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ABSTRACT

Corporate Governance and Firm Strategy in the Pharmaceutical Industry

by Steven Casper and Catherine Matraves

Using the case of the pharmaceutical industry, this paper assesses how the leading German and UK firms are adapting to changes in their competitive environment, at both the national and international level. We attempt to link how firms create governance structures (management decision-making, the organisation of the R&D process, etc.), and the national system of innovation, impact the innovation strategies adopted in leading German and UK firms. Our results show that first, the firm competencies created in order to compete globally may still originate within national economies, in part because the generation of R&D remains relatively national. Second, towards the end of the 1970s, the scientific basis in the pharmaceutical industry began to change rapidly. The evidence presented shows that UK firms rapidly developed new competencies in biotechnology and other research areas in response to the structural changes. However, German firms tended, until very recently, to maintain and in some cases strengthen competencies in traditional research methods based on organic chemistry.

ZUSAMMENFASSUNG

Corporate Governance und Unternehmensstrategie in der pharmazeutischen Industrie

Am Beispiel der pharmazeutischen Industrie wird in diesem Beitrag aufgezeigt, wie führende deutsche und britische Firmen sich an Änderungen in ihrer Unternehmensumwelt anpassen, sowohl der nationalen wie auch der internationalen Umwelt. Es wird gezeigt, wie die Unternehmen Governance-Strukturen (Managemententscheidungen, die Organisation von FuE-Prozessen etc.) schaffen und wie nationale Innovationssysteme die Innovationsstrategien beeinflussen, die von führenden deutschen und britischen Firmen verfolgt werden. Erstens gelangt die Studie zu dem Ergebnis, daß die Kompetenz der Unternehmen so ausgerichtet wurde, daß sie für den globalen Wettbewerb fit sind, aber ihre Wurzeln dennoch innerhalb der nationalen Volkswirtschaften behalten, teilweise deshalb, weil FuE verhältnismäßig national fundiert ist. Zweitens begann zum Ende der siebziger Jahre eine dramatische Änderung in der wissenschaftlichen Basis der pharmazeutischen Industrie. Diese Evidenz zeigt, daß britische Firmen rasch neue Kompetenz in Biotechnologie und anderen Forschungsbereichen entwickelten, um auf die Änderungen zu reagieren. Deutsche Unternehmen tendierten jedoch noch bis vor kurzem dazu, ihre bisherige Kompetenz beizubehalten und in manchen Fällen in traditionellen Forschungsbereichen, basierend auf organischer Chemie, sogar zu verstärken.

1. Introduction

In recent years, the question of how firms are organised and the resulting impact on product market strategies has become increasingly important. Commercial activity is not spread evenly across nations (Porter, 1990). Firms in the US and UK, for example, have tended to excel in high technology industries where the pace of innovation is very rapid and technological paradigms are shifting (Soskice, 1994). Examples include biotechnology, software, and network communications. German companies, by contrast, seem unable to successfully compete in these high-technology fields, but are very successful in established science-based industries such as traditional pharmaceuticals, as well as a number of high-quality manufacturing sectors such as machine-tools (Streeck, 1992; Katzenstein, 1989). An emerging literature explains cross-national variation in firm characteristics and their product market strategies as the result of differences in national institutional frameworks (Aoki, 1990; Hollingsworth, 1997; Soskice, 1994, forthcoming).

This paper considers these issues within the context of the pharmaceutical industry, which is an interesting case in that it is one of the few high technology industries where European firms are competitive in the global market place (Sharp and Patel, 1996; Panorama, 1996).¹ The main objective of the paper is to assess how the leading German and UK pharmaceutical firms are adapting to changes in their competitive environment, at both the national and international level, with particular emphasis on the links between corporate governance institutions, national systems of innovation and product market competition. During the 1980s, UK pharmaceutical firms substantially outperformed their German competitors in adjusting to changing industry dynamics. The paper links the relative success of the UK pharmaceutical industry to differences in national institutional frameworks in the two countries.

To provide a brief introduction to the competitive process in pharmaceuticals, first observe that this industry is characterised by dynamic competition. New products (and also processes) are continuously being introduced. Unlike basic chemicals, say, where innovation is rather more incremental and new products displace the old upon introduction, the pharmaceutical industry is better characterised as an example of a radically innovative industry. The firm's main goal is to introduce a new chemical entity (NCE) in an existing or new therapeutic market. Second, and importantly, competition is truly global. The results from R&D are easily transferable across national borders, with perhaps some local modification necessary to comply with the standards/regulations. In other words, the results from R&D can be exploited anywhere in the world, although note that the generation of R&D remains far less international (Patel, 1995). However, the competencies which firms must create in order to compete

¹ Sectoral comparisons of innovative performance between Europe, Japan and the US show the strength of pharmaceuticals, where Europe's capabilities were developed in the late nineteenth century.

globally, and the rules by which markets are organised, may originate within national economies. In part because the generation of R&D currently remains relatively national, although this is changing, we argue that leading firms' competencies will still be influenced by national institutional frameworks.

Towards the end of the 1970s, the scientific basis in the pharmaceutical industry began to change rapidly. The evidence presented in this paper shows that UK firms rapidly developed new competencies in biotechnology and other research areas in response to the structural changes. However, German firms tended rather more, until very recently, to maintain and in some cases strengthen competencies in traditional research methods based on organic chemistry. We attempt to link how firms create governance structures (management decision-making, the organisation of the R&D process, etc.), and the national system of innovation, impact the innovation strategies adopted in leading German and UK pharmaceutical firms.

In section two, we first summarise the national market characteristics of the pharmaceutical industry from the early 1980s to the present day. Second, section two examines how exogenous structural changes have affected the competitive environment beginning during the late 1970s. We consider the substantial rise in R&D expenditure, the increasing importance of the marketing and distribution networks, the increasing use of external sources of knowledge (research joint ventures, mergers, and acquisitions) and their resulting impact on the threshold size of the firm. Section three first analyses the importance of the typical patterns of firm organisation in the UK and Germany and secondly, shows how national institutional frameworks play a role in aiding firms to build specific competencies. Section four, using interview evidence for the most part, applies this framework to show the implications for and the actual differences in strategies across German and UK firms. Finally, Section five summarises and concludes.

2. Market Structure and Competitive Dynamics

This section first summarises the aggregate market characteristics for the five largest pharmaceutical producing nations, as shown in Table 1 below. Using several summary measures, we can construct a picture of a given nation's competitive position at the beginning of the 1990s. We particularly emphasise the trends in the UK and German respective competitive positions. We look at R&D expenditure, patent trends, NCEs, number of products in the Top 50, and firm market share in the US. We include the number of products in the Top 50 to account for the fact that although some NCEs introduced are genuinely original, others may be marginal improvements only which could then make the NCE figures somewhat misleading. We include firm market share in the US as a crude measure of competitiveness, because the US market is the most open and competitive market in the world.

To first give the overall summary, the data show that the US is the largest domestic market in the world (although total EU market size was \$47.7 billion in 1987 and \$88.8 billion in 1993). Mark-ups were highest, on average, in Japan and lowest in the UK; note that Japan was, until recently, an extremely regulated protected domestic market. Table 1 also shows that there exist variations in health expenditure between countries. Health expenditure as a percentage of GDP is highest in the US, and the gap is widening over time between the US and other nations. The US also has by far the lowest proportion of health expenditure funded by public sources. In 1989, the EU average for funding by public sources was 66%, so France lies below the average, with both Germany and the UK above the average.

Table 1 shows that the US pharmaceutical industry is strongest. The US has the highest R&D expenditure, the largest introduction of NCEs, and also, the products from its firms dominate the Top 50. Although Japan substantially increased its proportion of NCEs in the 1981-1990 period, evidence shows that if the number of breakthrough NCEs is considered, then between 1970-1983, US firms developed 42% whereas Japanese firms only developed 4% (Ballance et al, 1992; Thomas, 1996).² The trends in patenting activities show that among the EU member states, there has been a slight decline over time in patenting activities in the US, with a slight rise for Japan. Thus, Japanese pharmaceutical firms, unlike in electronics, for example, are not competitive in the US market place.

Consider now the summary of the UK and German 'national strength' aggregate measures. The success story in the EU has been the rise of the UK in the 1980s. Its leading firm, Glaxo, for example, rose from 17th in the world in terms of sales in 1983, to 1st in the world in 1995. We have observed a relative increase in R&D expenditure in the UK, and furthermore, its companies are extremely good at developing NCEs that are commercially successful. During the 1981-1990 period, only 28 new drugs were developed, but a relatively high percentage of these turned into blockbusters. Germany, on the other hand, has a much weaker position. It developed far more drugs (67 NCEs between 1981 and 1990), spends approximately the same amount on R&D, but has a very low number of blockbusters to account for this (only 5 in 1990).³ As a final measure of international competitiveness. Germany's share of the US market is only

² Looking at R&D expenditures note that in 1983, the lowest R&D to sales ratio was in Japan which was a protected domestic market, although between 1983 and 1992, expenditure did substantially rise.

³ In 1993 (Matraves, 1996), Glaxo (UK) had the highest R&D expenditure worldwide at \$1.3 billion, was operating in several therapeutic areas, with 6 Top 50 products, including the number one, Zantac (gastro-intestinal). SmithKline Beecham (SKB, UK) spent \$743.5 million on R&D, with 4 Top 50 products, including Tagamet (gastro-intestinal). Note that in Table 1, SKB's 3 best-selling drugs are credited to both the US and the UK as the company is of joint ownership. Hoechst (Ger) spent \$967 million on R&D but had no products in the Top 50, albeit a relatively strong position in cardiovascular drugs and anti-infectives. Bayer (Ger) spent \$723.5 million on R&D and had two products in the Top 50, including Cipro (anti-infectives). Note that R&D works with a lag, so it may be that we will see German firms becoming more research productive in a few years.

	USA	Japan	Ger	France UK				
Market size (\$ bn)		-						
1987	39.3	30.2	11.8	10.2	8.2			
1993	70.8	51.1	19.5	17.1	14.9			
Mark-ups								
(1970-1992)	1.44	1.54	1.45	1.04	1.16			
Health Expenditure (% GDP)								
1980	9.3	6.4	8.4	7.6	5.6			
1994	13.5	6.9	9.5	9.7	6.9			
% funded by public source								
1989	10	85	73	64	78			
R&D Intensity (%)								
1983	10.6	6.7	8.4	7.1	11.7			
1992	14.3	9.8	9.2	8.7	16.3			
New Chemical Entities (NCEs)								
1971-80	154	74	91	98	29			
1981-90	142	129	67	37	28			
No. of products in Top 50								
1985	23	5	5	1	9			
1990	27	2	5	0	12			
Patent trends								
1980-84	49.8	13.3	10.4	5.1	7.5			
1990-94	54.6	14.7	7.8	4.7	5.3			
Firm's market share in the US								
1991	70.2	0.3	4.6	1.2	14.6			

Table 1: International Comparison of Market Characteristics

Source: unless explicitly stated, the source is Sharp and Patel, 1996. R&D intensity is measured as a percentage of gross output; patent trends are measured as the distribution of US patents granted to innovators from different countries. Mark-ups (Martins, Scarpetta and Pilat, 1996): estimated using Roeger's method. Market size (Matraves, 1997): 'value of production' taken from the OECD 'Industrial Structure Statistics', accounting for ethical pharmaceuticals only. The dollar conversion was made using the nominal average exchange rate (OECD Outlook, June 1994). Global market size was measured at \$135.5 billion (1987) and \$239.5 billion (1993).

4.6%, compared to 14.6% for the UK.

Having provided a brief summary of aggregate market characteristics in the pharmaceutical industry, this section now goes on to examine exogenous structural changes observed over the past two decades. Beginning in the late 1970s, competitive industry dynamics have become more complex. This was due to radical changes in the nature of the innovation process and the introduction of new marketing and distribution

techniques. We will later link the differences in the performance of UK and German pharmaceutical firms, as highlighted above, to their ability to react to these changes in the competitive environment.

(i) the nature of the technological process: over the last twenty years, the development of biotechnology has fundamentally changed how drugs are discovered. The traditional methodology, prevalent in the 1950s and 1960s when knowledge about the properties of the compounds that could be used to synthesise new drugs was still lacking, screened thousands of chemical compounds for efficacy against a given disease (Schwartzman, 1976). In the 1970s, basic biomedical knowledge increased; the traditional methodology has been replaced by 'rational drug design', i.e., the development of more precise models of how particular diseases function, and the design of molecules designed to target particular cells or cause particular biological interactions within the body (see Werth, 1995; Powell, 1996: 204). Biotechnology is beginning to displace traditional 'chemical' capabilities.⁴

When such a new research methodology is adopted, it may be the case that organisational rigidity and inertia hinder incumbents' ability to take advantage of new opportunities. However, although the discovery process is changing, the assets needed for development and commercialisation are not, and these assets continue to be owned by the largest firms. As in any industry, the pharmaceutical industry comprises a valuechain of clusters of organisational, capital, and human resource competencies in areas such as research, development, production, marketing, distribution, etc. In pharmaceuticals, some processes in this value chain, such as manufacturing, are generic activities with low value-added. As research is one of the highly specialised and hence value-added processes, the fact that most biotechnological research is taking place within small start-up firms rather than large firms is an important change (see Powell, 1996).⁵ However, the vast majority of start-ups are crucially dependent on large pharmaceutical firms. This is leading to interesting networks of agreements being observed, where the biotech firms supply the ideas, etc., and the larger firms supply the *complementary* specialised assets (to use Teece's (1986) terminology) such as development, financing, obtaining regulatory approval, and finally marketing, that allow them to appropriate most of the gains from innovation.

To develop this further, the cost of developing a single new drug is currently about \$350

⁴ Biotechnology is based primarily on recombinant DNA and cell fusion techniques. In the pharmaceutical industry, biotechnology is used in 3 different ways: i) to produce drugs and vaccines using rDNA technology; ii) to make intelligent screens for new compounds; and iii) to apply techniques for rational drug design by understanding molecular structure.

⁵ It must be pointed out, of course, that although new start-ups may be undertaking proportionately more R&D, the leading firms still spend by far the largest amount, in absolute terms, on R&D. The leading Top 20 firms in the world control approximately 50% of pharmaceutical sales and 95% of R&D expenditure (Grabowski and Vernon, 1994a).

million (Pisano and Wheelwright, 1995; Di Masi et al., 1991); only a small proportion is spent in basic research (current estimates are approximately 10%, PhRMA 1997). Once compounds are discovered/designed, most development and virtually all marketing and distribution is undertaken by large pharmaceutical firms. Basic research results are usually not known for several years, so securing financing is a crucial problem for most start-ups. As a result, many biotech firms license all or part of their results to the large pharmaceutical firm in return for working capital.⁶ The existence of hundreds of specialised research firms increases the flexibility of large firms, and as long as they can appropriate most of the commercial gains from bio-medical research, then established firms have important reasons to support and engage independent third party research networks.

Also, by nurturing third party research, established firms may better diversify risk. It is estimated that only 1 compound from an initial 5,000 will be successfully developed (PhRMA, 1997). R&D costs have also substantially increased due to tougher regulatory requirements in clinical trials, which accounts for approximately 70% of total development costs (Gambardella, 1995). If in-house research in one therapeutic area is unsuccessful, purchasing compounds developed by third parties can help to fill gaps in the development pipeline. In the world of rational drug design, research in complex disease areas usually takes place along a number of distinct research trajectories.⁷ For example, Penan (1996) identifies fifteen distinct research programmes to fight Alzheimer's disease, each of which is supported by a different constellation of university departments, large pharmaceutical firms, and in some cases, biotech firms.⁸ Under these conditions, in which no one firm can monopolise a therapeutic field, the ability to scan research becomes crucial. Although it is still important to maintain in-house scientific and technological capabilities for monitoring and using external knowledge, developing licensing arrangements and research collaborations with biotech firms helps diversify the firm's 'bets' across a number of research programmes.⁹

Overall, these new research opportunities imply that firms may have an incentive to change the structure of their internal R&D activities, to broaden their activities across a

⁶ Doz (1992) argues that the more invisible and intangible the assets of a particular firm are, the more beneficial the partnership will be. However, it may be that the more the observed skills are system embedded, collective, culturally bound, etc., the less easily they transfer.

⁷ Note that rational drug design also allows firms to redesign established drugs for use against other diseases. For example, Glaxo (UK) recently transformed one of its established AIDS drugs into a hepatitis cure, while Eli Lilly (US) has redesigned its anti-depressant Prozac as a weight-loss drug. Furthermore, rational drug design also simplifies the task of developing 'me-too' drugs that are chemically equivalent, but do not violate patents held by other firms.

⁸ Furthermore, the therapies for some of the more complicated diseases, such as AIDS and perhaps Alzheimer's, often consist of 'cocktails' of two or more compounds developed through separate research programmes.

⁹ Interestingly, only 5% of Merck's R&D is carried out externally, whereas the figure is now much higher for other leading firms (up to 20%): Financial Times (24/5/97), Economist, 1997, 60.

larger number of therapeutic areas. Each therapeutic area becomes a platform from which the firm can monitor the field, purchasing promising compounds from third parties, developing collaborative research projects with universities or research firms, or starting in-house research projects. In addition to increasing the ability to scan the field, maintaining competencies in a number of therapeutic areas allows firms to better redesign compounds for use against new diseases, develop 'niche' markets, and 'me-too' drugs.¹⁰

However, given the massive increase in R&D costs, it may be that only the largest multinational firms will be able to cover a wide range of therapeutic areas.¹¹ Also, given the existence of knowledge spillovers (through journal publications, etc.), it may be extremely difficult to maintain a consistently successful research competency in one therapeutic area.¹² Although knowledge is a public good, it is not a free public good (Pavitt, 1991; Gambardella, 1995), and internal scientific capabilities will still be necessary for knowledge exploitation (Cockburn and Henderson, 1996). Substitute drugs are constantly being discovered; PhRMA, for example, estimates that the 'exclusivity period' before a substitute drug enters the market has decreased from 6 years in 1977 (Tagamet and Zantac) to 1 year in 1992 (Recombinate and Kogenate).

(ii) marketing and distribution networks: over recent years, large pharmaceutical firms have spent as much money on marketing and distribution as they have on development.¹³ Until recently, marketing was dominated by the labour intensive practice of sending thousands of 'detailers' to visit individual doctors, as well as some advertising in medical journals. However, recent pressure to increase the returns on individual drugs, coupled with important developments in the organisation of the US pharmaceutical market, have prompted leading firms to adopt new distribution and marketing strategies. Redeveloping prescription drugs into 'over the counter' (OTC)

¹⁰ Henderson (1994) argues that 'random drug design', via the screening of thousands of compounds required relatively little communication of knowledge, either inter- or intra-firm. However, the changing methodology of drug discovery means that modern scientists must be skilled in a wide range of disciplines many of which are advancing very quickly. This has greatly increased the need for the exchange of knowledge, both inter- and intra-firm. Also, the IT revolution has meant that drugs can be screened far more quickly.

¹¹ Henderson and Cockburn (1996) assert that firms typically invest in approximately 10-15 distinct research programmes, where each programme is targeted towards a particular disease area. Investigating the relationship between firm size and research productivity for 10 leading firms, their results show that larger firms are more productive, due mainly to economies of scope (the ability to sustain an adequately diverse portfolio of research projects and to capture and use internal and external knowledge spillovers).

¹² Henderson and Cockburn (1994) argue that 'local competencies' (abilities necessary for everyday problem solving) may give long-lasting advantages but firms also need 'architectural competence' (the ability to develop new competencies). Using data on cardiovascular drugs, they find that the better is outside-firm communication, and the better are within-firm information flows across therapeutic classes, the more research productive is the firm. The results are consistent with their hypotheses.

¹³ McGahan (1994) asserts the industry as a whole spent one billion dollars more in 1991 on marketing and distribution than on research and development.

versions is perhaps the simplest way to extend the life of a compound nearing the end of its patent life. This tactic requires direct to consumer advertising through the commercial media, as well as the development of distribution channels to retail outlets. These marketing and distribution competencies differ dramatically from the more traditional 'detailing' activities. Pharmaceutical firms that choose the OTC route have two options. First, they could establish costly relationships with advertising agencies and develop new distribution channels; or second, form marketing joint ventures (JVs) with firms who have already developed a competency in the areas required.¹⁴

The most important changes that have occurred in the US, however, have developed as a result of the reorganisation of links between doctors, distributors (pharmacies), and insurers. During the 1980s, health care and insurance functions began to merge into HMOs and other managed care organisations, encouraged by various reforms in the US health care system.¹⁵ This created networks of concentrated buyers. Towards the end of the 1980s, a similar fusion of pharmacy, marketing, and distribution operations began to take place within so-called 'pharmaceutical benefits management' (PBM) firms. PBMs serve these concentrated buyer networks, partly by providing drug utilisation reviews and other information such as drug usage rates that pharmaceutical firms can feed back into their development and marketing activities, but more importantly, by using the concentrated purchasing power to negotiate strong price discounts. This is done through managing the 'formulary' (the list of drugs that each doctor within a certain health care organisation can prescribe). In recent years, leading US pharmaceutical firms have acquired several of the largest PBMs (see Table 2), showing evidence of forward integration into health care markets.¹⁶

Such forward integration complements an expansion of research across several therapeutic areas. While firm profits are still driven to a relatively large extent by the control of a few 'blockbusters', the new distribution and marketing capacities ensure that the life-cycle of each compound can be maximised, especially as drugs nearing patent end are transformed into OTC versions. Having some guaranteed market access through controlling one or more PBMs allows leading firms to minimise the risk of not being first, i.e., if a firm loses a 'race' to develop a particular treatment, it can usually produce a 'me-too' drug within a few years, and assure a fixed volume of sales through the PBM.

¹⁴ Recent examples of the latter strategy include the Glaxo alliance with Warner-Lambert, and the Merck alliance with Johnson & Johnson, to develop and market OTC versions.

¹⁵ Over 100 PBMs emerged in the US during the 1980s (McGahan, 1994); by 1996, 53 million people were enrolled in HMOs in the US, up from 9 million in 1980. Generic substitution is now used by 85% of HMOs, and currently accounts for 40% of the volume of prescription pharmaceuticals.

¹⁶ The control of formularies does not mean that pharmaceutical firms can charge higher prices for their drugs, since each HMO can choose between a number of PBMs on the basis of the price and the availability of drugs. Nevertheless, guaranteed market access to a large network of buyers allows pharmaceutical firms to maximise the value of their drug portfolio; especially with respect to generics and 'me-too' equivalents of branded drugs where large sales volume is crucial.

According to a recent industry analysis, some 90% of patented drugs have direct competitors, and there exist three or more direct competitors in 15 of the top 20 therapeutic areas (Powell, 1996: 204).

Table 2: Mergers and Acquisitions

- **1985** Monsanto (US) and Searle (US).
- **1988** Kodak (US) and Sterling (US).
- **1989** SmithKline Beckman (US) and Beecham (UK) merged. Bristol-Myers (US) and Squibb (US) merged. Dow (Merrell) (US) and Marion (US) merged.
- **1990** Rhone-Poulenc (Fra) and Rorer (US) merged. Roche (US) bought 60% of Genentech (US) (biotech firm) for \$2.1 billion.
- **1993** Merck (US) paid \$5.9 billion for Medco (US distributor). Synergen (US) and Amgen (US) merged (\$2.6 billion).
- 1994 Ciba Geigy (Ch) paid \$2.1 billion for 50% of Chiron (US biotech firm). American Home Products (US) paid \$9.8 billion for American Cyanamid (US). Roche (Ch) paid \$5.1 billion for Syntex. SmithKline Beecham (UK) paid \$2.9 billion for Sterling Health (US) and resold part of it to Bayer (Ger) for \$1 billion; also bought DPS (PBM/distributor) for \$2.3 bn. Eli Lilly (US) paid \$4 billion for PCS (US distributor).
- 1995 Glaxo (UK) paid \$14 billion for Wellcome (UK). Hoechst (Ger) paid \$7.1 billion for Marion Merrell Dow (US). Pharmacia (Swed) and Upjohn (US) merged. Rhone-Poulenc (Fr) acquired Fisons (UK) for \$1.7 billion and BASF (Ger) acquired Boots (UK) for \$1.3 billion.
- **1996** Ciba-Geigy (Ch) and Sandoz (Ch) merged forming Novartis (with an estimated market share of 4.5%).
- **1997** Roche (Ch) acquired Boehringer-Mannheim (Ger).

Source: Matraves (1997)

This section has described the underlying changes in the competitive environment in the global pharmaceutical industry. Overall, minimal firm size is increasing due to the increased costs of R&D, and the marketing and distribution networks necessary to exploit the new drug globally. An additional factor is that if the largest firms are broadening their R&D activities, this may best be done in combination with forward integration into new marketing and distribution networks. Table 2 shows the extent of the recent merger activity in the pharmaceutical industry. Since the 1989 merger of SmithKline with Beecham to the Ciba-Sandoz merger in 1996 forming Novartis, the industry has been rapidly restructuring itself leading to a consolidation of firms at the top. Table 2 shows that this restructuring has been dominated by global (inter-regional) activity. What is interesting here is that the European firm is the more proactive. The leading firms which have been international in operation are now becoming international

in ownership. We now consider the question of whether national models play a role in how firms compete globally. Section 3 presents a framework for thinking about these issues.

3. The importance of national models

National political economies are characterised by complexes of institutions in different areas (e.g., industrial relations, capital markets, education and training) which firms draw on to support particular product market strategies. National institutions represent resources or 'tool kits' firms can engage to create and manage the organisational structures needed to sustain particular competencies. In this section, we first examine the typical patterns of firm organisational competencies. Second, we examine the role that national innovation systems play in influencing product market strategies. We will later suggest the superior performance of UK firms can be linked to corporate governance institutions that support rapid short-term adjustments to structural changes, and an environment created by the national system of innovation that supports radical innovation.

(i) corporate governance and large firm organisation patterns: firm structures form the organisational context within which managers adjust their product market strategies to compete (Bower, 1970). *Organisational structures* refer to decision-making structures, career paths, employee remuneration and other financial incentives, and also, inter-departmental links. To create successful product market strategies, the firm management must create and sustain relationships with a number of different groups, e.g., workers, technicians, scientists, banks, etc. We view each aspect of company organisation as a strategic response to a bundle of technical and relational problems. The rules chosen by top management to organise and monitor decision-making, manage careers, reward performance, etc., influence both the type of organisational responses that firms can adopt and the range of possible product market strategies (national and international).

Relationship between owners and top-management: many comparisons of corporate governance patterns within the UK and Germany focus on differences in the ability of firms to obtain finance to make long-term investments (Charkham, 1995; Vitols, 1995a). According to the argument, the preference for short-term returns held by capital-market based financial systems like those seen in the UK and US force firms to limit long-term investments. Similarly, because most shares within Germany's 'bank-centred' financial system are directly held or controlled by large banks with no short-term liquidity option, firms have access to 'patient capital' that may be used to finance long-term investments. The ability of UK pharmaceutical firms to make long-term investments is driven by investors using the current product portfolio and 'future drug' pipeline to judge both the

likely short-term returns and long-term viability.

While we argue that differences in the composition of ownership is one of a number of factors that create substantially different patterns of company organisation across UK and German pharmaceutical firms, in both countries firms have been able to invest massive amounts of funds into R&D. In fact, Table 1 shows that UK firms not only invested a higher percentage of R&D, but also substantially increased expenditure between 1983 and 1992. Although there is the risk that high R&D spending will not yield any blockbusters, it is clear that it is one of the best predictors of long-term success. In the short-run, investors will quickly sell shares if the firm begins to cut R&D expenditure.

A key feature of the UK corporate governance system is that company law protects the rights of dispersed shareholders by guaranteeing a market for corporate control. In the UK, most large firms have a single board of directors, consisting of several non-executive directors appointed to represent shareholders, as well as the chief executive officer (CEO) and several other executive directors (see Charkham, 1995). Representatives of share-holders create contracts to align the incentives of top managers with those of owners.¹⁷ Top managers of most large firms receive renewable short-term contracts; non-executive directors will remove the top management team if performance lags. The CEO is given unilateral decision-making control, and strategic initiatives are usually formulated within committees of top managers, approved by the CEO, and then quickly implemented throughout the hierarchy.

In Germany, company law promotes a 'stake-holder' system, in which various groups of employees in addition to owners are given a strong voice in firm management (Charkham, 1995; Lehrer, 1997). Company law creates a 'two tier' system consisting of both a supervisory board (the *Aufsichtsrat*) and an executive board (*Vorstand*). Under German company law, seats on the supervisory board are equally divided between firm employee representatives and owners representatives, with the tie-breaking vote held by the supervisory board chairman, also an owners representative. In the German system, power is dispersed across various 'stake-holders' on the supervisory board, and most decisions are consensual. Thus, while members of the *Vorstand* can be removed if their performance is severely sub-standard, they rarely receive the unilateral decision-making control or high-powered remuneration incentives seen in UK firms. Finally, as major ownership stakes are usually far more concentrated within German firms, take-overs are rare. Thus, major shareholders are usually not interested in short-term capital gains and have a preference for long-term earnings and stability. The broad academic consensus that the German corporate governance system provides 'patient capital' is driven by

¹⁷ To align preferences, stock-options and share-ownership are included within remuneration packages, where remuneration is extremely high, and is largely based on short to medium-term performance of the share price of the company stock.

basic differences in ownership. While the 'stakeholder system' of corporate governance is strongly driven by company law, it is likely that banks and other concentrated stakeholders continue to support this system because it makes the patterns of company decision-making predictable and rewards long-term planning and consensus decisionmaking.

*Relationships between top-managers and employees:*¹⁸ differences in the composition of ownership, combined with company and corporate governance laws and the structure of labour markets have led to the creation of different patterns of firm organisation. The firm organisational patterns we highlight include the structure of decision-making, career-paths of managers and scientists, and remuneration policy. These differences are conditioned in part by the incentive structures arising from ownership differences, but also by important differences in the structure of labour and company law in the two countries.

UK labour markets are relatively deregulated and open. This makes implicit long-term contracts with low-powered performance incentives less viable. There exists a market for managers and technical employees; courts will not uphold 'competition clauses' in employment contracts that limit future employment; and poaching is widespread. Furthermore, top management has more flexibility over internal labour market policy. If particular corporate units are not meeting expected performance standards or, due to a change in strategy, are no longer needed, they may simply be cut.¹⁹ While in practice, many middle managers and researchers will work with one firm throughout their careers, there are usually no long-term employment guarantees. Although top managers have a mandate to invest heavily in long-term R&D, they must contribute to measurable equity value creation, in terms of current profitability and/or share price, which also tends to mitigate against a strategy of offering long-term employment security. In the UK corporate governance environment, high wages are part of a broader incentive structure to reward superior individual performance. Thus, in UK pharmaceutical firms, both scientists and managers receive short-term contracts with no long-term employment guarantee, considerable scope for individual initiative, and performance-related pay.²⁰

By contrast, in Germany, while there exist no formal laws stipulating lifetime employment, German labour has used its power on supervisory boards as well as its

¹⁸ The generalisations on management-employee relations originate from interview evidence from UK and German pharmaceutical firms. Lehrer, 1997 forthcoming, undertakes an analysis of internal firm organsiation in the UK and German civil airline market, and comes to similar conclusions.

¹⁹ In order to keep the return on capital high, top management will limit funding for research teams that do not produce viable candidate compounds in areas with broad commercial appeal (even if the vast majority are not developed).

²⁰ One of the large UK firms, for example, offered stock options to over 3,200 managers, including virtually all scientists and financial managers; similar practices were seen at other firms. Firms also typically linked a large percentage of pay (up to one third) to yearly performance reviews.

formal consultative rights under codetermination law over training, work-organisation, and hiring, to demand unlimited contracts. Top management has acceded to these demands for several reasons: i) to secure a cooperative labour force; ii) to lessen the risk of other firms poaching highly-skilled employees that the firm has trained; and iii) because German labour law forces firms to pay most of the unemployment insurance for laid-off workers. Once the life-time employment norm was established, it spread to virtually all mid-level managers and technical employees. Migration of managers and highly-skilled technical employees across firms is limited, reinforced by the willingness of German courts to uphold clauses in employment contracts that forbid an employee to take a job at a different firm with the same skill classification for one year after leaving the original firm.

Given these constraints on personnel policy, top managers have created very different organisational structures than exist in UK firms. German employees receive salaries defined by their hierarchical position, with pay increases following fixed trajectories based on seniority and promotion. Bonuses are typically negotiated into standard contracts and are not performance related. Most employees begin careers in technical positions and at later levels of their career enter into formal management positions. Rapid promotion is rare. German firms rely on consensus decision-making across committees of several managers.

	Germany	United Kingdom
Owners	Allows banks to have	Asserts interests of
	industrial shareholdings.	dispersed shareholders.
	Restrictions on take-overs;	Active market for
	protection of interests of	corporate control
	concentrated shareholders.	
Top Managers	Power dispersed across	Decision-making power
	Vorstand; Aufsichtsrat	concentrated in CEO; non-
	consists of both employee	executive directors have
	reps and non-executive	little power; high powered
	directors and influences	performance incentives;
	firm strategy; Consensual	pay linked to firm
	decision-making; pay not	performance
	linked to firm performance	
Employees and scientists	Long-term employment;	No long-term employment
	fixed career paths;	guarantees; unilateral
	consensual decision-	decision-making control;
	making; low powered	high powered incentives:
	performance incentives	performance reviews, stock
	(pay not linked to short-	option plans, rapid career
	term performance	promotion

 Table 3: Corporate governance and large firm organisational patterns

This section has shown how differences in corporate governance institutions influence the type of contracts owners form with top managers and, in turn, the type of contract top managers create for employees within the firm. Table 3 summarises these relationships between corporate governance institutions and firm organisation in the UK and Germany.

(ii) national systems of innovation

We argued in section two that changes in the nature of bio-medical science necessitates that large pharmaceutical firms change their research processes. Instead of performing most research in-house, it may be that pharmaceutical firms in today's environment must create competencies to scan multiple scientific fields and establish numerous alliances with research firms and university scientists. While large pharmaceutical firms have, during the 1990s, developed capacities to scan scientific research programs on a global level, the national research environment in which they are embedded is crucial. Having access to a local and vibrant bio-medical research community lowers the costs of adjusting to changes in the discovery process. Experts on biotechnology have documented a rapid movement of scientists between large pharmaceutical firms, start-up research ventures, and university labs (Kornberg, 1995; Powell, 1996). These research networks are much easier to establish within a firm's local environment. Similarly, it may be argued that large firms can more easily play a role in scanning and, through supporting graduate training, shaping research at local universities and start-up research firms than at foreign ones. If major breakthroughs affecting a firm's research occur within the local research environment, it reasons that they can then be monitored more easily.

A large literature has in recent years examined institutions supporting innovation processes cross-nationally (see Nelson, 1993). Drawing in part from these studies, this section examines differences in the ability of UK and German national innovation systems to create the organisational competencies necessary to support radical advances in bio-sciences. In particular, we stress three factors which influence the ability of firms to support radically innovative research. These factors are the regulatory environment, venture capital, and the structure of labour markets and related career incentives. We consider how these factors operate first in Germany and then in the UK.

Within Germany a number of institutional and regulatory factors have combined with the labour market policies developed by large firms to produce a hostile climate to the development of a vibrant small-firm biotechnology sector. First, for most of the last decade, German law-makers, in response to widespread social distrust of genetic research, developed and enforced a regulatory process covering all genetic research. In reaction to a widespread perception that German is failing to develop high-technology industries in a number of areas, the approval process was simplified in 1993, and was

abolished altogether in 1996. However, the sum result was that for over a decade, this law discouraged practically all biotechnology research in Germany (Frankfurter Allgemeine Zeitung, 1993; Handelsblatt, 1996a).

Second, Germany's bank-centred financial system has not fostered the creation of venture capital pools to support start-up research firms. Most biotech start-ups in the US have been funded by the venture capital industry that emerged in the 1970s and 1980s to support the US semiconductor and software industries (Kenney, 1986). Venture capital is important not just as a means of funding, but also as a critical tool that managers of start-ups use to create high-powered incentive structures for employees (Florida and Kenney, 1988).²¹ The venture capital system often creates an ideal incentive structure for employees of biotech firms and provides a mechanism through which start-up capital is constantly recycled through the industry.

In recent years, German policy-makers and bankers have begun to understood the importance of venture capital, and the government has organised and given seed-money to pools of money to support small firms in the biotechnology and other industries (Handelsblatt, 1996b, 1996c). The problem, however, is that equity markets are massively undercapitalised in Germany compared to the US (or UK), and there exists nothing comparable to the NASDAQ exchange in the US. As a result, venture capitalists have no way to quickly liquidate their investments, making it difficult to recycle venture capital through subsequent rounds of investment. Additionally, offering employees of start-ups shares fails to produce a similar high-powered incentive structure, since there is no chance of an initial public offering for most small German firms.

Third, the career patterns developed by large German pharmaceutical firms, coupled with 'competition clauses' within employment contracts, limits the creation of an active labour market for scientists. It is difficult for scientists (and other managers) to move between different firms, since most hiring occurs at the entry level. Thus, leaving an established job to work in a start-up is much riskier than in the US and UK, where there is a large market for managers and scientists of different levels of experience. In Germany, a failed venture with a start-up could lead to long-term unemployment. This lack of a labour market of entrepreneurial scientists increases the difficulty of fostering a vibrant community of small, start-up firms backed by venture-capital. Table 4 summarises these arguments.

²¹ In most start-up schemes, all employees receive shares in the firm, along with venture capitalists. Once a firm achieves initial commercial success (or in a biotech firm, develops a compound that can be licensed), venture capitalists liquidate their shares through an initial public offering. When successful, venture capitalists receive a multiple of their initial investments, which are usually invested into additional start-ups. Employees can now also sell their shares, often making a large profit.

	Germany	United Kingdom
Regulatory environment	initially hostile; genetic technology law created complex approval process; law abolished in 1996	Permissive
Venture capital	Not well developed; difficult to support due to undeveloped equity markets for small firms	Well-organised venture capital infrastructure and equity markets for small firms
Labour market & career incentives	Labour market rigidities and benefits of long-term employment make joining a start-up risky	Labour market flexibility reduces risk of working for an unsuccessful start-up

Table 4: Influence of National System of Innovation on home market research

As shown in table 4 above, each of these factors previously emphasised is favourable to the development of radical innovation in the discovery of new drugs in the UK. The regulatory climate is permissive. No special legal regulations affecting genetic research have been created, and the results of research go through the normal clinical testing and review process. High stock market capitalisation fosters the creation of venture capital. Charitable trusts and private venture capital firms have all been active in fostering start-up companies in bio-sciences (reference). Several of the largest universities, including Cambridge and UCL, have started venture capital funds to create spin-off firms. Flexible labour markets reduce the risk of joining firms that face a high probability of failing. Finally, UK universities quickly adopted the US norms of dividing patent royalties between researchers, departments, and the university. This has encouraged the creation of research communities linking the corporate and scientific communities. Table 4 summarises these comparisons.

4. Implications for strategy

Recall that as a general point, Table 1 showed that first, there was a substantial rise in R&D expenditure in the UK between 1983 and 1992. Also, the absolute levels of R&D expenditure are approximately the same in the UK and Germany, and yet the UK is discovering substantially more blockbusters. Our evidence suggests that the reason that German firms appear to be 'less successful' is a function of a superior response by UK firms to the new competitive conditions in the global pharmaceutical market, as described in section 2, both in terms of R&D and marketing/distribution. We will now attempt to link this argument to the organisation of firms and the national system of

innovation. There are three inter-linked factors: i) owner/ shareholder market pressures; ii) the ability to create flexible organisational structures; and iii) the impact of the national system of innovation.

i) owner/shareholder market pressures are becoming increasingly important in the pharmaceutical industry. In the UK, dispersed shareholders demand a certain rate of return on their investment, or it is obvious that either they will sell their stock or not invest in the firm. In Germany, the absence of a market for corporate control and the concentration of company shares across a few large shareholders have muted pressures from small share-holders for increased short-term returns. As the competitive pressures have become more intense in the pharmaceutical industry, due to factors such as government pressures on the costs of health care, globalisation and increasing R&D costs (see section 2), pharmaceutical firms have come under more pressure to develop blockbusters.²² Research projects must be commercially viable.

In the UK, Zeneca was incorporated (demerger from ICI) in June 1992. Zeneca focuses purely on 'life-sciences', i.e., pharmaceuticals and agrochemicals. It was argued throughout the business press that this was market driven. The other leading firms in the UK, Glaxo and Wellcome (before the 1995 merger) are both purely pharmaceutical manufacturers. However, for both the leading German firms, Bayer and Hoechst, only a certain proportion of their sales are in pharmaceuticals. In 1993, the proportions were 23% and 24% respectively. It has been very interesting to note that Hoechst has recently begun to transform itself into a life sciences group, selling many of its basic and speciality chemical subsidiaries in order to pay for the take-over of Marion Merrell Dow and expand its activities in pharmaceuticals and agrochemicals (Handelsblatt, 1996). It would appear that the leading German firms are reacting later than the UK firms to changes in competitive pressures. This evidence is consistent with the hypothesis that the ability of British shareholders to quickly "punish" UK firms (through driving the share price down of poorly performing firms and the unilateral control of the CEO) has engendered better adaptation to changes in competitive pressures than observed in Germany.

The major UK firms are investing heavily in PBMs and other after-market firms in order to obtain better information on market trends, and possibly influence doctor prescription choices through 'formulary management'. This is clearest with SKB, which as a half-US firm, has been one of the prime movers in this area through its purchase of DPS, one of the largest PBMs. Also, Glaxo has formed a long-term marketing alliance with Warner-Lambert in order to expand its OTC opportunities, and has spun off a drug utilisation review company (Health Point) in order to obtain doctor prescription information to aid

 $^{^{22}}$ Grabowski and Vernon (1990, 1994b) show that i) the return to new drugs is highly skewed, a few 'blockbusters' dominate the product ranges of the major firms; ii) only the top 30 drugs worldwide cover average R&D costs.

its research decisions.

ii) UK firms have also created internal organisational structures to encourage a rapid response to changes in the market and scientific environment. Most importantly, the top management of UK firms linked finance and research departments, which is accomplished, in part, through linking promotion and bonus opportunities for finance personnel directly to the commercial success of research. Financial personnel are directly involved in research and development decision-making, by being included on all scientific committees charged with making research decisions. An additional practice is to train all lead scientists in management and financial analysis, primarily through sending them to executive courses within business schools. As a result, each of the UK firms we visited had developed extensive expertise in assessing the commercial viability of projects. Factors such as potential market size and spin-off potential in OTC markets were cited as central in all research decisions. Partly as a result of the above, these firms were able to stop, if it were necessary, the vast majority of all research projects at a very early stage of development. One example, widely reported in the press, was the fact that, at the time of the Glaxo-Wellcome merger, Welcome had as many research projects running as Glaxo, despite the fact that Wellcome was less than one third the size of Glaxo.²³ This highlights the success by which shareholder concerns for profitability have been transferred into organisational practices within Glaxo.

The interview evidence supports the notion that UK firms can move into and out of areas much more quickly than German firms. For example, upon deciding to enter into a new therapeutic area, one of the UK pharmaceutical firms we visited had recently hired not just a leading biochemist from a nearby university, but his entire research staff. Department managers in both finance and research also confirmed that firms are unable to make long-term employment guarantees. Therefore, if research units have not achieved sufficient profitability in terms of viable compounds over a period of years, then they are dismantled, or researchers whose scientific skills have gone out of date are released.

German firms, by contrast, cannot move into new areas as quickly as UK firms. This is in part because of the lack of a market for established scientists within Germany. New competencies must be slowly built up through hiring newly trained scientists and, when possible, reassigning internal scientists into new areas. Firms are also hesitant to dedicate resources for what can only be long-term research into new areas in which the probability of adequate returns is unknown. German firms can gradually reduce the work force through early-retirement programs, limiting new-hiring, or selling entire subsidiaries, but generally cannot lay-off full-time employees within particular

²³ Due to its previous status as a charitable trust, Wellcome faced far less stringent market expectations than Glaxo. According to the *Economist*, Glaxo has since the Wellcome merger laid-off around 7,500 managers and scientists from the combined firm's staff of 61,500 (Economist, 1997a).

departments. In recent years the largest German pharmaceutical firms, Bayer and Hoechst, have both attempted to increase the number of therapeutic areas within which they are active. This mirrors the strategy taken by the largest UK and US firms, and allows each of these firms to increase its capacity to scan different research programs occurring within universities and biotech firms. One probable reason why German firms have a lower rate of return on R&D (in terms of new blockbuster) is that they cannot quickly cut research programs that are not producing commercially viable results. Compared to UK firms, German firms cannot simply decide to lay-off research personnel dedicated to research programs that are not yielding commercially viable products.

A possible recourse for German firms is to limit research to a small number of therapeutic areas in which the company has a proven record of success. This is the strategy taken by the medium-sized German pharmaceutical firms (Schering and Boehringer Ingelheim, for example).²⁴ However, this has the adverse consequence of limiting the absorptive capacity of the company. Without a number of 'platforms' in different therapeutic areas, the ability of German firms to scan basic research in biotech firms and at universities becomes less. Furthermore, firms with a less varied product portfolio cannot create an efficient world-wide distribution and marketing network (which becomes more cost-effective the more drugs the company has to sell). These firms may become take-over candidates as a result.²⁵

iii) differences in the national systems of innovation within UK and German pharmaceutical firms are embedded have also played a role. UK firms are embedded within a vibrant bio-medical research community with a growing infrastructure of biotech start-up firms. According to a recent survey, over half the biotechnology companies active in Europe exist in the UK (Economist, 1997b). UK pharmaceutical firms enjoy access to a wealth of home market research firms that have been slow to develop in Germany.²⁶ This has probably influenced the speed with which UK firms have incorporated new research methodologies into their own operations, and helped them quickly establish joint ventures and licensing agreements with biotech firms.

Over recent years German firms have invested large amounts of research and development funds into biotechnology, but they have had to do this almost entirely

 $^{^{24}}$ This is not the only factor, of course, for a firm to choose to be present in only a few therapeutic areas. Other crucial factors include extremely high unit R&D development costs and lower access to capital for mid-sized firms.

²⁵ Note that Boehringer Mannheim has just been taken over by Roche (Ch).

²⁶ European biotech has developed primarily within large pharmaceutical firms and in non-profit institutes such as universities. This is quite different from the US where there are a lot of start-ups. There are more UK biotech start-ups than in Germany; one of the reasons is the unusual flotation rules which have been in place since 1993 and allow biotech firms to be floated on the stock exchange without the usual three years record of trading profits. However, the number of German biotech start-ups has been increasing recently due to changes in the genetic engineering law, and the government actively promoting the biotech industry (Financial Times, 26/11/96).

abroad. This is particularly true with the largest German firms, in particular Hoechst and Bayer. Hoechst, for example, now spends over 60% of its total research and development abroad, and has 90 overseas R&D centres (Handelsblatt, 1996). It has transferred most of its biotechnology research to US labs acquired during the take-over of Marion Merrell Dow, now spending about DM 400 million per year on biotechnology (Wirtschaftswoche, 1997). According to Sharp and Patel (1996), Hoechst and Bayer each have over a dozen different biotechnology collaborations with universities and biotech firms in the United States. Bayer has one dedicated biotechnology lab in Germany, while Hoechst has none.

5. Conclusion

In this paper, we discussed differences in corporate governance institutions and the national system of innovation in Germany and the UK, and how these differences impacted the firms' organisational structure and ability to take advantage of changing technologies. UK firms rapidly developed new competencies in research, marketing and distribution, outperforming their German competitors during the 1980s. We credit this superior response to national institutional frameworks in the areas of corporate governance and the innovation system. UK corporate governance institutions give an advantage in developing rapidly changing product market strategies necessitated by structural market changes. Due to share-holder pressures linked to ownership structure and organisational flexibility, the UK pharmaceutical firms reacted more quickly than their German rivals to changed competitive conditions. Similarly, the national system of innovation encourages radical innovation; UK pharmaceutical firms were able to easily tap into these research communities.

Our findings must be situated within the broader findings by Porter (1990) and others who document strong cross-national variation in the product market strategies firms successfully pursue. The Germans appear to be particularly successful within industries necessitating long-term capital investment, access to highly skilled workers, long-term managerial employment with relatively low-powered remuneration incentives, and inhouse research and development. A large literature has emphasised the German success in industrial machinery, automobiles, specialty chemicals, etc., – all sectors in which the very "short-termism" that proves so successful in extremely turbulent markets has undermined UK firm performance (see Katzenstein, 1989, Streeck, 1992).

Furthermore, we observe that the leading German pharmaceutical firms have, in recent years, strongly reacted to the changing industry dynamics. As discussed above, the majority of value-added within pharmaceuticals consists not in discovery, but development and marketing and distribution. German pharmaceutical firms, lead by Hoechst, have created elaborate international production chains during the 1990s. The

leading firms have spent billions of dollars creating research and development networks in biotechnology. However, in contrast with the UK firms, this money has not been invested in the domestic market, but primarily in overseas networks, accessing the US science base. Compounds developed abroad can be easily transferred back to Germany, where further development may ensue.

This leads to a powerful argument against those arguing that globalisation must lead to a convergence of institutional frameworks (Ohame, 1991). German firms are adjusting to changes in the pharmaceutical industry, but not through attempting to reconfigure German corporate governance or innovation institutions (if indeed, that were possible). In this case, German firms are embracing globalisation, but are continuing to invest within the national economies where the organisational competencies for each part of the value-chain may most easily be created.

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