Lessons from the US: innovation policy

Monograph (Other)

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LESSONS FROM THE US

Innovation Policy

A Policy Exchange Commentary

Policy Exchange

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Introduction

Where are Britain's Googles, Apples and Amgens? Why has Britain, despite its well-regarded universities and its many Nobel Prize-winning scientists, produced so few world-leading companies in science-based and high-technology industries?

Britain's lag in these industries has been a matter of concern for policy-makers throughout the post-war period, and it continues to figure in the current debate about the new Government's Industrial Strategy.

As part of this debate, attention has focused on the reasons for US supremacy in most of the high-technology industries that have come to the fore since the war, and on how far the factors which underpin that success can be replicated in Britain.

This paper seeks to shed light on these questions by looking at two sectors where US firms have markedly out-performed their British rivals - information technology and biotechnology. The aim is not to provide a comprehensive history of these two sectors but to highlight some of the distinctive features of the American business environment, including the role of government, which have contributed to US leadership.

Information technology

The early post-war years

In the years following the Second World War, the US Government committed itself to large-scale support for scientific research. The thinking was that, just as science had played a crucial role in the war (for example, in the Manhattan project that led to the atomic bomb), so in peacetime scientific prowess would strengthen the economy and help to meet society's needs.[1] Among the agencies that were created or enlarged after the war were the National Institutes of Health (NIH), responsible for biomedical research, and the National Science Foundation (NSF), which supported research and education in other fields.

Although the various institutes within the NIH had laboratories of their own, most of the research that these two agencies funded was conducted in universities. Support from public funds, on a scale that no other country could match, made possible a big expansion of university science departments. The leading research-based universities were responsible for several key innovations in information technology and biotechnology, but the universities' principal contribution was to provide a stream of well-trained scientists and engineers upon whom these industries could draw.

In the case of information technology, government support was reinforced by the purchasing policies of the Department of Defence (DOD). As relations with the Soviet Union deteriorated and the Cold War intensified, the Department formed an increasingly close relationship with companies whose technology could be used in sophisticated weaponry and other military equipment. For example, military requirements in such areas as missile guidance and early-

warning radar systems stimulated the growth of the computer industry.[2] The Department of Defence was both a large customer for this industry and a funder of scientific research in universities and in firms.

A further expansion of Federal support came in 1958 with the creation within the DOD of the Advanced Research Projects Agency (ARPA, later renamed the Defence Advanced Research Projects Agency, or DARPA). This was a response to the launch of the Soviet satellite Sputnik, which had raised fears the US might be losing ground to the Soviet Union in military-related technologies. DARPA had no involvement with procurement or with current military programmes and had no laboratories of its own, but it was charged with exploring frontier areas of science that were relevant to military needs.

DARPA's focus at the start was on preventing technological surprises, like the launch of Sputnik, and on countering the threat that the Soviet Union might launch missiles with nuclear capabilities against the continental US. The three main areas of research were space, missile defence and nuclear test detection, but DARPA's space activities were soon transferred to the newly created National Aeronautics and Space Administration (NASA). In 1962, DARPA set up the Information Processing Techniques Office. This was to become a major funder of university research, along with the National Science Foundation, in the emerging discipline of computer science.[3] One of the programmes which this office started in the 1960s (and which was to lead to the creation of the Internet) was the development of a new technology known as packet switching that enabled computers to communicate with each other.[4]

Support for new entrants

The beneficiaries of military spending included established companies such as IBM, but the DOD and DARPA actively sought to encourage new entrants, thus ensuring a variety of competing approaches to the technologies they wanted to exploit. Several of the firms created during the 1950s and 196Os relied initially on military business, and they were able to use their work for the Government as the basis for serving non-military markets.

For example, following the invention of the transistor by Bell Laboratories in 1947, the subsequent development of the semiconductor industry was strongly influenced by military demand. Pressure from the Department of Defence and from NASA for the miniaturisation of electronic components boosted demand for integrated circuits (ICs). Fairchild Semiconductor, one of the inventors of this technology, was the principal supplier of ICs for the Apollo project. “These early purchases hastened American firms down the slopes of their learning curves. And the government insistence on second sourcing sped the diffusion of IC technology”.[5]

Although the UK and other European countries invested in military-related technologies after the war, spending by the US Government was on a much bigger scale, and by the 1960s the US had a world-leading position in most branches of the information technology sector, including computers, semiconductors and computer software.

By this time, commercial markets were expanding rapidly, and, while spending by the Department of Defence continued at a high level, the next phase in the growth of the sector was driven by firms such as Intel (founded in 1968), Microsoft (1975) and Apple (1976), which concentrated almost entirely on non-military markets. These three companies were spectacularly successful. They were followed by hundreds of new entrants, some of them breakaways from

established firms. As the sector grew in size, it attracted scientific and entrepreneurial talent from all over the world. In 1990, one third of the scientists and engineers in Silicon Valley were immigrants, mostly of Indian and Chinese descent.[6] Some of the immigrants went on to build sizeable businesses. [7]

Growth of the IT sector

How did the US convert its early-mover advantage, derived in part from military procurement, into sustained international leadership? Part of the answer lies in the distinctive character of the information technology industry as it took shape in the 1970s and 1980s and in the large role played by new entrepreneurial firms. It was during these years that the structure of the computer industry was transformed from the IBM model – a large, vertically integrated corporation covering all parts of the value chain including components and software – to the Silicon Valley model – a vertically disintegrated industry that allowed new entrants, specialising in particular components, to insert themselves at various points in the value chain.[8]

The US provided a more fertile soil for firms of this type than Europe or Japan. A key ingredient in what became a hugely productive innovation system was venture capital. This was a means of financing start-up firms that took off more quickly in the US than in other countries after the war. The first non-family venture capital firm, American Research and Development, was founded in Boston in 1946. Its biggest success was its investment in Digital Equipment Corporation, the leading manufacturer of mini-computers. Over the following decades the US venture capital industry supported scores of new entrants in information technology and in other fast-growing industries. The dynamism of Silicon Valley owed a great deal to the

presence in the region of numerous venture capital firms, some of them led by executives who had come out of established electronics companies.[9]

The venture capital firms themselves were financed largely by institutional investors, including pension funds; the inflow of funds from that source increased significantly after 1979 when the rules governing company pension funds were changed to allow them to invest in more risky assets.[10]

An essential complement to venture capital from the 1970s onwards was the emergence of a stock market, NASDAQ, whose rules and procedures were better suited to young, high-growth companies than the old-established New York and American stock exchanges.[11] Firms such as Microsoft, Apple and Cisco chose to list their shares on NASDAQ. This exchange fostered a community of investors, private and institutional, who developed a deep understanding of high-technology industries and were willing to back early-stage firms. The availability of finance from outside investors at each stage in a firm's development, from start-up through to public flotation, allowed the most promising new entrants to scale up more easily than their counterparts in Europe or Japan, where financial markets were less well developed.

Entrepreneurial universities

No less important than an accommodating financial system was the role of US universities in facilitating the creation of new firms. Close links with industry have long been a feature of the American university system. This dates back to the Morrill Act of 1862, which created land grant colleges, financed by the sale of federal land, in many states. Part of their mission was to support agriculture and

industry in their regions. Higher education in the US is also distinctive in its diversity, with well-endowed private universities co-existing with strong state institutions, all of them competing for talent and for funds.

A further stimulus for technology transfer from universities to business came in 1980 when the Bayh-Dole Act changed the rules governing the commercialisation of publicly funded research. Universities were given the freedom to patent inventions resulting from government-funded research and to use them as the basis for licensing deals with established companies or for the creation of spin-out firms.[12] The porous boundaries between academia and industry in the US constitute a major source of strength for science-based industries. As Nathan Rosenberg has written, "American success in high-technology sectors of the economy.....owes an enormous debt to the entrepreneurial activities of American universities".[13]

That new firms could be the source of radical innovations, and that barriers to entry should be kept low, has been recognised from the start by the Federal Government and its agencies. There has been a consistent determination, both by the big purchasing departments such as the DOD and by the antitrust agencies (the Justice Department and the Federal Trade Commission) to curb tendencies towards monopoly in any significant part of the information technology sector, and to widen the opportunities for new entrants.

One example was the pressure put on IBM, at the end of the 1960s, to end the practice of tying the supply of software to the sale of its computers. The unbundling of IBM software gave a fillip to the growth of independent software vendors. Another example was the antitrust suit against Microsoft in 1998, prompted by the tactics used by that company to stunt the growth of Netscape, whose popular

browser threatened Microsoft's dominance in the supply of operating software for personal computers.

These three elements – access to finance for new firms, the entrepreneurial role of universities, and the promotion of competition – were crucial to the growth of information technology in the US. But the industry also benefited from supportive public policies.

The role of public policy

In contrast to the UK, France or Japan, the US has never had a centrally directed innovation policy. National security and public health have been the primary motivations for US technology policies since the Second World War.[14] Government-funded research was important in several sectors, but there was nothing resembling a government-wide R & D strategy. "Agencies with particular missions supplied R & D dollars with little or no coordination, review or external oversight".[15]

It is true that in the 1980s and 1990s, when anxiety about German and Japanese competition was at its height, some steps were taken in the direction of a European-style or Japanese-style industrial policy.[16] These included the creation of Sematech, a government-backed consortium of semiconductor producers, coordinated and partly funded by DARPA. Its aim was to develop cutting-edge production technology that would match or surpass the methods used in Japan. Japanese producers had been gaining market share in semiconductor memory chips, raising fears in the DOD that an industry crucial to national security might be in decline.

Members of the consortium found it difficult at first to agree on an appropriate research strategy. The focus shifted away from the

development of new manufacturing techniques, from which all member firms would benefit, towards strengthening the capabilities of US semiconductor equipment manufacturers, many of which were small and under-financed. Some progress was made on that front, and Sematech is widely regarded as a success. The subsequent resurgence of the US semiconductor industry was, however, mainly due to the strength of US firms, led by Intel, in the microprocessor segment of the market, where the Japanese were weak.[17]

Another initiative, launched in 1982, was the Small Business Innovation Research Programme (SBIR), whereby federal agencies, including big funders like the NIH and the DOD, were obliged to allocate part of their research budgets to small firms. While some critics have argued that SBIR crowds out privately-funded research, a recent study by the National Academies of Science concluded the programme had been "sound in concept and efficient in operation", substantially increasing the role of small firms in the commercialisation of government-funded research. [18]

Government-funded research

These and other interventionist measures are dwarfed in importance by the scale and consistency of government support for scientific research – research that has contributed to many, but by no means all, of the innovations on which the US information technology industry has been built.[19] How should that contribution be assessed?[20]

The primary goal of the funding agencies was not to create new businesses but to create new knowledge that would help them fulfil their missions. Take, for example, the case of Google, the search engine company founded by Sergei Brin and Larry Page in 1998.[21]

This company has its origins in research funded by the National Science Foundation at Stanford. As part of its digital library initiative, designed to improve the science of large-scale information retrieval and storage, the NSF awarded a research contract to two Stanford professors, Hector Garcia-Molina and Terry Winograd. Brin and Page were PhD students who joined the two professors in 1994 and 1995. “Founding a company was not their primary goal at that point, nor was it an explicit goal when the NSF first began to fund their work”.[22]

Stanford was not the only university to receive funding under the NSF’s digital library programme, and there were other doctoral students who, like Brin and Page, came to see the commercial potential of their research. When Brin and Page first looked for financial backers, they had great difficulty in standing out from the crowd. Eventually, they found a San Francisco-based angel investor, Andy Bechtolsheim, who had been a co-founder of Sun Microsystems and was on the lookout for PhD students with interesting technological ideas.[23]

DARPA and the Internet

The NSF was not directly concerned with the commercial potential of its digital library research. But there is another agency, DARPA, whose interaction with the private sector has been closer than that of the NSF. Although DARPA’s primary mission is military, its projects have contributed to major advances in information technology, the most spectacular example being the Internet.

The Internet story began in the 1960s when DARPA started to research new information processing techniques that would enable computers to communicate with each other. Part of the motivation

for this project was to improve communication between military computer sites and to make the command and control system more resilient. Out of this work emerged the packet-switching technology embodied in ARPANET, a computer network designed to meet the needs of the armed forces and of the research community that served them.

As further advances were made, some coming out of DARPA-funded research, some from outside sources, the managers responsible for the project saw that ARPANET had commercial potential. The involvement of commercial users would speed up the development of the network, to the benefit both of DARPA's prime customer, the Department of Defence, and of the information technology sector as a whole. Control of ARPANET was transferred in 1985 to a non-military agency, the National Science Foundation and the network was fully privatised in the 1990s.

DARPA's contribution to the Internet was based on an approach to technology development that is different from other funding agencies. It is a small, non-bureaucratic, and highly autonomous agency, kept separate from other parts of the Department of Defence, and it uses what has been called the island-bridge model. The innovative entity is located on an island, free from the bureaucratic pressures of the parent organisation; but it also has a bridge to senior decision-makers – in DARPA's case, the Secretary of Defence - who can press the innovation forward and provide the necessary resources.[24]

DARPA's programme managers are charged with identifying technological problems that, if solved, will enhance national security, but which go well beyond existing practice and knowledge; they are interested in transformational, not incremental, innovation. Once the problem has been identified, DARPA looks for experts in the chosen

area and brings them together to work out an agreed approach. The experts are drawn from industry and academia, and DARPA has made extensive use of start-up firms that are often better equipped to tackle "out of the box" research projects than established companies; neither IBM nor A T & T showed much interest in ARPANET in its early stage.

Erica Fuchs, a US academic, has described DARPA's approach as "a new form of technology policy, in which embedded government agents re-architect social networks among researchers so as to identify and influence new technology directions in the US to achieve an organisational goal". These agents "do not give way to the invisible hand of markets, nor do they step in with top-down bureaucracy to pick technology winners. Instead, they are in constant contact with the research community, understanding emerging themes, matching these emerging themes to military needs".[25]

DARPA's approach has been remarkably successful (although there have also been numerous failures), and it has prompted several attempts to apply the same model to non-military areas. In 2009, the Department of Energy set up the Advanced Research Projects Agency – Energy (ARPA-E) to fund energy technology projects.[26] Some observers questioned this decision, pointing out that DARPA had a single client and could directly influence, through the Department of Defence, the implementation of whatever usable technologies emerged from its research. The energy market was more diverse. It had many long-established technologies that might have to be displaced by novel approaches coming out of ARPA-E and many powerful vested interests committed to existing methods. ARPA-E is much smaller than DARPA – it has an annual budget of about $300m compared to DARPA's $3bn - and is unlikely to have the same transformative impact on energy as DARPA has had in

information technology. Nevertheless, the new agency appears to have made good progress in its first few years and continues to enjoy Congressional support.

Diversity and competition

Whatever the outcome of this and other DARPA clones, there is no doubt that DARPA itself has played a catalytic role in information technology. But it is only one of several sources of government support, and this diversity of funding has been a source of strength in the US innovation system. As a review of government support for computer research pointed out a few years ago, "Federal funding agencies differ widely in their cultures, goals, resources and perspectives, and thus in the kinds of research projects they support. The result has been a federal research establishment that has nurtured diverse approaches to research".[27]

Diversity and competition are hallmarks of the US innovation system – among funding agencies, among universities that compete against each other for talent and for funds, among innovation clusters such as those based in San Francisco and Boston and among firms.

In the case of the Internet, a government agency explored technological possibilities that were too speculative to interest the private sector, but, as Shane Greenstein has written in his history of the project, "the commercial era of the Internet played to the strength of market-based innovation. It permitted decentralised exploration from commercial firms facing a wide array of incentives and a wide variety of idiosyncratic circumstances". The result was "a dizzying array of applications that were not envisaged by the sponsoring government agencies".[28]

The US innovation system rests on two pillars: massive government support for basic and applied research, including technology that is too risky for the private sector, and an intensely competitive business environment that promotes a variety of approaches to commercialisation.

Implications for the UK

For the UK, catching up with the US in branches of information technology where American firms have already established a leading position is not a feasible objective. That was a lesson learned in the 1960s and 1970s when the British Government tried without success to build national champions in computers and other areas. What governments can do is to improve the organisation of publicly funded research and to create an environment conducive to the creation and growth of new firms. As ARM has shown in microprocessor design, and Raspberry Pi in low-priced computers, there is no lack of opportunities available in parts of the market that are not dominated by US-based firms.

In the UK, most public funding for research is channelled through the seven Research Councils, which have traditionally enjoyed a high degree of autonomy in deciding which projects to support. There is also a separate agency, Innovate UK (formerly the Technology Strategy Board), which supports near-market research, generally on the basis that half the cost of the project will be borne by the recipient company.

Under plans announced by the Cameron Government in 2016, the Research Councils and Innovate UK were brought together in a new organisation, UK Research and Innovation. The new structure, the Government said, would provide “a greater focus and capacity to

deliver on cross-cutting issues that are outside the core remits of the current funding bodies".[29] It would also improve collaboration between the research base and business.

When Theresa May became Prime Minister in July 2016, following the EU referendum, she announced plans for a new Industrial Strategy Challenge Fund that would "draw on the experience of DARPA….and focus on the challenges, opportunities and technologies that have the potential to transform existing industries and create entirely new ones". [30]

How far the Government plans to go in a DARPA-like direction is not yet clear. It is possible that the Government will want to infuse UK Research and Innovation with the mission to identify and address technological challenges that go beyond the scope of the research councils. An alternative would be to set up an entirely new body with a DARPA-like purpose and organisation. Any such body would have to be given substantial autonomy, connected to but independent of its sponsoring government department.

Whatever changes are made in the structure and organisation of research funding, support for the science base will remain a central ingredient in UK innovation policy. But if the Government wants to improve the commercialisation of publicly funded research, it must focus most of its attention on other features of the US business environment – access to finance for young, high-growth firms, making universities more entrepreneurial, and the promotion of competition.

Biotechnology[31]

Origins

Biotechnology in the context of this paper[32] refers to a set of techniques, sometimes described as genetic engineering, whereby living organisms are manipulated or modified to make new products. These techniques, born out of earlier scientific advances in molecular biology and genetics, came to the fore in the 1970s and opened up a novel approach to drug discovery.

In 1973, two American scientists, Stanley Cohen and Herbert Boyer, invented the recombinant DNA or gene-splicing process, which made it possible to transfer genes from one organism to another. Another breakthrough came three years later in the UK, when César Milstein and Georges Köhler found a way of making monoclonal antibodies, which recognise and attach to specific molecules, marking them for destruction by the body's immune system.

These techniques, which were soon put to use in drug discovery, had little in common with the chemistry-based methods on which the established pharmaceutical companies – generally referred to as Big Pharma - mainly relied. Partly for that reason, these companies were slow to recognise the importance of biotechnology and left the field open to new entrants. The application of biotechnology to medicine was largely driven by newly formed entrepreneurial firms, many founded or co-founded by academic scientists. In that respect, the growth of biotechnology in the US had some similarities with what had happened earlier in semiconductors, although the links with academic science were much closer.

The US had no monopoly over the science on which biotechnology was based, but American entrepreneurs were quicker to exploit the new techniques than their counterparts in other countries and went on to establish a dominant position in the world market. Today, despite strenuous efforts by other countries to catch up, US-based firms are even more pre-eminent in biotechnology than in information technology.

The US as first-mover

That US firms were the first movers might be regarded, in part, as a matter of luck – the fact that recombinant DNA was invented in the US and proved easier to commercialise than monoclonal antibodies, a British discovery. But, as in information technology, the American pioneers had the benefit of a supportive domestic environment. Access to finance was available from a growing venture capital industry, and investors had a route to public markets through NASDAQ. The practice of academics leaving universities to found new businesses was an established part of the business scene. In both these areas the US was a long way ahead of Europe and Japan.

The most successful of the pioneering firms, often seen as the role model for the rest of the sector, was Genentech. This firm was founded in San Francisco in 1976 by Robert Swanson, a venture capitalist, and Herbert Boyer, co-inventor of recombinant DNA. Seed finance came from Kleiner Perkins, a leading venture capital firm which had earlier been active in electronics. Tom Perkins, one of the firm's partners, took on the role of chairman.

Swanson's plan was to use recombinant DNA to produce and sell drugs, but this would take time and money. In the meantime, to generate revenue, he sought partnerships with pharmaceutical

companies which would use Genentech's technology to complement their own research. Insulin, a treatment for diabetes, was seen as a promising candidate for the new cloning technology.[33] Insulin was derived from the pancreases of pigs and cows, and Eli Lilly, the principal producer, feared that supplies from that source might not keep pace with the increase in the diabetic population. Animal-derived insulin also caused allergic reactions in some patients. In 1978, Lilly signed a twenty-year agreement with Genentech whereby it acquired worldwide rights to manufacture and market human insulin using the young firm's technology.[34]

This agreement put Genentech on a more solid financial footing. It also set the pattern for future relationships between biotech and Big Pharma; licensing deals, contract research and other forms of collaboration became vital sources of finance for biotech firms.

As Genentech was getting into its stride, there were two potential roadblocks that might have held back the growth of the sector. One was uncertainty over whether organisms created by genetic engineering could or should be patented. It was not until 1980 that the legal position was clarified when the US Supreme Court, in the Chakrabarty case, ruled that living organisms engineered by man were potentially patentable under existing statutes.

The other concern related to the risks of genetic engineering, the fear that the cloning of genes could get out of control and cause an environmental disaster through the release of superbugs. The need for safeguards was generally accepted within the scientific community, and the form they should take was discussed at a conference at Asilomar in California in 1975. The outcome was a sixteen-month moratorium during which the National Institutes of Health worked out a set of guidelines for genetic engineering

experiments. The guidelines were permissive enough not to impede the growth of biotechnology firms in the US.[35]

Investor attitudes

By 1980, anxiety surrounding the risks of cloning gave way to a sense of optimism among politicians, commentators and investors about the potential of the new techniques to transform the treatment of disease. The age of 'biomania' was dawning.[36] When Genentech was floated on NASDAQ in October 1980, the share price rose from $35 to $89 within twenty minutes and closed the day at $71. It was one of the most spectacular IPOs in Wall Street history. The Genentech IPO, as Tom Perkins remarked later,"established the idea that you could start a new biotechnology company, raise obscene amounts of money, hire good employees, sell stock to the public. Our competitors started doing all that".[37]

There were thirty-nine biotechnology flotations between 1980 and 1983, then a pause for breath as investors began to look more critically at what they were buying into, followed by a revival of interest in 1986 and 1987 that allowed several more firms to go public. This was a foretaste of the volatility that would affect stock market attitudes to biotechnology throughout its history.

Genentech's insulin was approved by the Food and Drug Administration in 1982. This was followed by a series of drug introductions by other firms, some of them involving partnerships with pharmaceutical companies. Amgen, destined to become the largest and most profitable of the first generation firms, launched its first blockbuster drug, a treatment for anaemia branded Epogen, in 1989.[38]

Most of the first biotech-based drugs were developed for therapeutic applications that were known and understood, such as insulin and human growth hormone, and used new manufacturing methods that made the drugs more readily available. These came to be described as “low-hanging fruit”, generating high returns for the firms that produced them and for their investors. Although there were a number of setbacks – monoclonal antibody technology proved more difficult to commercialise than expected – there were enough successes in the early years to keep investors interested and to attract more scientists and entrepreneurs into the field. By the end of the 1980s, US biotechnology had established a momentum of growth which was to see it through the ups and downs of the next two decades.

Growth of the US biotech sector

A distinctive feature of biotechnology, as the industry evolved, was the increasing concentration of innovative activity in a few regional clusters, of which the most important were in San Francisco and Boston.[39] These cities had two assets in common: an established venture capital industry and an array of universities, research institutes and teaching hospitals whose scientists were working at the forefront of molecular biology. Scores of new firms were created. Some were later acquired, but others, such as Gilead, founded in California in 1987, went on to become industry leaders.

The progress of the sector was by no means smooth. Investor sentiment towards biotech fluctuated wildly, often in response to successes or failures in leading firms. The most spectacular boom-and-bust occurred in 2000-2001, when the imminent completion of the Human Genome Project raised hopes that the new genomics technology would unleash a wave of innovative drugs. When the

realisation dawned that many years of development would be necessary before genomics-based drugs came to the market, share prices dropped precipitously.

Over the next few years the flow of capital into the sector slowed down. There was also a change in the relationship between biotech and Big Pharma. In the early days there had been speculation that fast-growing biotech firms might eventually dislodge the older pharmaceutical companies from their dominant position as suppliers of medicines – a form of "creative destruction" that had taken place in parts of the electronics industry. But while biotech firms might have the edge in drug discovery and early stage research, many of them were dependent on one or two drug candidates, which made them more fragile than the broadly based pharmaceutical companies. Big Pharma had other strengths – in clinical development, and in marketing and distribution – which most biotech firms could not hope to match.

Moreover, by the 1990s the earlier scepticism in Big Pharma about biotechnology had given way to a recognition that this new approach to drug discovery had to be integrated into their own operations. In 1990, Roche, the Swiss group, acquired 60 per cent of Genentech for just over $2bn, with an option to buy the remaining shares at a later date. This deal was one of a series of partnerships and acquisitions that altered the structure of the biotech sector. By the end of the decade, several of the pioneering firms had been wholly or partly absorbed into Big Pharma. From that generation only Amgen, Biogen and Genzyme remained fully independent.[40]

However, this did not mean that biotech was becoming a mere appendage of the pharmaceutical industry. Although the flow of capital into the sector fell sharply in the early 2000s, new firms continued to be formed, and some of them had ambitions to become

large, free-standing companies, as Amgen and Biogen had done. New scientific opportunities were emerging from academic research in such areas as gene therapy, and small, agile biotech firms seemed better equipped to exploit them than large, bureaucratic pharmaceutical companies.

One analyst noted in 2012 that the public biotech sector had finally achieved sustained profitability after many years of losses, and that investors could look forward to a further period of improved performance.[41] He pointed to several factors which justified an optimistic view: a more favourable regulatory climate; the development of speciality drugs for severe diseases, including targeted cancer therapies and treatments for hepatitis C; the likelihood that more of these drugs would become "mega-blockbusters", with sales exceeding $2bn a year; and the prospect of increasing sales in emerging markets.

The biotech boom of 2014-2015

For these and other reasons, investor sentiment swung back in favour of biotech, leading to a remarkable boom in share prices, and in the number of flotations, in 2014 and 2015. Although the boom petered out in 2016, its effect was to reinforce the position of the US as the global centre of biotech innovation and investment. With the emergence of four large, profitable companies at the top end – Amgen, Biogen, Gilead and Celgene - the structure of the industry was less fragile than it had been ten years earlier. Below the big four there was a group of sizeable companies, including Regeneron, Alexion and Vertex, which seemed capable of joining the top league.

What had emerged after forty years of often erratic progress was a distinct sector of the life sciences industry that had made, and was

continuing to make, an outstanding contribution to the development of innovative drugs. It was a dynamic sector that was constantly replenished by the flow of start-up firms coming out of universities. While many of these firms were likely either to fail or to be acquired by Big Pharma, the best of them were able to attract sufficient support from investors to stay independent, and in a few cases to achieve a market capitalisation as high as that of the leading pharmaceutical companies.

Many biotech firms were created in Europe during this period, some of them supported by their governments. But the US biotech sector has remained far ahead in the number of companies, and in the size and sophistication of the investment community which support them. To an even greater extent than in information technology, the US has been a magnet for biotechnology entrepreneurs and investors from the rest of the world.

The role of public policy

US success in biotechnology is intimately linked to government support for scientific research. This is partly because of the close connection between academic science in molecular biology and genetics and the new approach to drug discovery. It also reflects the sheer scale of government spending on biomedical research, far larger than that of other industrial countries (Table 1). An important feature of this support has been its consistency. Whereas support from venture capital and the stock market was volatile, there was little variability in the growth of NIH funding between 1980 and the late 1990s.[42]

Table 1: National expenditure on academic and related research in the life sciences in 1987[43]

	Life sciences spending ($m)	% of total academic research spending
US	7,285	48.9
Germany	1,483	36.7
France	1,116	34.7
UK	864	30.9
Japan	1,261	33.7

The NIH was mainly focused in the early years on pure or fundamental research aimed at generating knowledge about how the body works rather than finding cures for disease. But from the 1970s onwards, the agency played a bigger role in the applied phase of drug discovery. According to a recent study, just over 20 per cent of all drugs approved by the Federal Drug Administration between 1990 and 2007 had their origins in the NIH and other public sector institutions, the rest coming from research carried out by private sector firms.[44]

The NIH was a valuable partner for the emerging biotech sector, not only as a provider of knowledge but also in enabling universities to expand their teaching and research in the disciplines that were coming to the fore at that time, including bioinformatics, genetics and bioengineering. This nurtured a skilled workforce that could find employment either in academia or in business – or in a combination of the two. "The highly interdependent nature of the life sciences innovation network has the consequence that a period of employment in the private sector need not come at expense of returning to public sector scientific employment in the future".[45]

The links between universities and business were strengthened by the Bayh-Dole Act of 1980, which was described in the last section. Other measures taken during the 1980s, though not specifically directed at biotech, were helpful to the growth of the sector.[46] These included the creation of the SBIR and the change in the rules governing pension funds, allowing them to invest in venture capital on a larger scale.

The sector also benefited from changes in the arrangements for regulating drug safety and efficacy. One was the introduction of the Orphan Drug Act, designed to encourage firms to develop medicines for rare diseases - defined as those that affected less than 200,000 people. For firms that developed orphan drugs, the Act provided a seven-year period of exclusivity, faster approval procedures and tax incentives that partially offset the cost of research. Several biotech firms, notably Genzyme, focused much of their development effort on orphan drugs, where there was less competition from Big Pharma and less need for a large sales force.

As an incentive for innovation patents have been much more important in biotechnology than in information technology. Patent rights over new molecules are generally "straightforward to obtain, to delineate and to defend", and they play a crucial role in allowing innovators to appropriate returns from their research.[47] The intellectual property regime was strengthened by the Hatch-Waxman Act of 1984, which set out clearer rules on patent exclusivity and strengthened the ability of generic drug manufacturers to enter the market when the patent expired.

The incentives arising from patents are reinforced in the US by the absence of government controls over prices. While the high prices charged by manufacturers for drugs have recently come under heavy criticism in Congress and elsewhere, and some changes in the system

may be made by the Trump administration, the pricing freedom that the industry enjoys is one of the factors to encourage non-American suppliers to launch their drugs first in the US. Another is the speed with which new drugs, once approved by the Food and Drug Administration, can be put on the market. In the European Union, even after a drug has been approved by the European Medicines Agency, the manufacturer has to negotiate prices with national governments, all of which have their own reimbursement regimes. The US has an integrated market for medicines, regulated in a way that stimulates intense competition - on the basis of therapeutic value rather than price - and generates large rewards for the winners.

In its approach to publicly funded research in biomedical science and its exploitation, the US has relied more on initiatives coming out of the scientific community, and from firms, than on top-down direction from the government or its agencies. There have been some top-down projects, such as the NIH's artificial heart programme in the 1960s and President Nixon's War on Cancer in 1971 - both were partly motivated by the Apollo moon-landing programme - but they have had only limited success.[48] The unpredictable nature of the drug development process does not lend itself to government planning.

Implications for the UK

There is a widely held view that the UK, given its strength in biomedical science, should have done better in biotechnology – better, that is, in terms of developing and bringing to market big-selling drugs and in fostering the emergence of medium-sized or large biotech firms comparable to those in the US. It is certainly true that after an apparently promising start in the 1980s and 1990s the UK biotechnology sector failed to generate enough successes to

retain the support of local investors and as a result the flow of capital into the sector declined from the early 2000s. With limited access to finance at home, some of the more promising firms either moved to the US or sold out to pharmaceutical companies. There was a revival of investor interest in 2014 and 2015, partly as a spill-over from the biotech boom that was taking place in the US, but today the gap between the US and the UK remains as wide as it was at the start of the millennium.

The gap is as much a European as a British phenomenon. Biotechnology is unusual in the extent and persistence of US dominance, and this partly reflects features of the US environment that cannot be replicated in the UK or in any other European country. The UK cannot hope to match the scale of government support for biomedical research that is provided by the NIH, nor, given the financial pressures on the National Health Service, can it offer the same level of reward for innovative drugs as the US.

The focus of government policy has to be on making the best possible use of one of the UK's most valuable assets, its high-quality biomedical research, and on creating an environment that facilitates the commercialisation of academic discoveries. This means encouraging universities to become more entrepreneurial and improving the flow of finance for start-up and early-stage firms.

How many of these firms grow into medium-sized or large companies is a matter over which the Government has no control. Creating a British equivalent to an Amgen or a Biogen is almost certainly not a feasible objective, but there have been concerns that too many of the UK's biotech firms have been sold too early and often to non-British companies before they have achieved their full potential. This is blamed, by some commentators, on a chronic tendency towards short-termism in the British financial system; the

Government has recently set up the Patient Capital Review, which will investigate the problems faced by innovative firms as they seek to scale up. But biotech is a global industry, and the UK sector has benefited from the inflow of capital from non-British sources such as the US and Japan. Preserving national ownership is less important than maintaining and improving the attractiveness of the UK as a location for discovering and developing innovative medicines.

An important lesson from US experience, apart from the specific measures discussed earlier, is the need to provide a stable framework on which scientists, entrepreneurs and investors can rely. The US life sciences innovation system has been built up over a long period, reflecting policy choices that for the most part have been supported across the political spectrum.[49] In biotechnology, as in innovation policy more generally, there is no scope for quick fixes.

Conclusion

The two industries discussed in this paper represent only one aspect of US innovation policy. There are other areas - for example, advanced manufacturing – where the performance of US firms has been less impressive.[50] There are also important differences between biotech and information technology that limit the scope for generalisation. The extent of government regulation is more extensive in biotech, and the interaction of biotech firms with academia is much closer. Nevertheless, there are common elements in the two stories that highlight some of the distinctive features of the American system.

Two aspects of public policy are worth emphasising. The first is the need to avoid over-centralisation in innovation policy. The US has benefited from the existence of a number of funding agencies with different missions and priorities. While the UK cannot replicate that structure, and the allocation of funds will always be influenced by political or social concerns, governments should be wary about trying to steer research in preconceived directions.

A second, related point is the limited relevance of the top-down model used in the Manhattan and Apollo projects – projects where the goal is identified, planned and funded by the government. In industries where technology is advancing rapidly and in uncertain directions, success generally depends on multiple sources of initiative and innovation. Some of the initiatives may come from established companies, but new entrants are often better equipped to identify and exploit new lines of research.

For the UK, US experience in information technology and biotechnology reinforces the case for maintaining a strong science base, supported by publicly-funded research. But it also underlines

the importance of a vibrant and competitive private sector, which encourages new science-based firms to get started and grow. This points to the need to improve the UK's innovation system in three ways. First, public procurement should be geared more actively towards the encouragement of new entrants. Second, Government should seek to remove any obstacles, whether arising from the tax system or other factors. that limit the access of growing firms to external sources of finance. Third, the entrepreneurial role of universities should be strengthened, making their technology transfer offices more efficient and their interaction with business more productive.

Endnotes

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