support for patenting searches as there are so many of them • Underutilised potential in research base • Entrepreneurship in universities is increasing but more is necessary	• Universities have real problems with SMEs • There is more entrepreneurship at universities, but still too little • University scientists have no concept of what it means to set up a business
Commercial professional infrastructure	• There is a tight network of support agencies • Commercial support is expensive	• Variable quality across the company • Duplication is an issue • Commercial support expensive
Physical infrastructure	• Excellent	• Major source of competitive disadvantage: 'World class scientists need a world class infrastructure. We can't offer them this.'
Market openness	• When big pharmaceutical companies are involved they are strongly supportive of start-up biotech companies	• Flexibility in labour market • Strong support from large pharmaceutical companies
Culture	• Scientific entrepreneurship is an increasingly popular career choice because of the intellectual freedom it gives researchers • Negative attitude to failure • Working hours culture is changing in Germany and this will be positive • Public understanding of science could be improved • Heavy reliance on government programmes	• Persistent 'anti-science' culture in the general population made worse by media coverage • University–industry links still generally weak and not based on mutual understanding

Source: Harding, 2002a; Bergmann and Sternberg, 2002

What is clear from this table is that problems in the relationship between universities and business exist in both countries:

- There is *too much regulation*. In Germany the experts focused specifically on patenting requirements and technology assessment regulations in biotechnology, while in the UK the regulation was seen in the broader context of labour market regulations and taxation.

- The *support structures* that help R&D to commercialise are seen as too expensive in both countries. This includes patent searches and access to professional business support (for example accountancy firms and legal practices).

- The *R&D transfer system* doesn't always work as effectively as it might – there is still mistrust between industry and the science base in both countries.

- The *patenting and intellectual property rights (IPR) systems* in both countries are viewed as unwieldy or ineffective.

However, there are also some stark differences between the two countries:

- *Government programmes:* in Germany interviewees were very positive, while in the UK University Challenge was seen to have excluded non-university bio-innovators. It was also pointed out that UK policies are not focused explicitly on biotechnology and that this might restrict the potential for biotechnology exploitation.

- *Finance*: seed and early-stage funding for biotechnology in Germany was considered to be good. Respondents in the UK argued that there is still a shortfall in equity-based funding for biotechnology.

- *Universities*: these were seen in the UK as still having real problems in dealing with spin-outs as well as with small and medium-sized businesses in their local communities. In Germany attitudes were generally more positive – that universities were developing along the right lines but that there is still underutilised potential.

- *Physical infrastructure*: this was seen by experts as 'awful' in the UK but excellent in Germany.

4.4 The regions

The UK's market-based policy contrasts with Germany's 'engineered' cluster development policy through BioRegio. BioRegio is based on an analysis by the German government in the early 1990s that concluded, first, that biotechnology was likely to be central to future economic growth (prompted by the Delphi programme) and, second, that mechanisms had to be established to facilitate a quick and effective catch-up. It was considered that this was best achieved through the regions. Regions with established biotechnology sectors (through the Gene Centres) along with other regions with strong biological or biomedical research universities competed for funding in a competition launched in 1995. The BioRegio programme assessed proposals against four criteria:

- That the networks would create a motor for biotechnology 'catch-up'
- That the proposal would stimulate biotechnology start-ups
- That the proposal would grow existing biotechnology R&D
- That venture capital provision would be an integral part of the cluster design.

The overall aim of the programme in 1997 was to make Germany 'number one' in Europe by the year 2000 (for further reference on BioRegio see Dohse, 2000). A total of 17 projects were approved, with three selected as 'models': Munich, Rhineland and Rhine-Neckar. These model regions received more public money and priority access to future competitions. None of the regions received more than a maximum of 50 per cent of public-sector funding. However, being a model region provided greater leverage to private resources.

Dohse (2000) argues that cluster development in Germany was strongly influenced at a policy level by the literature on regional innovation systems as drivers for national technological specialism and competitiveness. Similarly, UK policy has been influenced by the literature and by policy and practice in other countries – especially the US and Germany (DTI, 1999). The theory behind cluster development in the two countries is very similar, therefore, and, as shown in Table 10, this translates into a very similar set of critical success factors against which the policies can be assessed.

Table 11 considers biotechnology clusters in four regions – two in Germany and two in the UK. Cambridge and Munich are compared as models of 'best practice' in the two countries. Alongside this Jena and Manchester are compared as examples of regions with a strong historical research base but weaker economic and infrastructural support at the outset. The material in these tables is based on publicly available material and further research would be necessary to assess or evaluate the actual performance of these biotechnology clusters.

In all regions the biotechnology cluster strategy appears to have created jobs, attracted private capital, stimulated Higher Education Institute (HEI) spin-outs and created research specialisms.

Table 10
Critical success factors in regional policy

Germany	UK
Strong research base	Strong science base
Entrepreneurial culture	Entrepreneurial culture
Role models	Increasing corporate base
Integrating management culture with scientific research	Capacity to attract key staff
Incubation	Premises and infrastructure
Supported upstart phase	Business support services and related international large companies
Guidance to market	Skilled workforce
Access to finance and investment	Effective networks
Corporate involvement	Supportive policy

Source: DTI, 1999 and BioRegio.com

Table 11
Regional clusters in Germany and the UK

		Other regional facts and figures			Market areas	
	Size of the biotech community	**Biotech companies**	**Employment**	**Research**	**Biotech Companies**	**Specialist service providers**
Munich BioRegio Munich	• BioM AG: number of biotech companies grown from 36 in 1996 to 107 in 2000 • 2001: 130 biotech and pharma companies (of which 110 are SMEs) • 10 international pharma companies including GlaxoSmithKline, AGFA, AUDI, LINOS, Rodenstock, OSRAM • Munich BioTech Region: 120 pharma and biotech companies; Martinsried – growth from 10 in 1996 to 50 now	• 50 VC-financed biotech companies • 5 *Neuer Markt* listings • BioTech region Munich: 85 start-ups • 500% growth in direct employment	• BioM AG 2,500 employed in biotech SMEs in Munich region • Bayern Photonics: global turnover of DM 2.5bn + 5,500 employees • BioTech region Munich: 1,800 jobs created	• 82,000 students • Ludwig-Maximilians University • Technical university • 2 teaching hospitals • 2 applied science universities • 13 non-university research centres • 3 biotech-oriented Max Planck Institutes • Society for Health and the Environment	• Micro-optometry • Materials • Optical communications • Photonics	• *Kapitalgesellschaft* for seed financing of biotech start-ups • Hub of Munich biotech network (includes VC fund) • 10 dedicated VC firms • 1 dedicated consulting company • 4 knowledge transfer consultants • Boston Consulting Group • Fraunhofer Management • KPMG • McKinsey • 3 *Kompetenz-netze* – networking structures to provide mentoring and support as well as international links • Munich Business Angel network • Investors include: 3i, Apax Partners, Atlas ventures
Cambridge	• 175 biotech companies • 250 specialist service providers • 30 research institutes • 20 multinationals (pharma, agbio and food) • 4 leading hospitals	• 1995: 5 quoted companies (£400m market cap) • 2000: 20 quoted companies (£7bn market cap) • 20% of Europe's publicly traded companies • 7 of top 15 LSE-quoted biotech companies • 25% of Europe's top 50 publicly quoted companies • £1bn in VC funds • 900,000 sq ft utilised by lab-based biobusiness • 29 publicly quoted companies (17 UK, 8 US, 2 Canadian, 2 Euro)	• 10,000 employed directly related to biotech • 20,000 in life sciences • 20,000 in network membership	• 11 Nobel Prize winners • 3,500 students • 350 research groups • 6 of top US biotech companies with operations in region • Large company research – AstraZeneca, GlaxoSmithKline, Dohme	• 30% develop biopharma products • 28% pharma services • 15% diagnostics and reagent supplies • 11% with agbio development • 12% biotech instrumentation and equipment	• 40% offer technical services • 9% offer financial services • 5% offer legal services • 15% offer dedicated consulting services • 31% offer other related services (e.g. biotech centre of excellence)

(continued)

Table 11
Regional clusters in Germany and the UK (continued)

		Other regional facts and figures			Market areas	
	Size of the biotech community	**Biotech companies**	**Employment**	**Research**	**Biotech Companies**	**Specialist service providers**
Jena	• Large firms: Jenoptik; Carl Zeiss, ABS, AGFA, H&W optical instruments, OSRAM semiconductors • 56 members of BioRegio Jena • 50 members of Bildverarbeitung Thüringen (training-oriented) • 34 BioInstruments start-ups, • Opthalmoinnovation Thüringen • 60 members of OptoNet Jena	• 31 new biotech companies since 1995 from BioRegio	• Bildverarbeitung Thüringen: worldwide turnover of companies – DM 80m + 850 jobs • BioInstruments: 350 jobs; 170 patent registrations; DM 98m in Jena biotech companies • DM 270m investment in university campus + DM 30m from BMBF • Turnover of DM 1bn worldwide in OptoNet + 6,000 direct jobs created	• Jenaer Friedrich-Schiller Universität • Erfurter Universität • 2 FE colleges of applied science (focus on medical technology, neurology, fibroptics, optometry and data analysis) • 11 non-university research centres including Fraunhofer, Steinbeiss & 2 Max Planck Institutes • 1 government laboratory	• BioInstruments (platform technologies) • Optometry and opthalmics • Cellular & molecular biology • Drug targeting • Materials	• 4 venture capital firms • 4 banks • 1 consulting firm • 4 *Kompetenznetze*
Manchester & NorthWest Public funding package for BioNow: £24.5m (DTI, NWDA & ERDF) Manchester Incubator: £15.4m total project funding from ERDF, University of Manchester, Wellcome Trust and Hulme Regeneration Ltd	• 120 biotech & biomed companies in region • 60 dedicated biotech in region • 15 listed companies in NW • 9 funded companies in Manchester incubator • 5 companies in Manchester Science Park • 5 multinationals (AstraZeneca, Aventis, Bristol Myers Squibb, Eli Lilly, Novartis Powderjet)	• 8 biotechnology companies in total	• £25m VC funds • 75,000 sq ft incubator building (fully occupied May 2001)	• 9 'biotech related' departments in NW universities (at 5 or 5* 2001) • 8,000 S&T graduates from University of Manchester • AstraZeneca's largest world R&D centre • NHS networks • DTI networks (MerseyBio, BioNow)	• Vaccines, immunotherapy and gene therapy • Molecular diagnostics • Sensor technology • Speciality chemicals • Instrumentation and spectrometry • Pharma companies • Wound healing and tissue engineering	• Specialism in biomanufacture

Source: Rebecca Harding fieldwork, 2002

5 Critical success factors – assessment of regional cluster initiatives

Regional level delivery especially has been an especially important policy instrument in both countries. The evidence of dynamic development in both countries is clear from Table 11.

Combining the 'critical success factors' outlined in Table 10 with a number of conditions for successful regeneration provides some initial analysis of the success of the strategies in the two countries against five criteria:

1. *Actual research and patents*: this gives an indication of the strength of the science base and its potential for producing the critical mass of research necessary to develop commercial products in the future. All four of the regions have strong research universities and specialisms with active patenting activity in core biotechnology areas. Cambridge, Manchester and Munich have attracted R&D capacity from large multinational firms, while Jena has developed its own commercial R&D strength through Jenoptik.

2. *Numbers of large companies*: this gives an idea of the private-sector networks and investment that have been leveraged through an initial public-sector investment. The market is most developed in Cambridge, although Munich has also had a strong track record in recent years for attracting private investment. Manchester and Jena have also been successful in attracting some investment from large companies, especially in related technological areas.

3. *Private finance raised and numbers of venture capital firms*: venture capital is seen by policymakers as a means of stimulating start-ups and science-based entrepreneurship and, although it is by itself not enough to guarantee this, evidence from the US suggests that it is a necessary if insufficient condition. All regions have been successful in attracting large amounts of venture capital funds. However, the key difference is that in Germany these funds have been leveraged by strong policy efforts through the KfW and DtA, while in the UK the government has played a minimal role.

4. *Numbers of start-ups and SMEs:* this gives an idea of the 'lead generation' of growth businesses in the cluster. All regions have been successful in creating spin-outs and start-ups. Cambridge is the most established region and has the largest number of publicly listed biotech businesses. The other regions are still in the catch-up phase and have more embryonic life science businesses (ELISCOs). Evidence on the sustainability of these tiny businesses is sparse.

5. *Jobs created*: all regions record job creation through life science and biotechnology businesses. Cambridge, where the cluster is arguably most developed, attributes 10,000 jobs to the biotechnology sector; Munich has a similar number. Jena is slightly different to Manchester in that it already had a large and established life science-based business before BioRegio and hence claims that 6,000 jobs have been created as a direct consequence of growth in biotechnology.

6 Why bother with biotechnology?

Whether we like it or not, Europe (in this case Germany and the UK) have to have a biotechnology industry to underpin the competitiveness of the pharmaceutical industry as well as the long-term viability of the life science sector. The analysis in preceding chapters arguably only scratches at the surface of what is actually happening on the ground, but it nevertheless points to the potential of the sector to provide jobs, improve health and well-being, create innovation and, hence, to stimulate economic growth.

We can learn a lot from the analysis here. First, the market-based strategy in the UK and the more ‘engineered’ strategy in Germany cannot be compared directly in terms of their effectiveness or suitability outside their national context. Germany has a networked science system that is characterised by the ‘symbiotic tension’ under which firms and research institutions compete for and collaborate in research projects. The BioRegio contest and the spread of other related initiatives through the institutional system of German R&D and technology transfer has produced a rapid catch-up in biotechnology. This in itself has been impressive to watch – especially for those who judged the German system incapable of rapid change!

By contrast, the UK’s more market-based system would not be effective in Germany but has merits within the context of the UK economy. Universities are used to compete in research and this ensures that the quality of research conducted remains high. There are issues around the extent to which the system can be adapted to further technology transfer, and some of the reduction in the competitiveness of the UK biotechnology sector relative to Germany in the last couple of years may stem from the difficulties that UK scientists and businesses have in collaboration – there is ‘tension’ but no ‘symbiosis’ between the users and the producers of science.

The issue of sustainability is key, especially for Germany, where criticisms of its strongly public-sector approach centre around the small size of many of the biotechnology start-ups. Where the UK’s structures are more established, for example in Cambridge, the sustainability of the sector can be taken much more for granted.

However, we can learn two key points from the speed with which Germany has caught up:

1. Regions are important as vehicles for appropriate policy formulation and delivery
2. Substantial funding is critical – biotechnology requires substantial investment because it is expensive and intrinsically risky to the private sector.

In conclusion, then, there is a role for strong and careful regulation and monitoring of the technology. Along the way, in order to ensure that the public keeps abreast of the pace of change in this sector, it is also critical that public understanding of the science itself is increased.

Finally, a more detailed Anglo-German comparison could provide greater understanding of the way the biotechnology sector works. Further research should concentrate on addressing the following issues:

1. So far policy in the biotechnology sector has been a 'leap of faith' and measuring effectiveness has been hard. We need new measurements that incorporate the role of the tacit knowledge transfer and network development that are intrinsic to biotechnology research. In short, we need to be able to measure 'symbiotic tension' and its effect on the development of biotechnology.

2. Germany has a higher number of 'platform technologies' – i.e. equipment and supplies or drug delivery systems that have clear commercial potential – than the UK, which is still more research-oriented. This may be because of differences in the applied research funding structure and, in particular, the use of equity-based finance in the early stages of biotechnology start-ups. The area of biotechnology finance warrants further investigation since it may well be that the form this takes fundamentally alters the trajectory along which biotechnology research develops.

3. The management of small biotechnology firms is an interesting area for further comparative research. This has been examined in some detail in Germany (Kulicke *et al.*, 2002), but there is scope for substantially expanding this research in order to examine the impact of networks on the trajectories along which biotechnology develops.

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