

H A R V A R D | B U S I N E S S | S C H O O L

Biotechnology | Life Sciences in Munich/Germany

Final Report

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HBS 1260/PED 329

May 4, 2007

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Disclaimer

This paper describes and analyzes the biotechnology/life sciences cluster in the Munich region in Bavaria, Germany. All remarks base on the presentation given in the MOC class of 2007 at Harvard Business School and result from collaborative group work of all group members named on the cover sheet of this report. One of the group members is a native German who lived and worked in Germany prior to his studies at Harvard University. Neither this member, nor any other member of the group had any special or nonpublic access to information about the country or cluster that is utilized. None of the group members traveled to the country during the project period.

Most of the data used in this paper are taken - if not noted otherwise - from the *OECD Data Panel*.¹ The reasons therefore are twofold: Firstly, the OECD provides the most diverse and actual data set available that deals with both macroeconomic and microeconomic indicators across different countries as well as different industries. Secondly, the statistical consistency of the OECD data permits a direct comparison of the data without analytical concerns.

Preface: The German *Competitiveness Paradox*

Many observers, politicians, and business people see biotechnology as a keystone of a knowledge-based economy. Especially in industrialized countries, new technologies like biotech are seen as some of the most important industries that sustain economic growth and productivity in the future. In recent years, biotechnology has become an increasingly important factor for the economy in Europe and Germany in particular, yet the industry has far from fulfilled its potential and, when compared with the USA, shows a number of shortfalls.

1 Cf. Organization for Economic Co-Operation and Development, see: www.oecd.org

Despite these shortfalls, German biotechnology is an interesting industry to focus on in the course of an analysis on competitiveness. The main reason for this significance resides on the special 'interplay' between macroeconomic and microeconomic factors in the German economy. Biotechnology in Germany in this regard is a catalyst that reveals both the strengths and weaknesses of Germany as a business location. Whereas the macroeconomic factors generally expose the fundamental challenges of Germany's long-term competitiveness, the microeconomic factors that also determine Germany's biotech sector show Germany's potential for productivity that lie within the business environment.

This *competitiveness paradox* in the German economy can be exemplified with the biotech sector. For this purpose, subsequent explanations will describe and analyze the overall political and social context of Germany, macroeconomic and microeconomic environment of German biotechnology to show the difference between Germany's long-term macroeconomic and recent microeconomic potential for productivity and competitiveness. To elaborate this paradox, this report focuses on the biotech cluster in the Munich region in Bavaria, one of Germany's 16 states, and Germany's most important biotech region.

I. Introduction

As Europe's largest economy and most populous nation, Germany is a key player of global and Europe's economic and political development.

I.1 Background: Germany at a Glance

Physical Information: Germany is located in the center of Europe, with Denmark and the Baltic and North Seas to its north borders and between Poland to the east and the Netherlands to the west. It covers an area slightly smaller than Montana. The country's terrain is lowlands in the north and the Bavarian Alps in the south. In total, the country borders 9 countries (Austria, Belgium, Czech Republic, Denmark, France, Luxembourg, Netherlands, Poland and Switzerland). The country's natural resources include iron ore, coal, timber, uranium, natural gas and copper which were basic goods for its growing steel industries after the end of World War II (WW II).

Population: Germany's population is about 82.3 million people. The population's ethnical composition is dominantly German (92%). The strongest minority is Turkish (2%) and other minorities include Italian, Serbo-Croatian, Greek and Polish. The population practices the following religions: Protestant (38%), Roman Catholic (34%) and Muslim (4%). The official language is German.

Structure and Legal System: Germany is a social constitutional federation consisting of 16 federal states, each with its own constitution, parliament and government. It is based on the principle of a division of powers and lawful administration. The highest political authority is pursued by the federal government that is answerable to the lower chamber of the national parliament, the "Bundestag". Through the higher chamber of federal government, the

“Bundesrat”, the states (“Länder”) are represented at the federal level and participate actively in federal legislation. The Basic Law of the Federal Republic of Germany guarantees every individual citizen basic and human rights and requires that the structure of each state-level or federal government must obey the principles of republican, democratic, and social government (Article 28).

German policies carry strong implications for federal politics that face strong critique as being inefficient. Opposition victories in elections for State Parliaments, which take place every four years, can weaken the federal government, because state governments via the Bundesrat have to approve many laws after passage by the Bundestag. During the last few years, the powers of the state governments in their own territories also have been diminished as the result of an ever-increasing amount of federal legislation. The states are in particular responsible for culture, law enforcement and the entire educational system.

States have low immediate tax revenues from state-level taxes. All important legislative powers as regards economic and fiscal policies principally are the sovereign right of the federal government.

Economy: Germany’s economy is the leading industrial economy in Western Europe. It is the biggest net contributor to the European Union budget. Its traditional strong base in matured industries such as heavy goods, autos, and chemical products is gradually being supplemented by high tech development. The German economy is both conservative and dynamic. It is conservative in the sense that it draws on the part of the German tradition that envisages some state role in the economy and a cautious attitude toward investment and risk-taking. It is dynamic in the sense that it always has been directed toward growth, even if that growth may be steady rather than spectacular. The united German economy is a dominant

force in world markets because of the strong export orientation that has been part of the German tradition for centuries. German industry continues to produce some of the best machine tools, automobiles, trucks, chemicals, and engineering products in the world. Its management culture, which mingles competition and cooperation, stresses quality and durability above all other virtues.

Businesses: The German economy is very much characterized by “Small and Medium-sized enterprises” (SMEs), the so-called “Mittelstand”. Although the term “SME” is commonly used in many countries, it lacks a general definition despite the fact that it is commonly operationalized by two statistical figures that differentiate SMEs from “Large-sized enterprises” (LSEs) - total number of employees and annual turnover.² The “Mittelstand” is an essential part of Germany’s economy. According to the German Institut für Mittelstandsforschung, German Mittelstand employs 70.2% of all employees in private business, provides professional training for 81.9 % of all apprentices in Germany, and realizes 41.2 % of all turnovers subjected to German VAT (INSTITUT FÜR MITTELSTANDSFORSCHUNG, 2003). However, in Germany, the “Mittelstand” has more than a statistical or quantitative dimension. It also differentiates from LSEs by more qualitative indicators, like the identity between corporate ownership and personal responsibility and liability of the entrepreneur (which is mostly family-driven) and thus the personal responsibility of the owner or entrepreneur for the company’s operative and financial success. Because of this qualitative dimension, SMEs require a special macroeconomic environment that supports their competitiveness and long-term potential for growth and innovation. Today, many of the bigger SMEs in Germany are widely acknowledged as low-profile

2 Since 2005, German „Mittelstand“ is defined according to the definition approved by the European Commission. According to the EU-classification, small enterprises range between 10 and 49 employees and/or have a turnover between 2 and 10 million €. See http://ec.europa.eu/enterprise/enterprise_policy/sme_definition/sme_user_guide.pdf.

high-performance companies (so-called “hidden champions”) which competitiveness rests uponn the protection of (intellectual) property, the freedom of trade, a stable financial environment, or a sound and reliable fiscal and economic policy that especially benefits microeconomic productivity on a long-term basis.

Institutional Integration: Germany is a member in all key European and international organizations. It is a founding member of the European Union (EU) and it has been a full member of the United Nations (UN) since 1973 in which it is the third largest contributor. Additionally, Germany is a member of NATO (since 1955), the Organization of Economic Cooperation and Development (OECD), the Organization for Security and Cooperation in Europe (OSCE), the World Bank and the International Monetary Fund (IMF).

I.2 (Economic) History

Post-War Period: In the 20th century Germany became involved in two devastating World Wars. After the end of WW II in 1945, the country was left beaten and occupied by allied powers - the US, UK, France, and the Soviet Union. The monetary, economic and institutional reforms from 1948 initialized a phase of consolidation in both political and economic terms. Industrial production increased by 24% in 1949 and 12% in the first half of 1950. Over the period the average annual growth rate was 15% per year which was the foundation for labeling German development since 1948 as the “German Miracle”. Although the economy still suffered several challenges (e.g. capital shortages due to reparation confiscations of capital equipment which depleted the capital stock), both profitability and productivity of the German economy was increasing. German foreign trade recovered dramatically despite the loss of Eastern European markets due to the emergence of the cold war. Foreign trade increased 84.4% per year

over the two year period 1948-1950. Throughout the 1950s it increased 16% per year in real terms. (West-) Germany was able to reduce its trade deficit and commence running a trade surplus. Since the 1950s exports were mainly manufactured goods. During the 1960s and 1970s, labor and capital became fully utilized, unemployment rates dropped to 1 percent and German exports increased dramatically due to an undervalued currency (“Deutschmark”).

The German Welfare State: Since 1960, Germany created a cooperative system between politics and business that was called the “social market economy”. German wages increased constantly and stable labor-management conditions enabled Germany to recover its place in industrial markets. Unemployment was so low that Germany had to draw in a labor force from other countries, so-called “Gastarbeiter”, especially from Turkey and Italy which until today formed Germany’s largest minorities.

In 1970, German governments enacted several social welfare programs, e.g. enabling German workers to get six weeks of sick leave at full pay and 80 percent of pay for time off beyond six weeks. The cost of these social welfare programs showed up in the government budget. By 1980, these costs amounted to about 30 percent of GDP, leading to a West German budget deficit. This deficit was not only due to the social welfare programs. The government has been increasing its employment. The net result is that the public-sector share of output increased from 38 percent in 1970 to 47 percent in 1980.³

Unification: With the advent of the Cold War, two German states were formed in 1949: the western Federal Republic of Germany (FRG) and the eastern German Democratic Republic (GDR). The democratic FRG embedded itself in key Western economic and security organizations, while the Communist GDR was on the front line of the Soviet-led Warsaw Pact. Ger-

3 Cf. Statistisches Bundesamt, Source: <http://www.destatis.de>

many, Berlin in particular, became the front of the cold war. The decline of the USSR since 1989 allowed the German unification in 1990. In economic terms, it was the first time in history that a capitalist and a socialist economy suddenly became one, and there were no precise guidelines on how it could be done. Since then, Germany has expended considerable funds to bring Eastern productivity and wages up to Western standards, which totaled 250 billion Euro between 1990 and 2005. However, even with the incredible progress that has been made, the discrepancies in living standards have not been erased. Additionally, private investment and economic growth in Eastern Germany are increasing at a relatively slow rate. With little new equity capital for investment, most government transfers are used for consumption alone and thus do not help to build up a substantial foundation for sustainable long-term productivity.

European Integration: Germany's history since 1945 has closest ties to the development of the European Union (EU). During the process of European Integration since 1957, but especially after the creation in a monetary union in 1999, Germany is at the forefront of European states seeking to exploit the momentum of monetary union to advance the creation of a more unified and capable European political, economic and social institution.

I.3 Context

Although not sufficient alone, a sound macroeconomic, political, legal, and social context is important in creating opportunities and long-term potential for productivity growth and competitiveness.

3.1 Macroeconomic Context

In economic terms, Germany is very well integrated on a global scale. It benefits from the world's highest balance of trade-surpluses (200.1 bn €) and a dynamic international activity

that allows the country to account for almost 9% of the global trade between 2000 and 2004. However, tensions remain. The growth of GDP/capita has slowed down and is now only 1% versus 2.5% for the OECD average. More worrisome, the unemployment rate continues to be at a high 9%, which is 2 points above the OECD average. Despite Germany's strong export performance, the economy suffers constantly low domestic demand. One of the reasons for that is the wage moderation pursued since 1999 which led to weak household income growth and a holding back of consumption. Structural reforms can contribute to stronger domestic activity and would improve the capacity of the economy to turn favourable external impulses into higher growth and employment.

One of the most important goals of the government still is to reduce the country's public debt that has been accumulated in the course of expansive fiscal policies during the 70s and 80s and the fund transfer to boost economic development in East Germany. Although recent development show significant progress has been made in limiting public spending, deficit targets of the European Growth and Stability Pact have repeatedly been missed; the debt-to-GDP ratio is high.

3.2 Political Context

The German political system is considered one of the most stable in the world. Since 1949, the party system has been dominated by the Christian Democratic Union and the Social Democratic Party of Germany. It operates under a framework laid out in the 1949 constitutional basic law. The federal government consists of the chancellor and the cabinet ministers ("chancellor democracy"). The chancellor's executive authority emanates from the provisions of the Basic Law.. The Basic Law creates a dual executive but grants most executive authority to the

federal chancellor (elections are held every 4 years), as head of government, rather than to the president, who acts as head of state. The presidency is a ceremonial post.

3.3 Legal Context

The West German system of government, outlined in the Basic Law, reflects in particular a desire to transcend the interwar period of democratic instability and dictatorship. A federal system of government, considered vital to a stable, constitutional democracy, was put in place as a direct response to lessons learned from the Nazis' misuse of centralized structures.

Federal legislative power is vested in the legislative system consisting of the Bundestag and Bundesrat, which together form a unique type of legislative body. Although the system has proven to provide a stable framework, it has given rise to a rigid and tedious system where Germany is globally number one in terms of number of regulations. Germany's federal system is characterised by the separation of policy making and implementation functions between the federal (national) level and the Länder levels. As a result, Germany's overall regulatory system – as well as the fiscal or legal system – is complex, characterised by an increasing number of federal regulations, often expressed in complex legal terms, and with a regulatory “reality” that varies from state to state, either due to specific Land regulations or different implementation of federal regulation.

3.4 Socio-Cultural Context

Overall, the country has very good social indicators, enjoying a wealthy population with one of the highest GDP/capita among the OECD countries. However, Germany will be challenged by demographic change (45% of the population will be over 65 years old in 2020 versus 35% on average for OECD countries) as the birth rate is constantly below the replacement level, one of the lowest among OECD countries.

Another important issue is the regional differences between East and West Germany in terms of unemployment and GDP/capita despite the tremendous efforts and investment devoted to reunification management since 1990. As far as the openness and future-orientation of the German society is concerned, business leaders become more confident in the German ability to perform well in the future while the general public still generally is mentally bounded by German “Angst”.

I.4 Reforms

During the last five years, started under the so-called “Red/Green Coalition” under the social-democratic led government of Chancellor Gerhard Schröder, the German governments made serious efforts to gain a new competitive edge. Pressured by new competition from emerging countries like India and China, rising performances especially from the small European countries and a growing number of structural economic challenges like long-term unemployment and a worsening dept-to-GDP ratio on both the federal and regional administrative level, the German government initialized four major reforms to enhance the business environment as well as the factor input conditions.

4.1 Reduction of taxes on labor income

The government re-directed a considerable quantity of revenues resulting from the VAT increase to lower social charges. Additionally, public spending on ineffective active labour market policies has been reduced and the statutory pension age has been raised, creating scope to restrain social expenses.

4.2 Improvement of efficiency in the education system

German states have agreed on some minimum standards for schools and introduced centralised examinations more widely. Funding for providing full-time education has been raised, high-level research institutions at Universities have been provided with additional finances in the course of a national “elite-contest” among Germany’s public universities. University fees coupled with income-contingent repayments also have been introduced in some states. Additionally, the budgetary self-government of universities has been strengthened.

4.3 Reduction of regulatory barriers to competition

An efficient and effective regulatory regime for network access has been introduced in the national energy industry and a regulator has been established for all network industries to level the playing field for new competitors. Administrative costs to some extent have been lowered to reduce overall transaction costs for doing business in Germany. Most recently, the federal government under Chancellor Merkel established a regulatory impact analysis unit in the German chancellery.

4.4 Improvement of efficiency in job placement agencies

By conveying administrative tasks related to job placement more effectively and reinforcing the conditionality of benefit receipt on the willingness to take up work, the federal government since 2002 improved the placement of long-term unemployed into jobs and realized efficiency gains within Germany’s highly-regulated labor market.

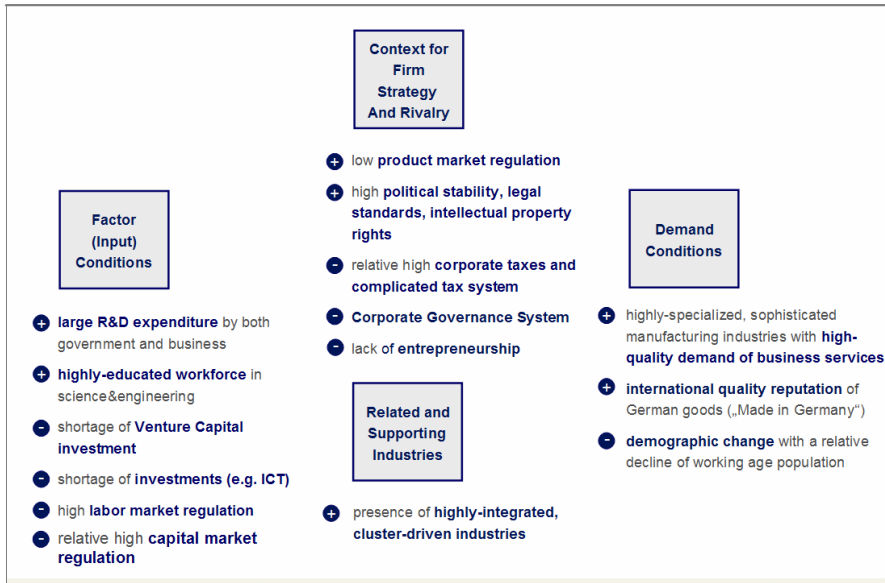
II. National Competitiveness: Germany

As a high-income country, Germany has achieved strengths in many aspects of the business environment.⁴ Although its relative high position is remarkable, Germany’s competitive-

⁴ Cf. <http://www.weforum.org/en/initiatives/gcp/Global%20Competitiveness%20Report/index.htm>.

ness is also challenged by structural weaknesses especially in terms of its factor input conditions and its context for firm strategy and rivalry.

Exhibit 1: National Diamond of Germany

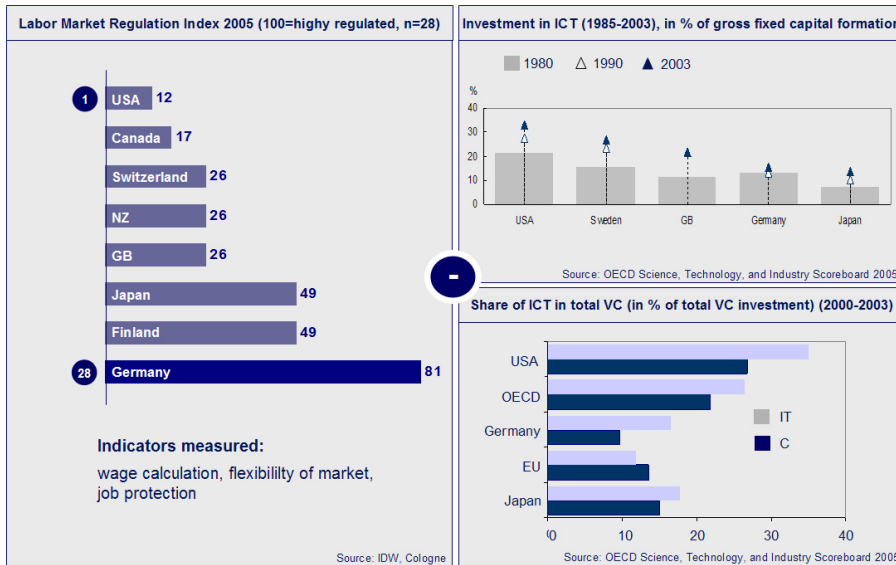


In terms of *factor conditions*, Germany stands apart in its level of investment in R&D, spending 8% of the total OECD budget and being the country with the third largest private R&D investment (behind the US and Japan). It also outperforms many OECD countries in triadic patents⁵ with a higher number of patents per million inhabitants than the U.S. This strong position in R&D bases on its legacy and tradition in high-level research and sophisticated scientific engineers that are one of the biggest prerequisites of Germany being able to achieve the dominant global position in its traditional industries like automotive or chemicals. Overall, Germany benefits from a very highly skilled workforce, thanks to its overall quality of education and vocational training. However, the general access to equity and venture capital is lim-

5 Triadic patents are a series of corresponding patents filed at the European Patent Office (EPO), the United States Patent and Trademark Office (USPTO) and the Japan Patent Office (JPO), for the same invention

ited, accompanied by a lack of labor market flexibility and a low level of investment in ICT (information, communication and technology).

Exhibit 2: Weaknesses of Germany's National Diamond (examples)



In terms of *context for firm strategy and rivalry*, German companies can rely on a very stable and well organized political and social system. Intellectual Property rights are also very highly secured. However, a relative low degree of entrepreneurship compared to the U.S. or Great Britain limits the country's opportunities to take risk and launch innovative ventures.

In terms of *demand conditions*, the country benefits from an internal market of highly sophisticated wealthy consumers.

III. Regional Competitiveness: Bavaria

Bavaria is the largest and oldest state among Germany's 16 states. It is Germany's largest state by size (70,548 km² = 27,239 miles²) and second largest state by population (12.3 mil).⁶

6 Cf. Bavarian Ministry of Economic Affairs, Infrastructure, Transport and Technology (2006).

Bavaria is Germany's southernmost state and its central location in Europe brings it access to European as well as the international markets.

III.1 Macroeconomic performance

Bavaria accounts for 18.4% of Germany's GDP and 15.1% of the German population.⁷ With a gross national product of 385.2 billion euro, Bavaria even exceeds the GDP of 19 of the 25 EU member states.⁸ Bavaria's economic performance per capita of 30,993 euros is considerably higher than the German and European average, which means that Bavaria represents a market with one of the highest purchasing powers worldwide.⁹ The gross value-added by economic sectors in 2006 consists of business services (51.5%), manufacturing (31%), trade and transport tourism (16.5%), and agriculture (1%).¹⁰ Bavarian manufacturing ranks second only to the State's service industries, and it employs 27.5% of the German workforce.

Bavaria outperforms most of any other German state. It exceeds West Germany and Germany in terms of GDP per capita and GDP per employee. In 2005, Bavaria's GDP per capita was 31.5 thousand euro while the average West German GDP per capita was 27.4 thousand euro.¹¹ Additionally, Bavaria's share in Germany's international trade was 14.2% of exports and 6.7% of imports with the European Free Trade Association (EFTA) countries, 15.4% of exports and 15.6% of imports with the 25 EU member states, and 16.3% of exports and 15.7% of imports totally. In terms of economic growth, Bavaria enjoyed 9.3% of growth between 2000

7 Ibid.

8 Ibid.

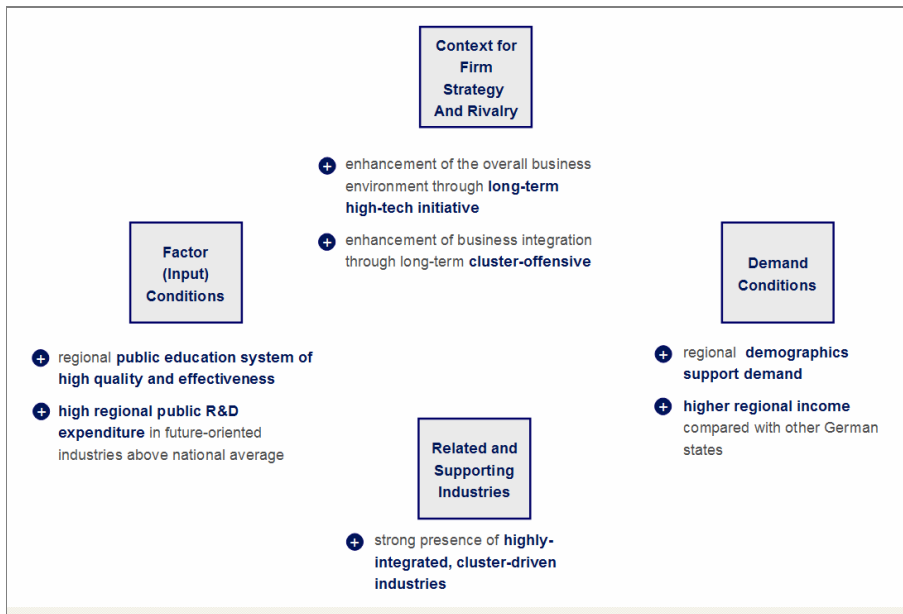
9 Ibid.

10 Ibid.

11 Cf. http://www.destatis.de/e_home.htm

and 2005 while the USA only did 13.4%, Japan 7.4%, or Germany only 3.8%.¹² The reasons for Bavaria's outstanding performance can be enumerated according to its regional diamond.

Exhibit 3: Regional Diamond of Bavaria



III.2 Factor Conditions

Bavaria's high quality education and R&D expenditure cause its higher income and prosperity compared to other German states. Bavaria is within convenient reach of all European business centers. Especially since the accession to EU of Malta, Cyprus and the Central and Eastern European countries of Estonia, Latvia, Lithuania, Poland, Slovakia, Slovenia, the Czech Republic and Hungary in May 1, 2004 and that of Romania and Bulgaria in January 1, 2007, Bavaria has been a gateway to Central and Eastern Europe.¹³

Bavaria has the highest National Education Index (2005) though its educational expenditure per capita is lower than that of Baden-Wuerttemberg, Thuringia and the average of the

¹² Cf. Initiative Neue Soziale Marktwirtschaft (2005).

¹³ Cf. Bavarian Ministry of Economic Affairs, Infrastructure, Transport and Technology (2006).

other states.¹⁴ Public expenditure on R&D is 11.3 billion EUR, which is second after Baden-Wuerttemberg. Bavaria's growth rate of public expenditure on R&D per GDP was 3.0%, which is more than 2.5% of Germany overall in 2003. Bavaria has 112 universities, 17 Universities of Applied Sciences, 3 major research facilities, 11 Max-Planck institutes and 7 Fraunhofer installations, which make it a world leader in research.¹⁵ This depth of knowledge-based organizations provides the best prerequisite for the development of new technologies and services.

III.3 Related and Supporting Industries

Bavaria has developed 19 clusters of manufacturing, business services, and high-tech industries to maintain its leading position in Germany¹⁶, covering all new technologies such as information and communications, biotechnology and genetic engineering, energy and environmental technology. In all these clusters, an active Bavarian state government supports firms to actively communicate with each other to approach specific information, consultation and support, which causes a positive spiral for improving Bavaria's economic performances.

III.4 Demand Conditions

Germany's overall strong demand conditions are even outperformed in Bavaria, which higher income supports its general demands. Additionally, with the enlargement of the EU, East Bavaria was taking up position at the very heart of the European Single Market with 455 million consumers, and international firms and a dense network of small and mid-sized industrial, trade and service firms make up the Bavarian economy, a spectrum of competitive suppliers, customers and potential partners.¹⁷

14 Cf. http://www.destatis.de/e_home.htm

15 Cf. Bavarian Ministry of Economic Affairs, Infrastructure, Transport and Technology (2006).

16 Ibid.

17 Ibid.

III.5 Context for Firm Strategy and Rivalry

One of the most important strengths the state of Bavaria has in relation to the federal level or other German states is a very future-driven government that pursued a focussed market-driven and strategic economic policy based on a five-pronged supply-side oriented strategy. The goals of this strategy are (1) to provide cost reductions to enhance industry global competitiveness; (2) to promote strategy growth and employment gains by strengthening the dynamics of the market economy by privatizing its financial holdings and other interests, eliminating unnecessary bureaucracy, accelerating planning and approval processes and introducing deregulation with medium-sized companies; (3) to modernize and systematically improve the infrastructure; (4) to champion a policy of new products, new plants, new markets for business sectors confronting economic structural changes by encouraging investments and innovations as well as facilitating starts-ups – policies designed to benefit especially small and medium-sized enterprises developing their global markets and (5) to maintain workforce sizes by ensuring a high level of investment in education and ongoing vocational training.

This overall strategy was implemented by three major steps. At first, the “Future Initiative Bavaria” program in 1994 invested 3 billion euro gained from the process of privatization primarily in education, research, technology transfer, start-ups and strengthening foreign economic policies. Secondly, the Bavarian “High-Tech Initiative” was launched by the state government in 2000 to consolidate Bavarian’s leading position in life sciences, information and communications technology, new materials, environmental and medical technologies as well as mechatronics, to bolster the technical competence in the state’s administrative districts, enhance the technology infrastructure, advance the internationalization of the economy and sciences and make Bavaria still more attractive as media location.

Thirdly, a Bavaria's cluster campaign initialized, the "Alliance Bayern Innovativ", was launched to modernize strategy designed to enhance Bavaria's role as a top location for business and science, which systematically follows on from the Bavarian High-Tech Initiative. Its aim is to build state-wide networks interlinking business and science in 19 defined competence clusters, strengthening collaboration and thus to activate innovation and productivity potential in these clusters.

IV. The Biotechnology Market

The field of biotechnology is subdivided into groups by process application. Biotechnology preliminarily refers to "red biotechnology" and summarizes an industry that has close links with the pharmaceutical industry. Red biotechnology is applied to medical processes and is the designing of organisms to produce antibiotics, or engineering of genetic cures through genomic manipulation. White/grey biotechnology is applied to industrial processes and green biotechnology is applied to agricultural processes.

The 30-year old global biotechnology market has experienced strong growth in recent years and this trend is expected to continue. In 2005, revenues increased by 18% and the sector crossed the \$60 billion threshold for the first time. Similarly, the industry grew by 17% from 2003 to 2004. Although growth is expected to slow as the industry matures, annual growth is projected to average 8% through 2015. R&D expenditure is a critical component of this sector and represented about one-third of revenues in 2005. Although this industry continues to experience net losses, these losses declined by 30% in 2005. United States' firms comprise the bulk of the industry, representing over three-fourths of global revenues. Within the U.S., the majority of life sciences clusters are concentrated in nine metropolitan areas. The industry has

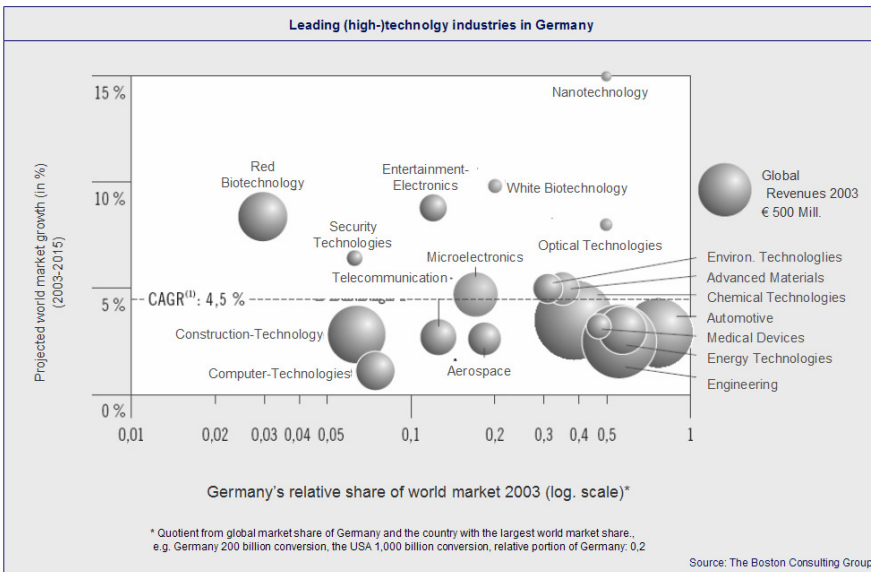
its roots in Boston and San Francisco and these clusters continue to be global market leaders. Europe is a distant second to the United States, representing about 15% of global biotechnology revenue.

The pharmaceutical market, a much more mature industry relative to the biotechnology sector, constitutes a central component of the broader life sciences industry. The industry reached \$455 billion in global revenues in 2005 but grew at a much slower rate than the biotechnology sector (7% versus 17%). Based on 2003 data, Germany was the leading exporter in this sector at €1.3 billion and the U.S. followed with €1.0 billion.

IV.1 German Biotechnology Market

Red biotechnology represents 89% of biotechnology market share in Germany and is the focus for this project. Red biotechnology is one of the fastest growing, dynamic sectors among global high-technology industries. As can be seen in Figure 1, the industry is growing more rapidly than more mature high-technology industries such as medical devices, automotive and engineering. The y-axis displays projected world market growth and the x-axis represents Germany's share of the global market in 2003. Given that Germany's market share in each industry differs widely, a log scale is used to view the sectors on the same chart. Figure 1 indicates that Germany's share of the global biotechnology market is much smaller than its share of other more mature high-technology markets with less growth potential. The data illustrates an opportunity for Germany to increase market share in the high-growth biotechnology sector before the industry is fully mature.

Exhibit 4: Leading Industries of Germany



IV.2 Development of German Biotechnology

The German federal government began its support for biotechnology in the 1970s with the creation of the German Research Center for Biotechnology Ltd. The government renewed its commitment by creating Biotechnology 2000, a national program designed to encourage research and development, as well as commercialization of results. To push the efforts of commercialization, the government in 1993 amended the “Genetic Engineering Act” (“Gentechnikgesetz”) to liberalize Germany’s legal framework around biotechnology and genetic engineering. The amendments improved the application requirements for biotechnology companies, thereby encouraging research, international co-operation, and an increase in venture capital funding. These amendments also stemmed the growing number of scientists, production facilities, and research funding from leaving Germany.

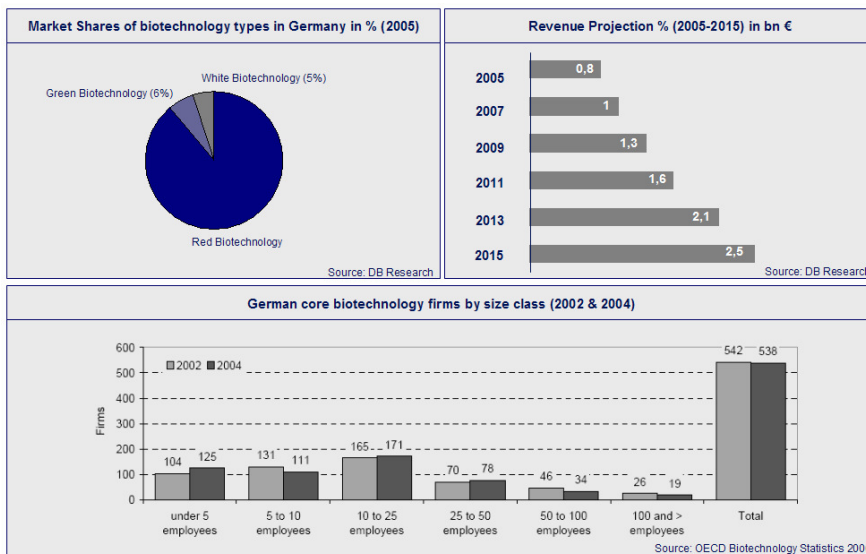
However, Germany’s drive to lead Europe in the biotechnology industry began not before 1995 with the creation of *BioRegio*, a competitive research and development initiative for the private sector. *BioRegio* projects have been enormously successful, attracting further ven-

future capital funding and maintain programs to encourage further growth in the industry. Further programs have been added to assist in the development of the biotechnology industry in Germany that developed in clusters, built around centres of research excellence.

IV.3 German Biotechnology Industry

Although the German biotechnology market is somewhat small at €800 million, it is expected to grow significantly over the next few years to €2.5 billion in 2015. According to their strong presence in the overall economy and the market’s emerging status, SMEs dominate Germany’s biotech market. The majority of firms in the biotech sector have 25 employees or less.

Exhibit 5: Indicators of the Biotechnology Market in Germany



SME’s thus drive the R&D intensity of the German biotechnology market that are one of the world leaders in total number of biotechnology patents and this lead has widened considerably in recent years. While Germany’s position in R&D is strong, patenting and innovation is challenged by new players in the global market. However, the market is characterized by an

extreme dynamic, initialized by latecomers to the biotechnology space like Russia, India, or China that have much smaller shares of biotechnology patents but their growth in patents has significantly outpaced Germany.

V. The Biotechnology/Life Science Cluster in Munich (BCM)

Germany's strongest Life Sciences Cluster is in Munich with nearly 300 companies focusing mainly on biotechnology & pharmaceuticals. Additionally, biotechnology companies tend to cluster in more tightly knit communities with contract research organizations & research institutes, while pharmaceutical companies tend to be more spread out in the area.

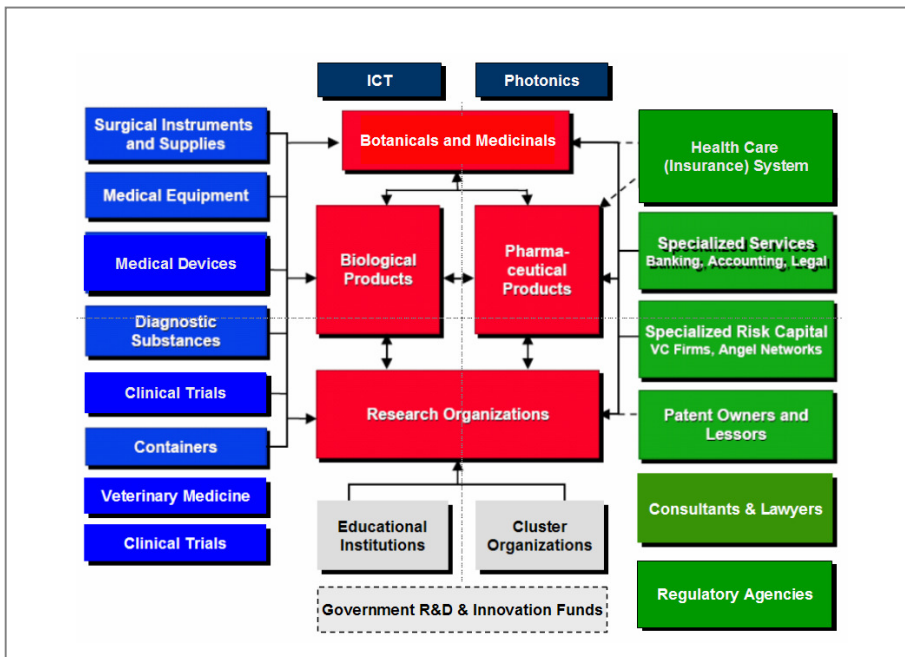
The cluster began modestly in 1990 as a spillover of the pharmaceutical companies, but began to grow aggressively from 1993-1999 as a result of the increased funding flows caused by the BioRegio Competition, its incentives & amendments to Germany's genetic engineering law. In 1997, BioM, the cluster's key institution of collaboration was founded. Since then, BioM plays three important roles: it coordinates cluster initiatives, including creating a market for real estate for laboratories, jobs & lab devices; it promotes the region to investors; & serves as a Seed/ VC Funder¹⁸.

V.1 The BCM Cluster-Map

BCM has become a rich ecosystem that reinforces the cluster's main industries: Biotechnology & Pharmaceuticals. The Cluster Map portrays the robust nature of the cluster with industry service providers (in green), interrelated industries (in blue), supporting organizations (in gray) and related clusters (in navy blue).

18 Cf. <http://www.bio-m.de/web/index.php4?lg=en>

Exhibit 6: Munich Biotech/Life Sciences Cluster Map



Withstanding the intricate supporting industries, Munich experienced in the late 1990s a simultaneous increase in small & medium size biotechnology firms, while the pharmaceutical industry has stayed stagnant. This has led pharma to report a substantially less positive business climate than do other industries in the cluster¹⁹. The pessimism of large pharma is a source of concern because of the long lead times associated with biotechnology product development & the demographics of the cluster. Biotechnology, which is at the heart of the BCMS Cluster, is dependent on capital flows from pharma & venture capital for its subsistence. Additionally, although pharmaceuticals account for only 26 companies compared to 96 SME biotech firms, nearly half (\$4,430 million euro) of the \$8,960 million euro revenues of the cluster and 63% of employment is attributed to pharma. This apparent contradiction may be due to Germany's restrictive labor policies which impact larger firms in a larger degree. In recent

19 Cf. Industrie- und Handelskammer für München und Oberbayern (2005).

years we have seen a trend towards consolidation of the biotech firms, resulting in 20 non-SME biotech firms, therefore more attention should be paid to reducing restrictions, like labor laws, which provide disincentives for pharma.

V.2 Factor Conditions

The strong scientific infrastructure in Munich²⁰ is key to the cluster's success. The educational portion of this infrastructure includes 8 world class research universities, 2 university hospitals, 60 institutes and/or professorships and research establishments in the field of advanced life sciences²¹. In a study 2005, only 77% of those interviewed perceived Munich as having a satisfactory or very satisfactory quality of life.²² A high number of Bavarians are trained in life sciences therefore, and because of increased labor Munich must focus on maintaining a good quality of life to retain that talent. Munich also has strong institutions that protect intellectual property and the regulatory expertise relating to product launches & financing. The combination of world class research institutions & intellectual property protection mechanisms have led Germany to rank as the 3rd country with most biotechnology patents. This expertise cultivated through pharma development translates into all areas of the cluster, and has spillover effects into the medical device & equipment clusters. Munich also has the business know-hoe to convert research into successful commercial products.

On the other hand, insufficient access to significant amount of capital is a source of concern for the cluster. From 2002-2004 both VC, silent partnerships and other R&D investments faced a downward trend which resulted in various companies filing for insolvency in

20 Ibid.

21 Cf. www.kompetenzetze.de

22 Cf. Cf. Industrie- und Handelskammer für München und Oberbayern (2005).

2004²³. Since 2004, these types of investments have increased, and IPOs also appeared as a source of funding as 4SC became the first Martinsried company since 2000 to list its shares in the Prime Standard of Frankfurt stock exchange. This recovery can be traced to a number of mergers, acquisitions, and collaborations which strengthened the drug pipeline, making these companies more attractive for investment & the increase in sales development since 2004²⁴. None the less, this is an area of concern considering that the number of VCs decreased last year, and that there is a high dependence of the industry on VC as 44% of biotech firms in Germany were financed through this means in 2005. Additionally, a lack of recognized Business Schools that support entrepreneurship are a lack of concern both from the perspective of attracting investors & developing the managerial expertise necessary to run competitive ventures.

V.3 Demand Conditions

The demand for the MLSs cluster can be analyzed by looking at the most common output of red biotechnology: drugs. Demand for drugs & new therapies is growing in Germany as population of Europe's most populous country ages. Under the current health care system, German residents are guaranteed state health insurance, or sickness funds, which pay for their health care. None the less, the aging demographics can prove a heavy weight on the German Health Care system which can impose prices on service providers. While the aging population is a positive demand condition, the cluster must be aware that rising cost of health care imposes constraints on the public payer system and its effect on pricing. Additionally, the life sciences cluster needs to counter the low level of acceptance of biotechnology by the population.

²³ Cf. Bio-M (2005).

²⁴ Ibid.

While drugs are the economic engine of the cluster, the time intensive nature of the industry which sports lead times of 15 years complicates this analysis. Munich Biotechnology has only 3 drugs in market, although the pipeline currently houses 40 compounds and is projected to launch an additional 1 to 2 drugs per year for each of the following 5 years²⁵. It is important to note that highly competitive clusters like the Massachusetts cluster had 207 compounds in the pipeline as of 2002, therefore, Munich needs to focus on increasing the flow of compounds into the pipeline if it wants to compete with world leaders in the field.

V.4 Context for Firm Strategy & Rivalry

BioM plays a fundamental role in the active management of the MLSs Cluster. As a private entity it functions as a collaborative non-regulatory mechanism whereby firms have access to high quality real estate, increased bargaining relationships between suppliers & buyers, pooled resources for promoting the cluster and an advocacy arm to anticipate policies that affect the competitive business environment. BioM monitors its performance through a yearly survey of firms analyzes competitiveness factors for each of the industries relating to Life Sciences in Munich. The quality of the business environment can be assessed through the results of BioM's annual survey as well as by the high level of competition with over 180 core life science companies in the area. A great breadth of supporting industries is also proof of the fertile rivalry environment. Government support of competitiveness in Bavaria is coordinated by the *Bavarian State Ministry for Economic Affairs, Infrastructure, Transport and Technology* which administers programs like *Invest in Bavaria, Bayern International & Bayern innovative* which promote the location, assist entrepreneurs, and provide services to encourage innovation & knowledge transfer. Germany-wide policies instituted by the Federal Ministry of Education

²⁵ Based on average figures for new chemical entities (NCEs); BCG analysis; Tufts Center for the Study of Drug Development & Biospace CCIS database; "A Revolution in R&D," BCG, November, 2001.

and Research (BMBF), like the BioRegio Contest, BioProfile Competition & BioChange, also promote competitiveness. However, as mentioned in the overview, issues of labor legislation impact the cost of doing business in Munich in a way that is not efficient & does not increase productivity. Additionally, the Health Care System regulations that can impose pricing on local demand of drugs may be detrimental to incentives that exist for R&D & drug discover.

V.5 Relating & Supporting Industries

Life Science is a human capital intensive industry that relies on firms capacity to generate new knowledge through R&D and take that knowledge to market, therefore a diverse array of supporting & related industries need to support the MLSs Cluster. These Supportive Industries can be divided up into five categories: Education & Research (E&R); Financing & Capital (F&C); NGO Institutions of Collaboration (NGO); Cluster Suppliers (CS); & Intellectual Property & Technology Transfer offices (IP).

The E&R Industry is strong in Science Based Training. The Munich Cluster has 4 world class universities, and 4 research centers as well as 2 university hospitals which are fertile ground for R&D, innovation & clinical trials. Bottlenecks in R&D are intertwined with limited access to capital, as the academic infrastructure already exists. The limitations of E&R reside in Management and Entrepreneurial educational opportunities.

Munich has a well established F&C Industry that includes the access to Capital Markets, Banks, VC specialized in biotechnology. However, investment in the cluster has varied significantly in the past years. Although the cluster is currently experiencing an upward trend, attention should be paid to ensuring increased capital flows.

NGO Institutions of Collaboration are essential to the entrepreneurial ecosystem, as they are at the intersection of promoting competition while stimulating collaboration. In this, the work of

BioM as a coordination agency that provides information, networking, PR work as well as funding is pivotal to the success of the cluster. Other important NGOs include the Innovation & Startup Centers for Biotechnology which provides laboratory spaces for start-ups near larger Life Science Companies & the Chamber of commerce & Industry for Munich and Upper Bavaria. IP industries provide the services and the structure necessary to protect investments in R&D as well as supporting in navigating this regulatory intensive field. Munich offers specialized services in patent law and licensing matters through lawyers & consultants, Intellectual Property (IP) Asset Management companies, as well as specialized institutions within the universities that give businesses access to the R&D performed by these institutions.

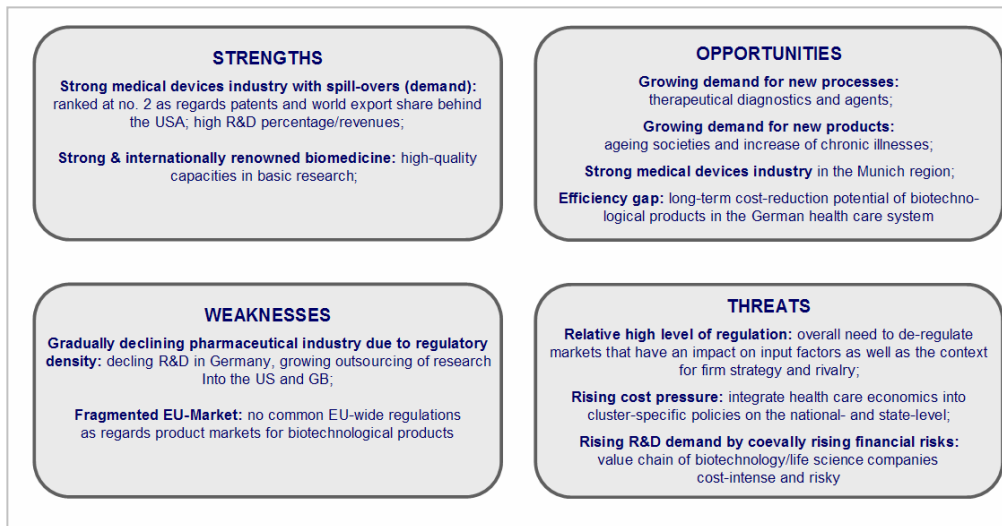
Munich also has a diverse array of Related Industries including: Medical Devices, Health Care, Medicinals/Botanicals, Photonics, Information Technology, Chemistry, Nutrition, Agriculture & Environment. Some of these industries have formed into well coordinated clusters, for example: IT SAAR Cluster (with over 300 researchers engaged in computer science research), MercatorPark (which unites mobile communication (GSM, UMTS), navigation (GPS, Galileo), geographical information, telematics and aerospace application technologies), & bayern photonics e.V (which focuses on optical technologies). The existence of these well coordinated clusters in related industries promotes the sophistication & growth of BioM.

VI. SWOT-Analysis and Recommendations

Any cluster never is a segregated part of a country's economy. Moreover, it's a fully embedded form of economic organization with a strategic environment. A significant step in an evaluation of a cluster thus is to perform internal assessments of the cluster itself and external assessments (including an analysis of the cluster's strategic environment) that result in the identification of strengths, weaknesses, opportunities and threats through what is termed a

SWOT Analysis. This is a tool of analysis which involves matching external possibilities with the clusters' internal capabilities.

Exhibit 7: :The Biotechnology/Life Science Cluster in Munich: SWOT-Analysis



As the analysis of the cluster diamond has shown, one of the main *strengths* of the biotech region in Munich is the strong presence of related industries that serve as an 'anchor' for the dominant biotech SMEs. Besides pharmaceuticals, this is especially the case with medical devices and biomedicine. As far as medical devices are concerned, Germany already has a leading position in the global market, ranked second in patents and world exports share behind the USA. In biomedicine, the Munich region has developed Germany's leading basic research capabilities that however haven't created spill-overs to the product level yet.

As far as the weaknesses are concerned, the Munich region especially has to cope with a development that preliminary has its roots in national legislation. Being the "world's pharmacy" for decades, Germany is actually facing an ongoing decline of the most important anchor industries especially for red biotechnology – pharmaceuticals. Due to an increasing regulatory density and a lack of stable, sustainable politics in relevant policy areas like fiscal and health care

policies, the pharmaceutical industry is experiencing a prosperity and growth gap in relation to other leading economies in that, the U.S. in particular. As a result, the strengths of the biotech region in Munich is very much rooted on the cluster level (e.g. strong R&D focus) whereas its weaknesses mainly result from developments that are initially shaped of the federal level. Besides the operational strengths and weaknesses of the Munich cluster itself, the German biotech industry in general faces threats and opportunities that are determined by the industry's strategic environment. The most important *opportunities* in this regard can be identified as the overall socio-economic developments. The global trend of demographic change and the increase of chronic illnesses imply a growing demand for new pharmaceutical and biotechnological products and processes especially in the field of therapeutic diagnostics, pharmaceutical agents, and drugs. Not less importantly in Germany is also the fact, that biotechnological processes can reveal an enormous efficiency potential for the health care industry and thus might be an important tool for cost-reduction in the German health care system.

Similar to the weaknesses of the Munich biotech cluster that are essentially determined rather on the federal level, also the threats within the strategic environment of the biotech cluster in the Munich region are fundamentally rooted on the national level. Most importantly, the high level of regulation is nearly very relevant policy area – R&D, taxes, labor – especially affect SMEs that the German biotechnology industry is dependent on. Against this background it is particularly difficult for SMEs to cope with the rising cost pressures in the industry and the increasing capital demands of the biotechnological value chain that come with a high R&D intensity of the industry. Additionally, unstable and unpredictable prospects as regard political developments especially in health care policies make it hard for many companies to adjust to a reliable, long-term business environment that is crucially shaped by political decisions.

The Munich biotechnology cluster and its companies compete in a global market. To maintain and enhance its leading position and competitive edge in the German, European and global market, concerted action is needed both on the national as well as the cluster-level. The cluster must strengthen its strengths to maintain a leading location for biotechnology in Germany and Europe. Additionally, the national government must pursue a clear market-driven, long-term strategy that enhances the overall business environment in Germany, especially for SMEs that the Munich biotech cluster is depending on. The following recommendations are ordered consequently.

VI.1 National Level

a. Pursue a clear, concise, and long-term national strategy for prosperity and competitiveness

Enforce fiscal consolidation: The federal government needs to develop a credible consolidation policy is needed that links expenditure control with public sector reform covering federal fiscal relations, removing distortions in the tax system and making the key government services more efficient. In this context it is crucial to gain consolidation wins on the expenditure side.

Increase efficiency of the education system: One of the biggest strengths of the German economy and the R&D-intensive biotechnology industry is the high-level education of its employees. Securing this supply of highly skilled workers is crucial for the development of new technologies and enhancement of the biotechnology industry. Any reform of the German education system thus has to address the whole “educational value chain” and generally move the responsibility of education from the regional state-level to the federal level in order to create national standards. Schools should be regularly evaluated and provided more freedom in de-

termining appropriate ways to reach national-wide educational targets. Allocation of government funding to universities should be more strongly oriented toward output indicators. Universities should introduce student fees coupled with a loan scheme and income-contingent repayments.

Continue labour market reform: Further institutional reform of the Public Employment Service is required. For this purpose, hurdles to labour force participation of older employees and females need to be further reduced to increase labor utilization. Wage rigidities need to be reduced further to fight very high unemployment rates among the low-qualified.

De-regulate markets for goods and services: Germany has to implement measures to reduce the administrative burdens on entrepreneurship and the involvement of the government in business sector activities. All policies favouring small enterprises need to be revised, exposing them to competition of larger firms. Many government support programmes target SMEs and are linked to firm-size limits, which may generate unintended incentives for firms not to grow. Privatisation of public sector enterprises should be accelerated.

Reduce administrative burdens: Entrepreneurship in Germany is still relatively low because of the negative impact of high administrative burdens. Diffuse responsibilities across different regulatory administrative units add to bureaucratic burdens. A centralized regulatory impact analysis has to reconsider the appropriateness of regulations and should incorporate the legislative process at the federal and state level.

Reform the federal system: The German federal system should principally be redesigned towards a more competitive federalism. Although previous efforts have been made to reduce the necessity of collaboration between the Bundestag and the Bundesrat, financial dependen-

cies and relations between the federal level and the state level should be diminished to provide German states with economic policy tools.

Implement a long-term health care reform: Booth the biotechnology industry as well as its strategic anchor industries (pharmaceuticals, medical devices, biomedicine) need an overall business environment that is reliable and thus provides the opportunity to plan with a long-term perspective. Industries like biotechnology that are highly sensitive to political developments and decisions (e.g. health care policies, regulation) are particular in need for business locations that provide the microeconomic prerequisites for productivity growth. The federal government in Germany lacks such a strategic imperative in many aspects. Moreover, “reforming the reforms” is an appropriate description for the past governments inability to develop and pursue policies with a more strategic perspective.

b. Strengthen the pharmaceutical industry in Germany

Correct the recent Competition Enhancement Act: Germany’s recent health care policy increases the regulations in the health care sector by implementing cost-benefit assessments, maximum reimbursement amounts, or discount agreements. In contrast to the urgency of deregulation, the governments’ policies since 2004 increase the regulatory density in the pharmaceutical sector. Administrative burdens of the companies will increase and their commitment in research and development will be negatively impacted as well as their long-term competitiveness. Against this background the federal government has to pursue a strategy that complies with the interdependency of policies with microeconomic competitiveness.

Establish a joint program for relevant education and training in pharmaceuticals: Similar to efforts in the IT-industry, the German government in collaboration with the state governments

should redirect funds and efforts to develop and maintain the most crucial foundation productivity in the pharmaceutical and biotechnology industry: education and vocational training. The government should establish a joint task force with professionals of the German pharmaceutical and biotechnological industry to develop a concise framework for the deficits and needs that should be addressed.

VI.2 Cluster Level

Maintain and strengthen the effective state-level education system: Germany's leading educational and vocational training systems are in effect in Bavaria, Munich in particular. The state government should consequently strengthen this particular strength by consequently revising the constantly changing needs of both the anchor industries as well as SMEs within the Munich region and the biotech industry in total. The government should particularly focus on the vocational training system by establishing the legal framework for shorter and more practice-oriented apprenticeships and coevally reduce the overall labor-related regulatory framework that especially affects SMEs negatively.

Strengthen the medical devices and biomedicine industry: Biomedicine and medical devices are the two most important anchor industries for the biotechnology industry in the Munich biotech cluster. As the pharmaceutical industry already is suffering intense regulation and short-term policies that impede reliable business planning, the state government should actively advocate for a sound and long-term political and legal framework on the national level that supports the development of both future industries.

Establish a European/Global competence hub for "Health Care Demographics": Demographic change as the consecutive process of global aging is one of the key trends in the future that

doesn't shape societies alone but also provides many business opportunities that help to address this challenge on a variety of levels. In the course of demographic change, the health care industry will become increasingly important. Having a leading position in the national, European, and global health care industry, the Munich biotech cluster could develop further from a biotech/life science cluster towards an integrated health care cluster that is organized as a global competence hub for health care-related industries that address demographic change. The Bavarian government should start investing in researching this future opportunity by appointing a task force within existing administrative structures to develop potential strategies and implementation tactics.

DATA SOURCES

Bio-M	http://www.bio-m.de/web/index.php4
Federal Statistical Office Germany (NBS)	http://www.destatis.de/e_home.htm
Institut der deutschen Wirtschaft	www.idw.de
KPMG Corporate Tax Survey	http://www.kpmg.co.nz/download/102964/110012/KPMG's%20Corporate%20Tax%20Rate%20Survey%202006.pdf
OECD Germany Panel	http://www.oecd.org/country/0,3021,en_33873108_33873402_1_1_1_1_1,00.html
OECD Science, Technology, and Industry Scoreboard	http://www.oecd.org/document/43/0,2340,en_2649_33703_35455595_1_1_1_1,00.html

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