OOD060I

Project Number: WVJ-DAR 4 - 49

LRN: OOD060I

Biotech Start-ups in the US and Germany

An Interactive Qualifying Project Report

submitted to the Faculty

of the

WORCESTER POLYTECHNIC INSTITUTE

in partial fulfillment of the requirements for the

Degree of Bachelor of Science

by

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Date: May 5, 2000

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Abstract

This project is concerned with biotechnology start-up companies in the United States and Germany. The focus is a comparison of variables surrounding biotechnology start-up companies in both countries. Using interviews and a case study, the roles of these variables were analyzed. Through research, it has become apparent that despite needing further improvement in Germany, these variables have created a favorable environment for biotech start-up companies. A manual of recommendations was also created to aid entrepreneurs in starting biotechnology companies.

Acknowledgements

The authors would like to thank the following people for their assistance:

Dr. Gerhard Stärk: Thank you for all of your support throughout this project. This project and overall experience would not have been possible without your guidance and knowledge.

Beatrice Koch: Thank you for taking the time to help us throughout our project.

Dr. Wesley Jamison: Thank you for preparing us for our cultural experience and for the guidance you provided us throughout our stay in Germany.

Also those who donated their time, knowledge and support to the completion of this IQP.

Table of Contents

Appendicies

Table of Figures

Table of Tables

Chapter 1 – Introduction

The rapid growth of the biotechnology industry has created new opportunities for entrepreneurs to start successful new companies in the field. However, there is a general misconception that it is quite easy to start a biotechnology company once you have a brilliant idea. Starting a biotechnology company is as much about business as it is about science. Unfortunately, those interested in starting new companies are generally either professors or students who are more knowledgeable in the field of science than business. Therefore, it is important for them to have at least a working knowledge of the business aspect of a biotechnology company or to become partners with those who can help during the process of starting their company.

The goal of this Interactive Qualifying Project (IQP) is to identify and compare the variables that influence the starting of a biotechnology company in the US and Germany and to create a manual that will aid entrepreneurs in the starting of new biotechnology companies. In the past, the US has had more success in encouraging biotech start-ups as evidenced by the size of the biotech industry. The German biotech industry was not as successful in its early stages. This IQP investigates the roles the university, government, and industry play in promoting biotech start-ups, the business aspects of biotech start-ups, and the way that public perception and cultural attitudes affect biotech start-ups in both the US and in Germany. Through the use of the literature review and methods employed while in Germany, the comparison of these variables between the two countries was completed.

This project was done at the request of Dr. Gerhard Stärk and the Technische Universität Darmstadt. The sponsors determined that there was need to complete a manual that would aid young bioentrepreneurs in the early phases of starting a company. The reason for this is that there are too many unfamiliar issues that need to be addressed by an entrepreneur and that often

times the entrepreneur does not know where to look for answers to some of the many questions that he or she may have.

The report that follows this introductory chapter is divided into four other chapters. Chapter two presents the background information that was gathered before arriving in Germany and is in the form of a literature review. The literature review established that the US had a greater growth rate for biotechnology companies than Germany. The slow start-up rate in Germany was related to historical events, government interference, public perception, and aversion to risk. Also from our literature review, we were able to extract five key variables that affect start-up companies in the US. These variables are the role the university, government and industry play in promoting biotech start-ups, the business aspects of biotech start-ups, and the influence of public perception and cultural attitudes in the starting of a biotech company.

The third chapter outlines the methods that were used in the completion of this IQP. These methods included the use of interviews and a case study to gather information that was used in making the comparison of the variables in the two countries. Individuals that represented each of our five variables were interviewed and four German biotech start-ups were used for our case study. Also included in our methodology is the web page analysis of Greenpeace International, Germany and USA. This analysis was done to obtain the opinion of how these organizations view biotechnology applications and companies.

Chapter four presents the results that were obtained from the implementation of our methodology while in Germany. Included in this chapter is the analysis of the five variables we chose to investigate that effect biotechnology start-ups. When analyzing these variables and their effect on German biotechnology start-ups, we found several similarities and differences when compared to the US. One of the similarities we found between the US and Germany was that universities in both countries provide biotech start-ups with lab space and equipment at low costs

and personnel to help with research within the company. A difference we found between the government role in biotech start-ups is that Germany has different state to state regulations while the US has nationwide regulations. Another difference between the US and Germany is that US biotech start-ups look favorably upon industry co-operatives, while German biotech start-ups see these relationships as unfavorable. A second similarity we found is that the business aspects of biotech start-ups are virtually the same in both countries besides the fact that German start-ups prefer venture capital in the expansion phase of their company and US start-ups prefer it in the seed phase of financing. One of the cultural differences we found is that US entrepreneurs have a "get rich quick" attitude while German entrepreneurs are more cautious when starting companies due to their aversion of risk, fear of failure and morals.

Finally, chapter five presents the conclusions that we arrived at from our research methods and the recommendations that we made as a result of our research. The first conclusion we made was that the best overall framework for the development of biotechnology start-ups depends on the interaction of a specific set of variables. These variables were identified in our literature review and confirmed through the implementation of our methods in Germany. We concluded that despite needing further improvements, these variables have created a favorable environment for biotech start-ups in Germany. Our conclusions go on to provide examples of the ways that these variables have hindered entrepreneurship and biotech start-ups in Germany and also the importance of these variables to US and German biotech start-ups.

The recommendations that we put forth are intended to offer advice on ways of improving the success of biotech start-ups in Germany. We offer this advice to the German government, university, and pharmaceutical industry. Recommendations are also presented in the format of a manual that is intended to provide entrepreneurs with a blueprint for starting a biotechnology company.

Chapter 2-Literature Review

This section is designed to give the reader an understanding of the background information that was collected from the most recent literature on biotechnology start-ups in the US and Germany. The advances of modern biotechnology have opened a number of possibilities in the fields of medicine, health, agriculture, food and environmental protection. In the US, these advances depend on the interaction of academia, government, and industry in transferring technology from the university to the market.

The biotechnology industry in the US accomplished this interaction, which resulted in the development of successful biotech start-ups. Although German federal support for biotechnology started very early, the innovative performance of this sector developed much slower than that of the US. To determine why the German biotech industry was slow to develop, the variables that support US biotechnology start-ups were identified. These variables were found to be the roles the university, government, and industry play in promoting biotech start-ups, the business aspects of biotech start-ups, and the way that public perception and cultural attitudes affect biotech start-ups.

2.1 Biotechnology

Modern biotechnology, which is the technical application of knowledge and information gained by the biological sciences, is seen today as one of the essential technologies for the twenty-first century. Even now, it already has a similar status to microelectronics and information technology. The various possibilities associated with modern biotechnology open up many opportunities for solving central problems and meeting major challenges in the fields of medicine, health, agriculture, food and environmental protection. Their influence extends into many other areas, resulting in fundamental theoretical and practical change (Casper, 1998).

Since the 1970s, biological research all over the world has been using genetic engineering methods. However, it is only in the last decade that real clarity has emerged regarding the true dynamic nature of biotechnology and its many possible applications. There are many expectations, particularly in the field of medicine. Biotechnological procedures are opening new prospects, e.g., the treatment of diseases and are becoming increasingly important in other areas too. For example, biotechnological methods in agricultural production and in the food industry have resulted in increased crop yield and in better product quality. As far as the environment is concerned, microorganisms created by biotechnological methods can be used specifically for environment-friendly processes, e.g. in sewage purification and soil regeneration (Thayer, 1998).

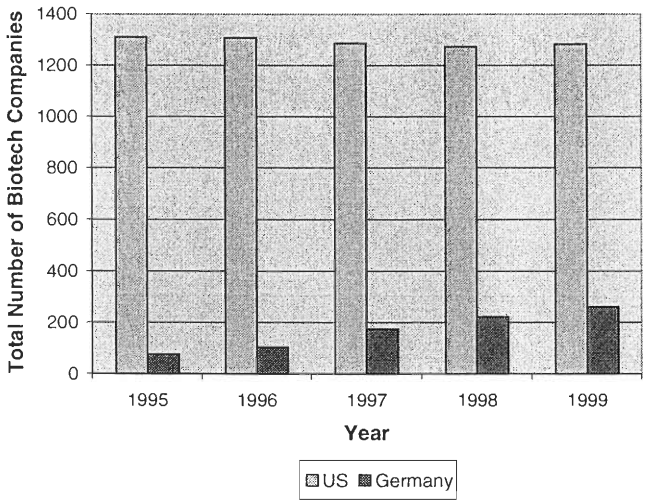
These advances in the industrial application of biotechnology depend on transferring scientific knowledge from the laboratory benches of universities and public sector research institutes, into the biotechnology industry. Knowledge has become a valuable asset for many companies as they search for new technologies and the university has taken on the role of developing these new technologies. Research and innovation no longer take place within the firm but take place in the relationship between academia, government and industry. Since academic knowledge needs to be transferred to the industry at an early stage of development, the success biotechnology is dependent on the cooperation and interaction of academia, government and industry (Gibbons, 1994).

In the US, this interaction has resulted in the development of start-up biotechnology firms. "Start-up biotechnology companies in the US are small companies, mostly founded by, or affiliated with, brilliant scientists, operating at the cutting edge of research and pushing the limits of science as they search for opportunities to commercialize their research" (Howells, 1996).

During the last thirty years, biotechnology start-up companies in the US and Germany developed at two different rates. In 1995, there were only seventy-five companies concentrating

on biotechnology research in Germany and one thousand three hundred and eleven total biotechnology companies in the US, with two hundred and sixty-five of these companies on the public stock exchange. Today, there are around four hundred and sixty-five biotechnology companies in Germany, with six of these companies on the public stock exchange. The total number of companies in the US consolidated to one thousand two hundred and eighty-three in 1999, with three hundred and twenty-seven of these companies on the public stock exchange. Figure 1 shows the total number of biotechnology companies in the US and Germany from the year 1995 to 1999.

Figure 1: Number of Biotech Companies in the US and Germany 1995-1999



There seem to be a number of reasons that help to explain why Germany was so slow in following the lead of the US in developing small firms in biotechnology. Historically, the development of life sciences in Germany has been constrained in a number of different ways. "First, the huge loss of human capital that started when Hitler came to power in 1933 resulted in the persecution of 'unwanted' scientists and students" (Momma & Sharp, 1999). In addition,

following the war there was an exodus of young scientists in search of better working conditions. Most of these young scientists fled to the US, which helped advance scientific developments in the US (Momma & Sharp, 1999).

The result was isolated pockets of excellence rather than the breadth of capability experienced in other science fields in Germany. These isolated pockets of biological research caused a dramatic shortage of experienced personnel throughout Germany and occurred at the time biotechnology advancement began in the US.

Germany was one of the first countries to acknowledge biotechnology as one of the essential technologies of the future. Germany's first governmental program to promote biotechnology dates back to 1972. The Federal Ministry for Research and Technology, known then in Germany as the Bundesministerium für Bildung, Wissenschaft, Forschung, und Technologie (BMFT) and now, as the Bundesministerium für Bildung und Wissenschaft (BMBF), was the center for activities for promoting new technologies. The BMFT set up the Central Commission for Biological Safety (Zentrale Kommission für Biologische Sicherheit). However, adherence to their guidelines was voluntary and it was not until 1986 that it was decided that the BMFT could not sponsor and regulate biotechnology, and responsibilities were shifted to the Health Ministry (Giesecke, 2000).

Two years earlier, in 1984, the Parliament set up the Enquete Commission for gene technology, which included people from a wide range of expertise (business, law, theology) as well as experts from science and industry. They developed recommendations for the handling of new biotechnologies, but were concerned also with the coordination between governmental bodies. Conflicts between the State and the Federal government, and between ministries within the Federal government, about the distribution of responsibilities delayed agreement and is one

reason why the German biotechnology innovation system got off to a sluggish start (Edgington, 1995).

Although the German federal government was the first to directly support biotech research and development (R&D) and several funding programs, the outcome has been quite different from the initial idea of making biotechnology a competitive industry. Despite solid research and federal R&D expenditures increasing from DM 48 million in 1973 to over DM 430 million in 1995, major innovations that can be transformed into marketable products have not emerged on the German pharmaceutical market (Ernst & Young, 1997).

Taking the figures of 1997 into account, Table 1 shows that the US outperformed all other countries in the biotech sector in terms of number of companies and employees as well as in terms of sales and R&D expenditures (Ernst & Young, 1998).

Table 1: Biotech Industries Compared

	Germany	Europe (including Germany)		USA	
	1997	1997	Percent change to prior year	1997	Percent change to prior year
Financial data (in million DM)					
Revenues	577	5.3869	58	31.498	19
R & D expense	282	3.764	27	16.292	14
Net loss	69	3.980	81	7.423	-9
Industry data					
# of companies	173	1.036	45	1.274	-1
Employees	4.013	39.045	42	140.000	19

Although German pharmaceutical companies were dominant in the world pharmaceutical market during the post war period, they have lost their share in the market during the last twenty years due to the lack of innovation in the biotechnology sector. While German pharmaceutical companies made seventeen percent of their revenue in the world pharmaceutical market in 1973, it decreased to eight percent in 1993 (BVK, 1997).

None of these pharmaceutical companies played a crucial role in the first decade of biotechnology development. Hoechst (now Aventis) had experimented unsuccessfully with single cell protein. Bayer began to build up in-house research capability in the mid-1970s and developed some links to academia, e.g. the University of Cologne. In the early 1980s, when the potential for biotechnology and genetic engineering began to be recognized, Bayer departed from the tradition of growth through in-house expansion, and moved their interests to the US. In 1979, they acquired the US pharmaceutical company Miles Laboratories. Then, they established a new pharmaceutical research center in New Haven, Connecticut based on the Miles research laboratories. Bayer also built up links with US universities, e.g. Yale, and entered agreements with several US biotech start-ups, e.g. Genetech in 1984 and Chiron in 1988 (Galimberti, 1993).

There has also been a lack of biotechnology innovation within German pharmaceutical corporations. Except for one medium-sized company, Boehringer Mannheim, which received approval for its genetically produced r-tpa factor Reteplase in 1996, the German pharmaceutical industry had no in-house biotech innovation on the market in therapeutics, vaccines, or antibodies. Of the thirty-one genetically produced drugs admitted on the German pharmaceutical market in 1998, only nine were distributed, six produced, and one developed by German pharmaceutical companies. Fourteen of these were developed entirely by or in cooperation with US companies and different European companies developed the rest of these products. In contrast, US companies have been dominating the US domestic market. Of the forty-one genetically produced drugs admitted in the US in 1998, thirty-three were developed, produced, and distributed by US companies, while only one by a German company (BIO, 1998).

US corporations in the biotechnology sector have been able to use their regional advantage of shorter physical distance and common cultural background to outperform German and other foreign competitors. During the beginning of biotechnology industry development,

start-up biotech companies in the US were more interested in forming strategic alliances with domestic pharmaceutical companies because they wanted to enter and take over the US market and needed strong partners with established distribution networks to do so (Forrest & Martin, 1992).

Although the US biotech industry has not relied on direct government support, it has remained one of the strongest industries in the US. The question arises as to which variables support biotechnology start-ups and how do they differ in the US and Germany (Giesecke, 2000).

2.1.2 Variables to Promote Biotechnology Start-ups

Depending on the nation, the set of variables that provides the framework for biotechnology start-ups can be comprised of government regulations and policies and the institutions involved in technology transfer. In the US these variables include academic research institutes such as universities, the industry structure, the legal system of academic education such as patent and licensing regulations, and institutions that promote technology transfer from academic research to the market such as business incubators. This framework comprises variables such as academic researchers, venture capital sources, and financial markets funding research and development projects. Biotechnology start-ups are dependent on the interaction of these variables to create the best possible overall framework for their future development (Howells, 1996).

2.2 Government Regulations

As previously mentioned, the role the government plays is one of the variables that can either support or hinder biotechnology start-ups. US and German approaches differ in regard to regulating products created by modern biotechnology. The US has rejected technology-specific regulation for the field of biotechnology. Instead, they used pre-existing regulations implemented for the advancement of other technologies.

The evolution and handling of biotechnology regulations in Germany from the early 1970s reflects the overall pattern of development of biotechnology, characterized by a slow start, allowing the interest groups to unite and build a consensus. From the start of biotechnology in Germany, committees of scientists and industrialists have initiated programs promoting technology transfer and the commercialization of biotechnology. In contrast to this support, regulation issues of biotechnology procedures have been strongly influenced and hindered by public opinion in Germany (Momma & Sharp, 1999).

Thus, it was in Europe that specific biotechnology regulations came into being. It was initially a political necessity: national divergences obliged the European Council to propose technology-specific directives, which were adopted in 1990. These technology-triggered regulations were consolidated by the subsequent intensification of concerns expressed by environmental and consumer organizations. High-profile campaigns and media attention in Europe has reinforced the regime of "genetically modified organisms" as an object of political attention and public concern. Beyond safety concerns, demands for product separation, identification, and explicit labeling have followed. The directives have subsequently been, and currently still are, the object of amendments (Cantley, 1999).

These concerns, coupled with a negative public opinion of biotechnology, are some of the reasons the biotechnology industry in Germany got off to a slow start. There are more reasons for this negative public opinion and many theories as to why this is true. To determine these reasons, many people and organizations have done studies to obtain the opinion of the public in Germany and in other countries in the European Union (EU). Perceived use, risk and moral acceptability are seen as determinants of public perception.

The difference in the attitudes between the American public and the European public is due to cultural differences. The concept of which risks are acceptable to what sorts of people is a

prime political question. This questioning causes the uncertainties surrounding current knowledge to be politically multiplied (Douglas & Wildavsky, 1982). In "Approaches to Acceptable Risk: A Critical Guide," Fishhoff, Lichtenstein, and Slovic (1980) conclude that acceptability is always a political issue:

> "That choice depends upon the alternatives, values, and beliefs that are considered. As a result, there is no single all-purpose number that expresses 'acceptable risk' for a society.
>
> Values and uncertainties are an integral part of every acceptable-risk problem. As a result there are no value-free processes for choosing between risky alternatives. The search for an 'objective method' is doomed to failure and may blind the searchers to the value-laden assumptions they are making...
>
> Not only does each approach fail to give a definite answer, but it is predisposed to representing particular interests and recommending particular solutions. Hence, choice of a method is a political decision with a distinct message about who should rule and what should matter."

Risk can be defined as insufficient information when complete consent is held back by uncertain knowledge. This definition is seen as a problem with the solution being seen as research. Nelkin and Pollak (1979) observed the way governments handle controversies over risk in Europe and America:

> "If lack of confidence is thought to be a problem arising from insufficient technical evidence, then the goal is to ascertain 'scientific truth.' This leads to a structure based on scientific advice to public representatives. If the controversy is defined in terms of alienation, a more participatory or consultative system is developed. And if the problem of public consensus is defined in terms of inadequate information, it is assumed that people oppose technologies because they are poorly informed. The task then becomes one of 'education.'"

The situation where knowledge is uncertain and consent is challenged is how any informed person would characterize the contemporary dilemma of risk assessment (Douglas & Wildavsky, 1982).

Many Europeans are uneasy about modern biotechnology, including new genetic technologies. While there is widespread support for traditional medical applications in the fields of diagnosis and treatment, few approve of the use of transgenic animals for research and

applications. Transgenic animals are those having chromosomes manipulated by artificially introducing genes. There is a distinct difference between the concerns of regulators and that of the public. Regulators have shown the traditional concern of risk and safety while the public centers on questions of moral acceptability (Klepsch, 1997).

Due to the importance of public opinion in shaping the prospects for biotechnology, in 1982 the European Commission (EC) emphasized the weight that public perception would play in the acceptance or rejection of the products of modern biotechnology. The EC's programs of research and technological development included initiatives to promote public understanding and dialogue with consumers. Nothing has seemed to persuade much of the public in the European Union to look as favorably on biotechnology as the North American public does.

The EC's Eurobarometer is a system of public opinion measurement used to gauge public response to a carefully chosen range of questions on biotechnology. These questions are summarized as, "What do you know? What is your opinion? What should be done by government? And who do you trust to tell you the truth about such matters?" The Eurobarometer has also consistently revealed wide and persistent differences of opinion between different member countries. These underlie the differences in national (governmental) positions regarding biotechnology-based innovations. Those differences in position generate friction and controversy within the European decision-making bodies that authorize the marketing of products (Cantley, 1999). The main lesson of the survey is that public confidence in emerging applications of biotechnology cannot be taken for granted (Klepsch, 1997).

The statement, that the more informed the public, the more likely it is to be supportive of biotechnology, is derived from the belief that knowledge is a crucially important determinant of support for science and technology. Comparison of the new Eurobarometer survey conducted in 1999 with earlier ones in 1996 and 1993 indicates that although the public's knowledge of

relevant basic biology has increased slightly, people responding positively to biotechnology and genetic engineering has decreased by five and six percent respectively (European Commission, 2000). "Furthermore, the new survey shows that knowledge is poorly correlated with support for the applications" (Klepsch, 1997).

For all sciences and technologies, there is some discrepancy in how people perceive the situation. The situation with biotechnology is more complex. "The new survey suggests, for example, that people with greater knowledge are more likely to express a definite opinion about biotechnology; but this opinion can be positive or negative" (Klepsch, 1997). "It has been claimed that mismatches between scientific and lay assessments of risk are responsible for public resistance to new technologies" (Klepsch, 1997). There have been public debates about some aspects of biotechnology concerning the issue of risk and moral considerations.

According to the Eurobarometer survey, people see biotechnology applications as potentially useful. However, there is a difference of opinion involving which applications are viewed as risky or morally unacceptable. Those involving crop plants, food production, and the use of transgenic animals are seen as risky. The use of transgenic animals for research is thought of as morally unacceptable. This pattern implies that use, risk and moral acceptability are all likely to be strongly correlated with overall levels of support for specific areas of biotechnology (Klepsch, 1997).

In the case of food production, risk perception appears to be more than a trivial predictor of support. The pattern of results across the various applications suggests that perceptions of usefulness, riskiness and moral acceptability could be combined to shape overall support. It is believed that usefulness is a precondition of support, people seem prepared to accept some risk as long as there is a perception of usefulness and no moral concern, and moral doubts act as a prohibition regardless of people's views on use and risk (Klepsch, 1997).

The finding that risk is less significant than moral acceptability in shaping public perceptions of biotechnology holds true in each EU country. This has important implications for policy-making. In general, policy debates about biotechnology have been couched in terms of potential risks to the environment or human health. If it us true that people are more swayed by moral considerations, public concern is unlikely to be alleviated by technical based reassurances or regulatory initiatives that deal exclusively with the avoidance of harm (Klepsch, 1997).

In Europe, the public's faith is in consumer and environmental organizations rather than in governments, industry, or academia. The 1999 Eurobarometer survey reveals that consumer organizations are regarded as trustworthy by over half of the population. Europeans choose national government authorities as their most trusted source of information while companies and political parties are trusted least. In comparison to the survey conducted in 1996, public trust has decreased for all sources of biotechnology. The two sources that have lost the most trust are environmental protection organizations and universities. They have lost the confidence of ten percent of the population (European Commission, 2000). Whether these reservations reflect political opportunism or real popular concern, it has become clear that consumer acceptance of the products of biotechnology can not be taken for granted (Cantley, 1999).

"It is because of the issues of risk and safety that modern biotechnology is so extensively regulated in Europe" (Klepsch, 1997). The public survey emphasizes that public concern may have risen as a result of lack of trust. This was suggested from the data obtained in the survey. The survey concludes that seventy-four percent of respondents consider that genetically modified foods should be labeled. Sixty percent believe that there should be public consultation about developments in biotechnology. Fifty-three percent say that current regulations are insufficient to protect people from the risks of biotechnology and thirty-nine percent think that religious authorities should be involved in the regulation of biotechnology. "If biotechnology researchers

and industry regulators are to command public confidence, they must incorporate openness and wide consultation into the policy-making process" (Klepsch, 1997).

2.3 Government Policies

Other than regulations, the policy that government implements on the biotechnology sector is another role it plays biotech start-ups. The German government has pursued a direct interventionist technology policy on the biotech sector through its Ministry of Science and Technology. This technology policy was less effective than the US approach of a pluralist, heterogeneous and contextual technology policy. The US approach was more effective because it supported an institutional arrangement that was favorable to the specific needs of biotech development (Giesecke, 2000).

The major government agency in charge of science and technology policy in the pharmaceutical biotech sector in Germany is the Ministry of Science and Technology. This agency designs and implements policies in almost all fields of science and technology, whereas the US does not have a central agency for this field of public policy (Giesecke, 2000). The German Ministry of Science and Technology did not have much in-house competence on the field of biotechnology. Accordingly, the agency relied on industry and science expertise to design support programs for biotech development. The science and economic experts upon which the government relied were usually affiliated with those academic institutions and industrial companies that got extramural funds from the Ministry of Science and Technology. In this way, new incentives from outside the "inner circle" of government research and development funding were excluded (Giesecke, 2000).

In the US, the Department of Health and Human Services (DHHS) and its research agency, the National Institutes of Health (NIH) are responsible for science and technology policy in the pharmaceutical sector of biotechnology. Since the US government made cancer research a

national priority, NIH was able to expand its capacities and competence and to establish a research area dedicated to the health sector. However, a specific program to support biotechnology development as it passed in Germany was never enacted in the US. Instead, biotechnology was never seen as an individual entity, but as a tool to expand the scientific frontier in medical research (Giesecke, 2000).

One of the differences between the US and German political structure lies in the capacity and competence of the agency that assigns the research projects. In the case of Germany, the instrument of governance is limited to monetary instruments while in the US, scientific knowledge on in-house research and extramural funds put NIH in a strong position to compete. The NIH emphasizes compatibility and benefits to in-house research projects and its policy assured the continuation of strategic research goals and opened up the possibility for integrating new incentive programs from outside sources (Giesecke, 2000).

In order to catch up with the US, the German Ministry of Science and Technology initiated several programs in the 1980s and 1990s as part of the project to support more applied research with the intention to yield products that would be competitive on national and international markets. Although industry cooperated with universities and public research institutes in several projects major technological breakthroughs and innovations with immediate industrial application could not be achieved.

2.4 Intellectual Property Protection

In addition to government regulations and policy, intellectual property protection is crucial to secure for all those interested in developing new technologies. Intellectual property (IP) is one variable that is of crucial importance to biotechnology start-ups. The reason that it is so important is that intellectual property can be stolen, copied, or sold easily. "On average, the biotechnology industry ploughs some forty-five percent of its annual income into R&D" (Moise,

1999). What this means is that almost half of the value of the biotechnology industry is embedded in its intellectual property. It is for this reason that protecting intellectual property is of the utmost importance. Currently, there are several methods for protecting intellectual property in the US.

The most common way to obtain security for an invention related to the field of biotechnology is to obtain a patent. There are several other forms of idea protection, but the most commonly used method in the biotech field is the patent. In the US, a patent grants its owner the right to exclude others from making, using, or selling the claimed invention without a license (Thumann & Hsu, 1997). It is granted by the government for a limited period, and allows the holder to benefit from his invention. A patent is usually a grant of monopoly for 20 years to the holder of the patent. In return for this protection, the holder has to publish the specifics of the invention. This informs the public of the patent, and allows others to develop additional inventions as long as the patent rights are not infringed upon. Patents are the most encompassing of the various types of intellectual property protection methods because "patent law protects the totality of the idea, expression, and implementation" (Moore, 1997).

Under US law, a patent can be issued to any new and useful process, machine, manufacture, or composition of material, or any new and useful improvement thereof (Thumann & Hsu, 1997). The new invention must be novel, useful, and nonobvious (Hunt, 1999). Being nonobvious means that an invention must be more than a trivial advance over what is already known. This is often times the hardest of the three requirements to meet.

There are currently three types of patents. Utility patents are designed to protect any new, useful and nonobvious process, machine, article of manufacture, or composition of matter, and new and useful improvements. Design patents are designed to protect new, original, or ornamental design for an article of manufacture. The last type is the plant type patent and is for

protection of any new variety of plants. Patent protection has been an important issue since the beginning of the US, evidenced by the fact that it is included in the Constitution.

The US Constitution gives Congress the power to promote the progress of science and useful arts by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries (Hunt, 1999). Often times it requires less effort and is cheaper to duplicate another's discovery than it is to discover something new. For this reason, patents give inventors a temporary monopoly to produce their invention. "Thus, by helping to ensure a reasonable economic return to inventive activity, patents provide an important incentive to engage in research and development" (Hunt, 1999).

Patents are usually granted for 20 years from the date of filing, and are available for all types of technology. However, there are renewal fees for patents issued after 1980. These fees occur in the fourth, eight, and, twelfth years of the patent. These fees are not mandatory, but if they are not paid the patent expires at the renewal date rather than at the end of the patent's full term (Hunt, 1999). Usually, owners opt to pay the renewal fees if the patent remains sufficiently valuable.

Several drawbacks arise from the process of patenting information. One drawback of the patenting process is that it can cause an inventor to remain quiet. That is, the inventor does not disclose the newfound information until awarded the patent, which can be a long process. One feature of patents that was designed to address this problem is the issuance of priority dates. When the initial submission is made, the Patent Office issues the inventor a priority date. The coverage for a valid patent does not start when the patent is awarded, instead, it is extended back to the date that the idea was submitted.

Another drawback to patents is that to be awarded a patent in the US, the inventor must have a very good understanding of what has already been done to ensure that the patent received

encompasses the ideas that the inventor intends to protect. For this reason, the time to successfully fill out a patent application can be lengthened substantially as the inventors write as thorough a procedure as possible. Not only must the procedure be as thorough as possible, but it also must be understandable to an average individual in the specific field. In addition, using as few technical terms as possible is highly recommended. This is often hard for inventors who work day in and day out with the technical aspect of their data and can take more time as the inventors try to rephrase what it is that has been done.

There are also some concerns over the economic impact of patents. One of the concerns is that because patents prevent others from selling the patented product, they create a monopolistic situation. This means that who ever holds the patent can charge a higher price than they could charge in an open market. "There will be some consumers willing to buy the product at the competitive price, but unwilling to pay the higher price charged by the patent holder" (Hunt, 1999). A second concern is that patents inhibit research by keeping a particular invention off-limits to other researchers or corporations. In many industries, making the best product or using advanced process may require using ideas developed by many different people. If the needed ideas are patented, their use requires the consent of the patent owner. This can be done if the user of the technology and the holder of the patent develop a license arrangement. Setting up these agreements can sometimes be quite costly. There are times when agreement cannot be reached and the parties involved resort to the use of litigation.

Another option to the patent is the trade secret. "A trade secret is almost unlimited in terms of the content or the subject matter that may be protected and typically relies on private measures, rather than state action, to preserve the exclusivity" (Moore, 1997). Just about any type of information or work can be considered for trade secret protection.

Some information to which trade secrets are applicable includes formulas, patterns, compilations, programs, devices, methods, techniques, and processes (Gregory, 1994). Trade secret information generally refers to method of production of goods but there are also a number of other areas that can be included in trade secrets. Business information such as methods, techniques, knowledge, procedures, forms, and programs are all protectable. Methods for conducting business can include internal manuals, forms, and programs used in the operation of the business (Gregory, 1994).

The restrictions on trade secrets are the requirements of secrecy and competitive advantage (Moore, 1997). In order to be declared a secret the work must not be generally known, cannot be published in trade journals or reference books, and it cannot be readily copied from products on the market (Moore, 1997). If a company distributes products that disclose the secret in any way, then the secret protection is lost. The competitive advantage requirement is weaker than that of secrecy, and is met as long as the company or owner benefits in some way from the secret (Moore, 1997).

One term of a trade secret is the owner has exclusive rights as long as the work remains secret. Should the owner make the secret public, the protection afforded lapses and anyone can use it (Moore, 1997). Within the secrecy requirement, owners of trade secrets enjoy management rights and are protected from misappropriation. This is an important aspect given today's levels of corporate espionage and employee theft of intellectual works (Moore, 1997).

There are several drawbacks of trade secrets. Trade secret protection exists only as long as the secrecy exists. Once the secret is destroyed, the protection is destroyed. Another problem with trade secrets is that reverse engineering of a public product can be legally done to uncover a trade secret. This means that someone can take the trade secret and discover how it was produced by working backwards. Trade secrets also hinder the spreading of information because the trade

secret cannot be published in an enabling form. The secret may be lost if another develops the secret and then applies for a patent. The final drawback to a trade secret is that it is often hard to prove that a secret has been stolen and given to a competitor.

2.5 University Technology Transfer

Obtaining intellectual property is of great importance in the technology transfer process. Technology transfer is the process that promotes the integration of creative works of university faculty, staff, and students to public use and commercial application through patenting, licensing, and start-up formation. The Office of Technology Transfer within universities provides assistance at all steps of the technology transfer process to faculty, staff, and students.

Three decades ago, universities supplied companies with employees and with personal consultancy through their faculty. Research was pursued largely independently, driven by traditional academic imperatives, and the results of university research were published in open literature. Small technology-based companies were very rare. Instead, industry supplied funds, often as donations or to act as good citizens, rather than to affect their production. Research funds were relatively plentiful and academic salaries were competitive with, if not ahead of, those of comparable scientists in industry (Jennings, 1998).

Economic changes in the 1970s squeezed university budgets, and industry itself became increasingly focused on short-term objectives and increased shareholder value. Research budgets in large companies were cut back, but new venture capital-funded companies started to appear in the US (Jennings, 1998).

New laws on technology transfer were enacted in the US during the 1980s to promote technology transfer and to remodel a structure that could not adjust to new economic developments that were dependent on high-technology changes. The Bayh-Dole Act of 1980 and its revisions helped to give birth to the US biotechnology industry. The Bayh-Dole Act reacted to

the fact that a lot of promising ideas and inventions born in academic research labs were not economically exploited on the market. These laws enabled universities to derive a commercial benefit from the research undertaken in their institutes. Technology transfer offices were set up to market and license innovations and to found new enterprises within the university's region (Abramson, 1997).

As universities tried to come to terms with the full impact of these developments, they could no longer regard publication of their results in the open literature as a full discharge of their duties to their sponsors and community. New resources and a whole new set of skills became necessary to transfer technology successfully (Abramson, 1997).

Start-up firms were created to fulfill these requirements and play a crucial role in the advancement of the biotech industry. They serve as a technology transfer mechanism to bring research results from the academic lab to the market. The start-up nurtures the new technology until big pharmaceutical companies become interested in forming a strategic alliance and undertaking all subsequent steps of the product development process (Giesecke, 2000).

Faculty members of academic institutions, sometimes with a lawyer or business associate, usually undertake start-up biotech companies in the US. Entrepreneurs with an academic background have expert knowledge and sometimes own intellectual property that grants them access to new scientific findings that no one else is able to exploit. Transferring this knowledge to a company is the prevailing mechanism for its commercialization and finally its medical application. Usually, academic entrepreneurs either keep their position as a scientist and researcher or find other ways to stay in close contact with basic research and the latest developments in their fields (Howells, 1996).

Unlike the US, German academic researchers never had any significant incentives to file patents. According to German law, employees of public universities fully own their intellectual

property. They do not have to share it with their employing institutions. In fact, an invention that has already been published, e.g. in a journal, cannot be patented afterwards in Europe. For researchers, it is more important to publish than to patent. This has turned out to be an obstacle to the overall innovative performance of German universities. Those wishing to start a company have to bear the cost of filing and sustaining patents all by themselves, and this can be very costly. In contrast, in the US the university's technology transfer offices pay for the fees and in return get a share of the profit that results from the intellectual property. However, technology transfer offices at German universities and at most public research institutes are not run as for-profit enterprises (Abramson, 1997).

In the US, the biotechnology industry originated in the university and it continues to be the source of most of the basic new technology that fuels the industry (Horton, 1998). Transferring this technology from the university laboratory into a successful company is the major challenge of the university technology manager. This is a cross-cultural job where the technology manager must put forth the attitudes, goals, and accomplishments of the academic scientist in terms that the industry can understand and accept. The job also requires a great deal of judgment and diplomatic skill to balance the competing needs of the university and industry. In order for the technology transfer process to be successful, the university technology manager relies on the presence of an equally sophisticated partner on the industry's side of the table (Horton, 1998).

2.5.1 The Nature of the University's Product

The first major difficulty confronting the university technology manager is the nature of the product (Moukheiber, 1999). University technology is basic and embryonic. Frequently the invention is little more than a discovery of a basic mechanism, supplemented by deductions of its utility (Horton, 1999). The invention may not yet have been tested on rodents, much less

humans. Neither the academic researcher nor the technology manager may have a clear understanding of the potential commercial utility of the invention, or even the different fields to which it may be applied.

What the company must realize is that it will be carrying the burden of developing the invention into a marketable product. The intellectual property that results from this early invention has the potential to be turned into a marketable product or drug. If the company can get exclusive rights to such an invention, it may be able to dominate the field of any products resulting from it. It is this potential of new technology that is leading so many biotechnology, pharmaceutical, and chemical companies to strengthen their relationships with universities (Moukheiber, 1999).

2.5.2 Industry Goals

Because of intense worldwide competition among academic researchers in the field of biotechnology and because of the development of new tools in the field, biotechnology is progressing rapidly. Significant new findings are occurring daily, and a company cannot afford to not have a relationship with the academic laboratory for long (Horton, 1998).

Consequently, pharmaceutical companies are expanding their liaison activities with universities and start-up companies. Even the smallest pharmaceutical company will have a technology acquisition specialist spending much of his time looking for new technologies in universities and seeking to create alliances (Jennings, 1998).

There are many reasons why a company may seek alliances with universities. One reason is the desire to get access to the technology early. This allows the company to get broad, exclusive rights that can be acquired relatively inexpensively and can lead to the development of many products. The university owns particular intellectual property rights, and the company wants a license. Most companies perceive that it is cheaper to do the work in the university than

in the company. However, this is usually a poor reason for a collaboration since the differences in the types of projects best carried out by a university and those best carried out in industry are such that if the company can do the work itself, it probably should. Some companies may think that a relationship with a university is a good idea. Experience has shown that for this reason, an alliance is one that is bound to lead to disappointment on one or both sides. Expectations should be clear before the alliance begins. Development work on the discovery is usually needed in most situations and the university is best prepared to carry out that work (Jennings, 1998).

2.5.3 University Goals

Financial considerations play a big part in the university's interest in industrial collaborations. Alliances with industry, including sponsored research, licensing of intellectual property, and investments in start-ups are seen as the major sources of funds (Jennings, 1998).

With one or two exceptions, even the most successful university licensing offices receive licensing revenue equal to only one to two percent of their total university research budgets. Since the expected income from licensing is so small, it is unclear why universities are putting so much emphasis on this aspect of technology transfer activities. Many of the reasons apply to all phases of the university technology transfer program.

One of these is the university's mission to transfer technology for the public good. Many universities realize that their basic research results will benefit the public only if these findings are effectively communicated to industry in a manner that will induce industry to invest in the product and market development. However, universities also want to enhance their overall reputation and feel they can do so by having a successful technology transfer program.

Another goal of this collaboration is the desire of researchers to see something real come out of their labors. Successful transfer of university technology to the industry provides the opportunity for researchers to see the results of their labors without having to leave the university.

A suitably structured licensing agreement also allows the researcher to share in the profits of such labors while remaining in academia. The use of licensing money is another benefit for the university. Since universities allocate a certain fraction of their licensing revenue to inventors, the money can provide a significant incentive to faculty, graduate students, and other researchers to report inventions and to cooperate in the patent filing and technology transfer processes.

Apart from licensing revenues, universities get information on the needs of the pharmaceutical industry, on breakthroughs of commercial research and can possibly obtain grants for research projects. Knowledge and information are crucial assets in the biotech business and the communication of knowledge that occurs between the industry and university is crucial to the success of the biotech industry. Collaborations with industry through sponsored research has helped bring reality into the academic laboratory and had allowed students to work on the most up-to-date problems while providing the pharmaceutical industry with much needed research and development (Howells, 1996).

University-industry collaborations in the US have also helped local economic development. University-based companies have built the biotechnology region known as Genetown located on Route 128, outside of Boston, Massachusetts, along with Silicon Valley around Palo Alto, California, and the Research Triangle in Durham, North Carolina. This has made state governments take notice and many are now explicitly encouraging collaborations with industry in order to build high value-added jobs in their regions (Jennings, 1998).

2.6 Business Strategies of Start-ups

Other than having an excellent science base, entrepreneurs also need to realize the importance of business and financial strategies when starting their company. As universities have become more active in protecting and licensing their intellectual property, they have also found it harder to obtain contracts with the pharmaceutical industry. Acceptance of a university invention

is unlikely unless that invention is directly related to an ongoing project in the company. Accepting to take on a university invention means redirecting already committed and scarce research and development resources inside the company to work on the new invention. Thus, few companies are willing to do so (DeCeglie, 2000).

Many entrepreneurs trying to start a biotechnology company are realizing that contracts with industry may not be suited for their start-up. Thus, many entrepreneurs are willing to start-up on their own and become independent of the industry. This way of starting a biotechnology company is most prevalent in the US but a number of obstacles must be overcome in order to insure the future of the start-up. One of these obstacles is the task of obtaining sufficient funds to get the company started.

2.6.1 Venture Capital

Due to the lack of quality contracts from industry and a willingness to become independent, universities have now turned to venture capital sources to form new companies specifically devoted to particular university technologies. Fortunately, there are still enough seed-stage investors in the US that are interested in the very high returns possible from successful biotechnology ventures to fund a number of new companies each year (DeCeglie, 2000). These seed-stage investors are the initial investors that help the young company get off the ground and are called venture capitalists.

Venture capital firms are private for-profit investment groups who provide funding to investments that they believe can provide a three hundred to five hundred percent return over a five to seven year period. Over twelve hundred venture capital firms exist across the US, with more than twice that number operating worldwide (Scarborough & Zimmerer, 1997).

While the first private US venture capital company was created in 1946 (American Research and Development, ARD), these kinds of businesses are only starting to develop now in

Germany. Yet, they are very reluctant to invest in high-risk industries such as biotechnology. A study done by Ernst & Young shows that the overall volume of venture capital in Germany is still small compared to the US figures. The venture capital invested in the US was DM 1287 million in 1996, seven times the venture capital invested in German biotechnology (Ernst & Young, 1997). Even though one out of one hundred entrepreneurs that apply receive venture capital, the industry has created a platform for many high-tech innovations that would otherwise have taken longer to develop or that would not have been developed at all (Lerner, 1994).

In 1998, one-third of venture capital invested in the US was spent on new technologies such as computer, software, telecommunication, and biotechnology. German investors were more hesitant, investing only seven percent of their venture capital in these new technologies. Federal and state funded institutions are backing a high percentage of venture capital investment in Germany. In the US, business angels, which are usually well established members of the finance community who are willing to provide advice and funding to biotech start-ups, pension funds and insurance companies, are bearing the largest share. In Germany, pension funds and insurance companies are by law restricted from investing in venture capital. Furthermore, there is no tradition in funding high-risk companies in Germany as was established in the US, starting with the electronics and information technology in the 1950s and 1960s. Since biotechnology companies have just recently gone public in Germany on the Neuer Markt, some young investors have shown some interest in investing in biotechnology companies but these investments have mostly been in companies that are in the production phase of development (Giesecke, 2000). The Neuer Markt is the portion of the German stock exchange that consists of technology companies.

Another factor that limited the development of a strong base of biotech start-ups in Germany was the absence of financing partners. Compared to the situation in the US, it was

difficult for German companies to obtain venture capital because there was no stock market equal to NASDAQ (the US stock exchange for technology based companies). Until 1993, NASDAQ was the only stock exchange admitting such companies and thus provided opportunities for early stage investors to exit their investment. Because Germany lacked a stock exchange for the new firms to go public, venture capitalists had no way to exit. That is, it was difficult for the venture capitalists to recoup their initial investment so they would shy away from investing in the start-up biotechnology companies. Since the established banks had virtually no expertise in dealing with biotechnology firms and did not understand their needs, they were also hesitant to finance biotech start-ups in Germany (Financial Times, 1995).

The managing director of Beteiligungs AG, a venture capital division of Deutsche Bank says, "People have heard for so long that we don't have enough entrepreneurs, that we lag behind in high technology, so when they see companies that seem to be in biotechnology they just buy these stocks." The new stock exchanges that cater to smaller and younger companies are providing a crucial source of capital that has long been present in the US but absent in Germany (Andrews, 1998).

The increased venture capital activity in biotechnology in Germany has gained some attention over the past few years. In 1992, there was almost no seed-fund financing available. In spite of this, MorphoSys of Munich became the first of a new wave of German biotechnology companies and has gained over DM 38 million in equity. Today, many venture capital companies will consider first-round financing for a new German biotechnology company. Part of the attraction for investors is the change in political attitudes toward biotechnology (Lytton, 1999).

The existence of favorable loan and grant schemes in Germany has led to the adoption of a unique mechanism for securing initial finance for a biotechnology company. Several years ago, a federal organization called the Technologie Beteiligungsgesellschaft (TBG) established a way

by which up to DM 1 million could be provided to a young company. The only requirement was that an equal sum needs to be committed from a third party in the form of equity. The money given by the TBG collects annual interest and needs to be repaid in ten years. Today, amounts up to DM 5 million are available from the TBG on similar terms and local governments have followed this model in creating their own schemes. In 1996, the state of Bavaria established Bayern Kapital to administer a similar scheme for the benefit of Bavarian companies. Through these schemes, founders have been able to sell less of the company than would otherwise be necessary to secure access to capital and venture capitalists have been able to gain enormous leverage on their investment (Lytton, 1999).

However, the supporting conditions of a venture capital industry that exists in the US meets three specific features inherent to the importance of biotechnology development. First, it enables the setup of small-specialized research units in high-tech clusters, where distances are short enough to communicate vital knowledge that is crucial during the first phase of biotech industry development. Due to its specific mode of generating knowledge and innovation, biotechnology as an industry can best advance in small R&D units in entrepreneurial companies. Second, it provides for the equity needed to finance biotech research until a patent becomes marketable and, thus, closed the equity and realization gap for early stage investors who wanted a profitable return before the start-up is listed on any common stock market. Finally, venture capital companies provide the managerial and business expertise needed to set up a biotechnology company. Academic researchers founding their own business are usually confronted with financing and managing issues for the first time and need the skill and help of experienced professionals (Dibner, 1991).

For any company that wants to be competitive in the global biotechnology industry, raising venture capital is an absolute necessity (Koberstein, 1999). For the rapidly emerging

German biotechnology sector, understanding the rules of how to attract venture capitalists is especially important and will help advance their innovative biotechnology sector.

2.6.2 Business Plans

One of the most effective ways to attract venture capitalists is to have a solid business plan. While most biotechnology business plans go in-depth about the technology behind the firm, few go to the same effort to explain how this technology will be used to make money. Most venture capitalists end up tossing these business plans on the pile of 'big science projects,' which consist of basic research that is best funded in an academic setting with corporate or government sponsors (Koberstein, 1999).

To avoid this fate, most experts say that it is necessary to spell out the company's strategy for creating commercial value. Product companies should create a timeline that charts out the regulatory and product launch strategy as well as the process of obtaining reimbursement, while explaining how the company will get there. Platform companies are suggested to describe a business model for how the company's tool or target can generate revenues. In addition, including a strategy for handling the downsides of the business model will be helpful (Koberstein, 1999). There is no guarantee that a venture capitalist will invest, but a solid, well-written explanation of the business opportunity is the first step to starting up the company (DeCeglie, 2000).

If a start-up group can satisfy themselves that they have enough knowledge of the field they are about to enter, and that a potential market opportunity exists, the next step is seeking out a source of capital to begin the new business. Another source of funding a start-up biotechnology company is the capital market. Accessing capital in public equity markets is a dangerous business and there are some guidelines to follow when planning an initial public offering (Menzel, 1998).

2.6.3 Capital Market and Initial Public Offerings

For biotechnology companies accessing the capital market, it can mean the difference between success and failure. Unfortunately, scientific discovery is not the only factor that defines the long-term future success of a biotechnology company. It is also vital to attract the interest of investors and the finances they provide. Without it, the entire process quickly breaks down. Given the frequent need of financing for biotechnology development, paying attention to Wall Street is a fundamental requirement of business (Menzel, 1998).

Therefore, rushing to finance new products with public money because the NASDAQ index is setting records can cause a company to fail (Menzel, 1998). A stock that should not be public and therefore trades below its initial public offering (IPO) price becomes tainted in the eyes of investors and can hinder the success of the larger and more important financing to come. The decision to access the capital market requires a striking balance between the desire to take advantage of financing windows and knowing when your company is truly ready to go public (Persidis, 1996).

Apart from the vagaries of the stock market, several prerequisites determine whether a biotechnology company is ready to launch a successful IPO (Menzel, 1998). These should be thought of as necessary steps rather than preferable options. Evidence of a compelling and differentiated business model is significant in the current market, which favors biotechnology companies that are able to create sustainable value and move as quickly as possible to provide earnings. Being able to articulate an easily understood equity story to investors is usually a major challenge, but worth the investment in time because the process of selling shares on IPO roadshows involves a combination of short management presentations and bankers pitching to investors. Furthermore, the number of biotechnology companies to choose from and the risk

involved creates a need to be a standout in order to attract the attention of investors (Menzel, 1998).

Part of being able to successfully sell an equity story is being able to provide tangible proof that it is real. In biotechnology, this means a number of things. The existence of a strong intellectual property is an absolute must in an industry marked by tremendous change. Advanced clinical trials, during which the effects of the drug are tested, are a significant advantage for therapeutic companies because they provide an investor with hard data that can be used to predict the probability of reaching the market. Technology companies need to prove that the product can be successful and that there is a potential market (Menzel, 1998).

Meaningful partnerships with pharmaceutical companies are also regarded as an essential validation by investors because experienced pharmaceutical companies are seen as the historical experts (Moukheiber, 1999). Two basic aspects need attention in a pharmaceutical deal. First, the partnership is best struck with a leader in any given field because they will be seen as the foremost experts. Second, the deal itself should have a bias toward advanced payments and achievable milestones, rather than a schedule that has money being funneled into the company at later dates, which is nothing more than an option contract (Moukheiber, 1999).

Milestones are also important in the context of driving stock performance. Investors look not only for an attractive, validated equity story, but also for specific events that will move the stock price once the company is public. Therefore, a company is best served to time its IPO when there will be a series of announcements in the so-called aftermarket. In biotechnology, these can include the results of clinical trials, additional partnerships and pending patent applications. In all these cases the investor requires tangible evidence before deciding to invest in the company (Menzel, 1998).

The final hurdle is the structure of the company. A strong team of researchers with a reputable scientific advisory board forms the backbone of the organization, but the senior management team is also critical because Wall Street is looking for commercial opportunities rather than beautiful science. There is an obvious link between market value and quality of science, but the ultimate destiny of a company is determined at the top. Thus, the company needs to have as many of the essential people in place as possible before the time is right for an IPO (Persidis, 1996).

2.6.4 Biotechnology Incubators

Another variable that promotes biotechnology start-ups is having institutions that aid in technology transfer from academic research to the market. For many years, through technology transfer and licensing programs, universities have advised their researchers on suitable ways to protect their inventions and make money from them. The past decade has seen the rise of a structure created to gather a number of companies together to pool business resources and exchange ideas (Cunningham, 1999).

This structure is known as a biotechnology business incubator. A biotechnology company needs more than just a patent to succeed. It needs management, space and money. Incubators are the answer to these needs. Business incubators are set up to provide the right advice, and often take the form of buildings offering workspace, legal, financial and management mentoring, and perhaps, staff members, at reduced rates. Business incubators are also designed to provide the assistance necessary to stave off disaster for the start-up and to give it every chance to make it on its own or to prepare for an alliance. Due to the way biotechnology companies emerge, no other industry needs business incubators more (Cunningham, 1999).

An incubator offers space for rent, normally at a reduced rate, to scientists or entrepreneurs to develop their ideas and use the facilities the incubators provide. However,

business incubators are meant to be only temporary homes for start-up companies. Within a few years, the incubator's occupants should have laid foundations to survive in the real world. Start-up companies, who rent space in an incubator usually sign one, three, five or ten year leases. How long they stay depends on any number of factors, e.g. the availability of space (Cunningham, 1999).

Alliances are a way of life in the biotechnology industry. Few companies remain wholly independent for long and there is a constant demand for money and the need for quality management. For the first few months, sometimes years, of existence, the start-up company is on its own and free to decide its own future. During this time, it is critical to be able to call on the right advice at the right time (Cunningham, 1999).

An incubator can provide direction for scientists coming out of academia, many of whom have no commercial experience and who need connections to the right people such as financiers and lawyers. The incubator provides the smoothest method for a business to get going and allows them to pursue science without undue regulation, attract private money and meet important people (Cunningham, 1999).

As the US adapted the biotechnology incubator idea before the rest of the world, it may be some time before success of the system outside the US can be identified. The BioRegio initiative, in which the German government gives financial support to foster the growth of the biotechnology industry in designated areas of Germany, only began in 1995 (Cunningham, 1999).

While business incubation works for a whole range of industries, biotechnology, with its demands for quality management, specialist advice and a considerable amount of money, appears suited to it more than most. Not only does the incubator serve as the access to specialist guidance and funding, it serves as an interactive network of experts in the necessary fields of biotechnology development (Cunningham, 1999).

Chapter 3 – Methodology

From our literature review we found that there were five variables that needed to be analyzed. These variables are the roles of university, government and industry in promoting biotech start-ups, the business aspects of a biotech start-up and the influence of public perception and cultural attitudes on starting a biotechnology company. This chapter outlines and explains the methods that were incorporated in this IQP in order to perform this analysis. The primary techniques used to complete the IQP were interviewing and case studies. The goal of the interviews was to supplement the information that was gathered from our literature review. The case study was used to test the derived theory of the steps that are needed to start a German biotechnology company and the influence and role the five variables played in the development of each company. This theory was derived from literature on companies in the US.

The methods that we used to complete this IQP were all qualitative in nature. Qualitative research is designed to give the researcher an idea of soft evidence. Soft evidence is the idea or patterns behind a given topic or area, where as quantitative methods typically deal with solid facts. "Qualitative research thus refers to the what, how, when, and where of a thing--- its essence and ambience" (Berg, 1998). From qualitative research, the researcher is able to derive the way that people think but can not extrapolate the data to the whole population. Qualitative analysis does not give the researcher any statistics to quote; however, it does follow some of the same principles quantitative research uses.

Qualitative research does contain some drawbacks. Typically, the sampling techniques for qualitative research are not as rigorous as for quantitative research. Another drawback is that there can be some volunteer bias for the groups that the researcher selects. Because qualitative research is typically on a smaller scale than quantitative research, the researcher needs to be extremely careful in making sure that these issues are acknowledged and addressed in the design

of the experiment. Our group addressed these issues in our sampling techniques and in the method used when obtaining and contacting new references. A more in-depth discussion on these issues follows in the interviewing section. Some of the other drawbacks of the analysis of qualitative research are evidenced during the analysis phase.

Qualitative research does not have universal rules for the interpretation of collected data. Because qualitative research incorporates the ideas and feelings behind what is going on, the analysis will be different for each case (Hedges, 2000). What this means is that the researcher has to draw conclusions and patterns from conversations and case studies using content analysis, which is a subjective process. The researcher sets the parameters for the content analysis and these parameters will be subject to the researcher's biases. In addition, it is very difficult to separate the evidence from the interpretations of respondents because the information comes from an individual who may blur the facts with their feelings. Another issue that arises involves the less extensive and flexible analysis of sub-groups. A final drawback to qualitative research is that you do not have the powerful analysis techniques that can be applied to quantitative data (Hedges, 2000).

3.1 Interviews

Interviewing is an important aspect of any research project with the objective of searching for information. Interviewing is described as conversation with a purpose, where the purpose of the conversation is to collect information (Berg, 1998). The purpose of the interviews was to supplement the information found in the literature review and from the analysis of case studies.

A list of five frames of people we wanted to interview was developed. The frame consisted of a representative for each of the variables that we chose to investigate. Our liaison provided us with an initial contact in each of the following frames: a bioentrepreneur, a government official, a university researcher, and an individual closely associated with venture

capital. Our project advisor provided us with the contact information of a person opposed to biotechnology. The bioentrepreneur, or an individual who was closely associated to the business in the early stages of its development, provided us with the steps that needed to be completed in the start-up of the represented company. The government official informed us of the role of the Hessen government in promoting and encouraging start-ups and of some incentive programs for starting a new business. The university researcher had several experiences in cultivating initial scientific findings into the creation of several different, yet successful companies. We asked for the steps that were taken to develop each scientific discovery into a company. The individual with venture capital experience talked to us about the funding given to start a company from both venture capitalists and from the banking industry. The person opposed to biotechnology shared ethical concerns about the ideas and technologies that surround biotechnology applications.

The sampling technique we used was reference sampling. This involved asking each of our initial contacts to provide us with the names and contact information of other persons we could interview. With each new interview we conducted, references were requested from the person being interviewed. We were unable to follow up on the references obtained in the interview with the person opposed to biotechnology because of time constraints and the distance that they were located from the project center. This continued until the information from the interviews became redundant or the references were repeated. Glaser and Strauss call the criterion for judging when to stop reference sampling 'theoretical saturation.'

In The Discovery of Grounded Theory, Glaser and Strauss refer to the situation in which:

> ...no additional data are being found whereby the (researcher) can develop properties of the category. As he sees similar instances over and over again, the researcher becomes empirically confident that a category is saturated...when one category is saturated, nothing remains but to go on to new groups for data on other categories, and attempt to saturate these categories also.

In using the five frames, biases were reduced by cross referencing information and checking for both consistencies and inconsistencies. The information gained in the interviews was compared to the literature for the same purpose.

Because there was a potential for risk and disclosure, attitudinal and behavioral interviews were performed using a funnel design. The funnel design starts with the most general questions and moves on to more specific, sensitive topics. The reason for using the funnel design is to gain the respondent's trust. Once the respondent trusts the interviewer, the respondent will be more likely to reveal sensitive information. Because some information was difficult to obtain from the respondent, particular attention was paid to the Social Exchange Theory (SXT). "In theory, the SXT posits that the actions of people are motivated by desire to maximize benefits or minimize costs---in other words, any individual that is involved in a social exchange like a conversation, interview, focus group or survey, implicitly desires to maximize the gain from that exchange while minimizing its cost" (Jamison, 2000).

It was imperative to the success of the interview to have a good social exchange. In order to improve the exchange, we first performed a cost-benefit analysis. The costs of the interview to the respondent, including time, fear of disclosed information, or the fear that someone may find out that the respondent participated in the interview, were analyzed. In addition, the benefits of the interview to the respondent were looked into. In order for the exchange to be as successful as possible, we minimized the costs and maximized the benefits.

A successful exchange is one in which the respondent accepts the interview and participates willingly (Berg, 1998). In order to facilitate this acceptance, we rewarded the respondent. Some of the rewards were given by convincing the respondents that they were acting in an altruistic manner, were increasing social good by helping to aid others in the starting of their

own company, or from encouraging the feeling of self-gratification by letting the respondents know that the report was completed with the aid of their knowledge.

The Total Design Method was also used to develop the list of predetermined questions. The ideas were first brainstormed and then discussed. After the discussion, the necessary corrections were made. Then, the questions were pre-tested and corrected again as needed. This continued until the instrument was as clear and comprehensive as possible. This was very important when conducting interviews in Germany because of both language and culture differences.

The method for conducting the interviews was structured before the actual interview. The majority of the interviews involved four participants, each having a different purpose. The primary figure in the interview was the interviewee, or the respondent. This person answered the questions. The interviewer was the one who asked the questions and was responsible for guiding the course of the discussion. It was the interviewer's job to probe and investigate new topics. The third participant in the interview was the interviewer's assistant. The assistant's function was to take notes on the interview. Included in these notes were the recordings, specific notes on the discussion, and notes on the surrounding environment. Included in the physical description of the surrounding environment were the dress of the respondent, notes on the behavior of the respondent, and the physical responses to certain questions.

All of the interviews for this IQP, with the exception of the interview with the person opposed to biotechnology, were conducted in Germany. This increased the difficulty in preparing and conducting the interview. The fourth participant acted as a cultural liaison to the respondent. In the case of this IQP, the liaison had an understanding of both German culture and German language. In some cases the liaison arranged and set up the interviews with his colleagues or the interviews with requested respondents. The reason for this was the liaison's knowledge of the

cultural practice of scheduling and arranging interviews. The cultural liaison also acted as the translator during the interviews in which the respondent did not speak English.

In two cases, five members were present at the interview. In these cases, there was the respondent, the interviewer, the recorder, the liaison, and the interviewer's assistant. This individual aided the interviewer in seeking out and exploring new topics. This individual allowed the interview to proceed as normal and asked any questions that he had after the primary interviewer had finished asking questions. In the interview with the individual opposed to biotechnology only the respondent, the interviewer, and the recorder were present. The reason for this is that it was not possible for the liaison to attend the meeting, and we were confident that his aid was not necessitated for this interview.

The types of interviews that were relevant to the completion of this IQP were the semi-standardized interview and the un-standardized interview. These methods are designed for the collection of information, but are implemented in different ways. The semi-standardized interview is the most rigid of the interviewing techniques that we used. The semi-standardized interview involves the implementation of a number of predetermined questions and special topics (Berg 1998). These questions are asked of all the interviewees in the same order. The semi-standardized interview gives the flexibility of an improvisational, non-standard interview in conjunction with some of the defined structure of a standardized interview (Berg 1998). What this means is that should an interesting or valid subtopic surface, the interviewer has the freedom to leave the outline to investigate the new topic. Berg suggests that not only are interviewers permitted to probe beyond the answers to the predetermined questions, they are expected to do so in order for the interview be to successful (Berg, 1998).

The un-standardized interview does not use a set of scheduled questions. This type of interview is conducted when the interviewer is unable to predetermine all of the necessary

questions beforehand. This type of interview is also used when the interviewer feels that some questions may be interpreted differently by different respondents (Berg, 1998). Un-standardized interviews were used to supplement the observations that were derived from the analysis of the case studies and from the literature review. The problem that stems from the free nature of the un-standardized interview is that it is often times impossible to analyze. Because there can be variation in the language and vocabulary used and interpreted by the interviewee, the results can be hard to code and analyze. For example, one word may have a particular meaning to one person and a totally different meaning to another. It is for this reason that cross-frame references are difficult. If German bioentrepreneurs used a word in one way and US bioentrepreneurs used it in a different way a culture liaison was consulted to clarify the meaning of the word. Our use of un-standardized interviews was intended to highlight and clarify points of background information.

In order to aid in the analysis of the interview, a tape recorder was used. Before starting the interview, the permission of the respondent was obtained under the knowledge that their confidentiality would be strictly maintained. The use of the tape recorder was favored over field notes and notes on the interview. The reason for this is that the assistant can inadvertently add bias to the notes taken by the use of paraphrasing.

To begin the analysis of the semi-standardized interviews, the tape recordings were first transcribed. During the transcription process, the questions asked were checked to make sure that they were understood and interpreted correctly by the respondent, and that the answers reflected this understanding. After one of the interviews, the tape was found to be unusable. In this case, the notes taken by the recorder were used in the analysis. The notes that the assistant took were based on the response of the interviewee and paid particular attention to any cultural translations.

Also in the notes of the recorder were any unusual or telltale physical signs such as long sighs or physical discomfort.

According to Berg (1998), there are five guidelines to follow when taking field notes. The first suggestion is to record keywords or phrases. The use of keywords or phrases helps to reduce memory erosion of the recorder by their memory-triggering effects. Berg (1998) describes memory erosion by saying "individuals vary in the extent and degree of accuracy with which they can remember, in detail, events and conversations witnessed during a field excursion." Essentially memory erosion is the inability to remember word for word a conversion or exchange. Memory-triggering effects are when a word or phrase causes the interviewer to remember parts or all of an exchange that he or she would not have been able to recall without the use of the key word or phrase. For example, a respondent said, "a business plan is crucial to the success of a company." The recorder couldn't write the whole sentence at the time due to the speed with which the respondent was talking. Instead, the phrase "crucial to success" was noted. Later, when transcribing the field notes, the recorder was able to recall that the respondent said, "a business plan is crucial to the success of a company."

A second technique that Berg (1998) recommends is to make notes about the sequence of events. "As researchers jot brief, cryptic notes, they should indicate their observed sequence of events: what occurred before the noted action, what was observed, and what occurred following this noted event" (Berg, 1998). In an interview, during which the tape recorder failed, the recorder took notes on the sequence of topics that arose. Afterwards, when the recorder reviewed the field notes, she was able to remember key points that had been mentioned before or after each new topic. This helped the recorder reduce memory erosion.

The third technique recommended is to limit the time that one is in the setting. In the case of interviewing, an inexperienced interviewer and recorder should try to keep the interviews

relatively short. In conducting our IQP, most of the interviews lasted between one and one and a half-hours. The use of the recordings helped to ease the burden on the recorder by allowing them to focus more on the actions and behavior of the respondent than on having to remember word for word what was said.

The time between exiting the field and writing up the full field notes is another area that needs to be addressed. "Erosion of memory begins immediately and progresses rapidly" (Berg 1998). Because of this, Berg (1998) suggests that the recorder transcribe the notes immediately after leaving the interview. Berg (1998) even suggests scheduling field sessions so that the notes can be written right after exiting the field. After each of our interviews the recorder began the transcription as soon as possible. For some of our interviews this time was less than fifteen minutes. In other cases, when the interview was located far away, the time was as long as an hour.

Berg's (1998) final suggestion is to write out the notes before sharing them with anyone else. The reason for this is twofold. First, telling someone about what was seen takes time. As previously discussed, reducing unnecessary time between the event and the transcription is of the utmost importance. Secondly, when describing the event to someone, the researcher may accidentally embellish the event. This contamination can flaw useful data. After our interviews, the recorder would type up the transcriptions before discussing them with the other members of our group. In most cases, the field notes were not discussed until after the interviewer finished transcribing the interview. This was done to insure that neither the recorder or the interviewer influenced one another.

Once the information from the interview was organized, content analysis was used to evaluate the content of the semi-standardized interviews. Content analysis is a systematic approach to quantitatively analyzing the data. In order to quantify the data, we counted different

elements of each interview. These elements included the number of certain words, the characters mentioned and their frequency, the number of paragraphs, the items discussed, and the themes that were discussed relating to the concepts of the five variables and their interactions with biotechnology start-ups. Along with the transcription, the notes from the recorder were used in the analysis of the interview. If the recorder noticed any unusual body language or detected an increase in the enthusiasm or discomfort level of the respondent, special care was taken to analyze the preceding passages and the answers or responses that followed. The reason for this is that a respondent can give the researcher an unspoken indication of his or her thoughts or beliefs through actions and behavior. Each of the interviews that we conducted fell into one of five different frames. Because each frame represented a different discipline in biotechnology, the strategy for content analysis of each frame was different.

For interviews where a bioentrepreneur was the respondent, the attitude toward all of the stages of development and those who were involved with forming the company were closely looked at. These interviews provided information about how and why they started their company, the steps they took to start their company, and aid they received from the university or from the government. To analyze these interviews we focused on the process that was used to create the company to see if it was common among all of the respondents and the various types of aid that each company received. Some ideas that were focused on are team generation, aid, idea generation, and business plans.

The government official gave us information on the ways that the government was aiding young bioentrepreneurs trying to start a biotech company. The official was interviewed for factual information but personal opinions about biotechnology were evident. These personal opinions were accounted for through body language and tone of voice. When using content analysis for this particular interview, the main points that were looked at were government aid

programs and changes that the government has made over the last few years. Legal jargon, aid (including financing), ethics, and restrictions were closely evaluated.

The university researcher discussed with us the phases of developing an initial scientific finding into a company. Focused on during this interview were the difficulties that one has to go through when trying to start a biotech company. Here we also analyzed the context that others involved with the start-up were used. The university researcher is concerned with patents, government aid, and private institutions. In addition, feelings toward the network they are involved in and university-technology transfer were observed.

The member of the financing community gave facts about what a start-up company needs in order to be funded. The analysis of this interview focused on what venture capitalists and bankers see as the essential components of a successful start-up. We looked for the negative and positive points in the discussion to see what types of start-ups will or will not be funded and why or why not. Management team, intellectual property, seed money and business plans are important ideas that needed to be analyzed in this frame.

The interview with the person opposed to biotechnology proved the most difficult and interesting to analyze. In this interview, the respondent had very strong anti-biotech feelings, which showed in both the responses given and body language used while being asked questions and while answering them. For this interview, the adjectives surrounding the word *biotechnology* were very important in the analysis of the interview. The common thread analyzed in this interview was the negative feelings both the respondent and the organization represented by the respondent have toward biotechnology.

Table 2: Frames and Information Obtained

Frames of Interviews	Information obtained
Bioentrepreneur	Stages of development, how and why company was started, aid from university or government
Government Official	Types of government aid, changes government has made and will make
University Researcher	Phases of developing a company, difficulties in starting a company, university technology transfer
Member of Finance Community	What start-ups need to do to get funded, essential components of successful start-ups
Person Opposed to Biotechnology	Negative feelings towards biotechnology and their reasons

Once the analysis for an interview was completed it was compared to other interviews first in the single frame, and then with all other frames. This was done to account for any information unusable due to biases.

For the un-standardized interviews, a different approach was used to extract the useful information than was used for the semi-standardized interviews. The interviewer had a predetermined set of ideas or topics that he or she would like to discuss with the respondent. Some ideas came from areas of the literature review that were unclear or from information from other interviews that needed to be corroborated or explained. As the respondent answered the questions, the interviewer and the recorder took notes on what was being said. If the respondent agreed or disagreed with a specific topic, it was noted and the reasons for these opinions were asked. In addition, the interviewer would ask the respondent what they thought of the ideas that were developed as part of the IQP. This was done in order to gauge the progress we, as a team, had been making and to see if the path that the project had taken was still on the correct course.

3.2 Case Studies

The objective of using a case study was to assess the impact of five major variables on biotech start-up companies. The variables that were chosen as the focus of the case study are the role of the university, the role of the government, the role of the industry, and the role of public perceptions and cultural attitudes in the starting of a biotechnology company. Several different sources of current literature provided a good outline of the way that these variables affected companies in the US. Also in the literature was that the German start-up system was different than the start-up system of the US. For this reason, the theory that these five variables also influence German start-up companies was created from the literature review. This theory was then applied to German businesses to develop an understanding of how these variables affected the German companies. The case study was comprised of four German Biotechnology Companies.

The case study technique that we used was the explanatory, multiple, embedded case study (Yin, 1994). An explanatory case study was conducted because the goal of the case study was to explain the influences of the five variables and the steps needed to start a new company. Descriptive and exploratory methods were not chosen because the goal of the case was not to investigate or describe the actual companies, but rather to explain how the variables affected them throughout their development. The case study was a multiple case study so that each company could be analyzed separately. What this means is that each company was viewed and analyzed as a separate case. This allowed the theory to be applied to each of the companies on an individual level. However, the complete multiple case conclusions were drawn from analyzing the single cases as a group. This method was chosen because the companies had slight variations in their history. By analyzing the individual case first, the differences could be highlighted and noted. A single case study for all of the cases would mask some of the differences by blurring all the data

together. The small differences are believed to be extremely important and the method was chosen so that they could be easily detected and noted.

Each single case was analyzed focusing on three embedded sub-units (Yin, 1994). Embedded sub-units are distinct pieces of each single case. The three sub-units that were chosen for analysis were the business, science, and legal aspects of starting a company. It was believed that each of the sub-units played a very different and distinct role in the starting of a company. The ways that the five variables influence a company is by affecting one of these three areas. The reason for choosing to analyze three sub-units was very similar to the reason for choosing a multiple case study. Since each sub-unit was believed to function different than the others, it was necessary to separate them in the analysis of the single case. By separating the sub-units, the differences were highlighted whereas analyzing each company as though there were no separate pieces would have caused the differences to be covered up. By breaking the single cases into the embedded sub-units, a more precise and focused analysis could be completed. The information on the sub-units was drawn from an analysis of the data collected.

In order to complete the case study, we attempted to collect three types of data. Interviews, documentation, and archival records were to be used to draw conclusions on the various sub-units. The reason that three types of data were chosen was the need to be able to triangulate the findings of the data as a whole. Triangulation is the process by which the biases of the individual sources of data are reduced through comparisons with the other sources of data. By using the method of triangulation the conclusions of the case study are much more likely to be convincing and accurate because the results are based on multiple sources of data (Yin, 1994). The interviews were of people who played a major role in the starting of the company studied. When possible, the actual entrepreneur of the company was interviewed. Documentation refers to letters, memoranda, agendas, administrative documents, formal studies of the business, and

other similar items. Archival records are composed of service records, organizational records, lists, survey data, or personal records.

Obtaining the documentation was accomplished by asking the target to provide us with any information that they could. During the initial contact phase, we requested that the specified company be prepared to provide us with as many forms of archival records and documentation as they could. This resulted in convenience sampling of the various data types. What this means is that we had to use what the companies could provide us with, which, in turn, means that the information obtained was biased in favor of the company. Often the company produced the information so it contained only information that cast a positive light about the company. Another drawback that arose was that it was not possible to gain archival records from companies. The information contained in such records was thought too important to reveal by all of the companies.

The analysis of the gathered information was performed in a similar manner to the analysis of the interviews. Once the information for a given company was collected, it was separated into the respective categories. The analysis of the documentation was done in order to separate the relevant information from any unneeded information. For our case, relevant information is defined as information that pertains specifically to the legal, business, or science aspect of the development of the company.

In order to determine if textual information was relevant, for instance a company pamphlet, we used several keywords for each of the sub-units to detect the underlying themes or ideas. Once a theme was determined, we analyzed the purpose and the goal of the theme using the previously mentioned content analysis techniques. If the theme was referring to one of the sub-units, the information was extracted and noted. Another form of documentation that was analyzed was previous studies on various German start-ups. These studies were conducted by

well-respected firms in the industry and were referred to us by several of the companies and individuals that we spoke with. Information on where they got their start, product information, and a detail of the company and its structure was obtained from these sources.

The results from the documents provided us with an idea of the history of the company. Included in the history is where the company came from, i.e. from a research institute or from a university, any aid that they received, the initial formation of the management team, the initial business strategy, and any later adjustments to the management team or business strategy. This information was then compared and contrasted to the interviews to ensure that all forms of data agreed.

Interviews were chosen as a data source because they offer both insights into the case study and can offer sources of corroboratory evidence (Yin, 1994). The methods for the interview followed the semi-standardized format. This allowed for a set of questions that could be analyzed across the cases to be asked. It also allowed for the probing of new or interesting topics. The strengths of the interviews related to a case study are that they are targeted and insightful. A targeted interview is one that focuses directly on the case study topics. An insightful interview is one that provides perceived casual inferences (Yin, 1994). By conducting our own interviews, we were able to ask the specific questions needed in order to gather data to support or contradict our theory. The interviews focused on the steps needed to start the company and the way that the five variables affected these steps. The questions were based on the information that was gathered from the literature review and, in the later interviews, on what other entrepreneurs said in their respective interviews.

The weakness of the interviews is that there can be biases due to poor questions. This is called response bias and is due to poor recollection, and reflexivity, in which the interviewee tells the interviewer what he thinks the interviewer wants to hear. The questions were pre-tested in

order to clarify poor wording or interpreted meaning. Responses were actively pursued using colleague recommendations to help convince the desired respondents to participate in the interviews. In order to help eliminate reflexivity, the funnel design was used in the conduction of the interview. The use of a tape recorder and research assistant aided in making the recollection of the data as thorough and accurate as possible.

Documentation was selected as a source of data for its usefulness in corroborating other evidence. "Documents must be carefully used and should not be accepted as literal recordings of events that have taken place" (Yin, 1994). Careful analysis includes comparing the other sources of information to the documentation to ensure that the data included in the documentation is accurate. In addition, content analysis was conducted on the documentation to help ensure the data gathered from the documentation was as accurate as possible. Documentation was used to corroborate the evidence from the interviews. If any discrepancies occurred, further inquiry on the topic was conducted. The documentation that was gathered on the selected companies came from several places. The company either provided the documents, they were obtained during the interviews, or they came from outside sources in the event that previous research was done on the company.

The strength of documentary data is that it is stable, unobtrusive, exact, and offers broad coverage. Stability refers to the fact that the data can be reviewed repeatedly. Unobtrusive data is data that was not created as part of the case study. The documentation also contained exact information on names, references and details of events. Finally, documentation covers a long span of time, many events, and comes from many settings. These traits give documentation its broad coverage.

The data collection followed three principles to ensure that it was reliable and reproducible. The principles included using multiple sources of data, creating a case study

database, and the maintenance of a chain of evidence (Yin, 1994). Multiple sources of data were used in order to increase the reliability of the case study. For our case study, the data came from documentation, and interviews. Creating a database aided in the internal validity of the study and aids in reproducing the study. The database was created as a place to store only the raw data. The data included the content analysis from the various sources of data. For example, if a company had a pamphlet that referenced some of the steps that the company had to undergo to ensure its own success, only the relevant information was extracted from pamphlet. The data was then entered into the database as raw data and references in the database indicated where the data came from. The data is not stored with any analysis or reports of the researcher. The reason for this is to make it easy for an independent, secondary analysis by another researcher. Since the data is stored free of any analysis, the work or ideas of the initial researcher will not bias those of the second researcher.

Maintaining a chain of evidence is the third principle that was followed. Maintaining a chain of evidence refers to documenting the derivation of evidence from the research to the conclusions of the case. This was done through specific referencing to the case study database. The database shows the evidence being referenced and highlights the circumstances under which the evidence was gathered. The circumstances are consistent with the procedures for the data collection. This allows another researcher to review each step of the case by giving them an easy method to go from the conclusions, to the data, and finally, to the procedures used to collect the data.

For this case study, the conclusions drawn from the research are based on and in reference to direct information from the database. In turn, the database includes a reference for every piece of data indicating where it came from and how it was obtained. These references are in compliance with the predetermined data types and with the methodologies that were set forth.

This allows our sponsor and other potential researchers to go from our research to our conclusions and vice versa.

The strategy for the analysis of the data followed a "reliance on theoretical propositions strategy" (Yin, 1994). The objective and design of the case study was based on propositions drawn from the literature review. Following the theory throughout the case study aided in focusing on the most important data and helped us to decide which data should be ignored.

In order to complete the analysis of the multiple case conclusions, we used the technique of pattern matching. "The pattern being matched is the key cause-effect pattern between independent and dependent variables" (Yin, 1994). Pattern matching is the process by which the researcher attempts to find a pattern between the various single cases. In the case of this IQP, the pattern that we found was that each company went through similar steps in their initial formation. We arrived at this conclusion by noticing the trend in a few cases and then matched the pattern to the rest of the cases during the comparative analysis. The whole purpose of the case study was to determine the necessary steps, the order they need to be completed in, and the role that the five essential variables played in the starting of each of the companies. Enough single cases were analyzed to ensure that the resulting data closely matched what happens in the business world.

Before the multiple case conclusions could be drawn, the individual cases needed to be analyzed. The single case analysis was conducted through a process of working from the bottom up. The embedded sub units were analyzed separately first. The results were then analyzed at the single case level. "The patterns or explanations for each single case may then be compared across cases, following the replication mode for multiple cases" (Yin, 1994). The conclusions drawn from the cross case analysis then became the conclusions for the overall case study.

3.3 Analysis of Greenpeace Web Pages

To complete the investigation of ethical issues and public concerns surrounding biotechnology in the US and Germany, we looked at three of the Greenpeace web pages. The content of the International, US and German web pages were analyzed separately. The analysis was done to determine the main concerns shown by Greenpeace in each of the selected countries. These included concerns from their own country and of the other country. The international page was used as an overview of biotechnology concerns worldwide, with particular focus on Germany and the US. The comparison of these three pages allowed us to logically conclude the main concerns Greenpeace has about biotechnology. The other factor that was looked at was whether or not these concerns were portrayed differently in each country.

To analyze the Greenpeace International page we first went to the genetic engineering link. The elements that we looked for on this page were headings and graphics. The main headings and sub-headings were looked at to see what style was used (bold letters, capital letters) and also to analyze the connotation of the words that made up the title. Under the sub-heading, there was a picture of a holding tank with a large "X" on it (see Appendix C). To get a better idea of what was in the picture, we enlarged it by clicking on the link. The enlargement gave a more lucid picture of what was going on and it provided a caption to explain exactly what was in the picture. After this was done, we returned to the main page for genetic engineering.

The next part that was looked at for analysis was the links to four individual categories: genetically engineered food, artificial organisms, patents on life and bio-safety protocol. We felt that because these were on the main page and divided into sections that the titles on these pages were important to look at. Once the titles of the four links were analyzed, we returned to the genetic engineering main page. The last part of the Greenpeace International web page looked at was the press releases section. We were able to access these directly from the genetic

engineering main page. This link had one hundred thirty six titles of press releases from 1996 until the present.

To begin our analysis we used the "find function" of Microsoft Word. Using this tool allowed us to locate words and phrases and determined the frequency with which they were used. The purpose for looking at these titles was to determine how genetic engineering is portrayed in both Germany and the US, the actions that Greenpeace has taken against genetic engineering and the products and companies that have been the focus of concern. The first search that was done was for Germany and the US. We looked at verbs and adjectives associated with each country and the amount of titles that they were in.

Next we searched for Greenpeace and looked at the surrounding words, particularly the verbs. The verbs are important when looking at the actions that Greenpeace has taken with respect to genetic engineering. The final aspect of the press releases titles that we looked at was the companies and products that Greenpeace opposes. To do so, we searched for words that were used with company names and then for the associated products. In doing so, we were able to determine if Greenpeace International had a positive or negative feeling about them.

The next page that we looked at was the Greenpeace USA web page. The same content was looked at for analysis but arriving at the actual content was different. Again, it was necessary to go to the genetic engineering link on the main page. Once at the main page for genetic engineering, we looked at all of the headings and sub-headings on the page. After the main heading of "genetic engineering," four sub-headings contained different areas of information. We did not use these for our analysis because these sub-headings were descriptions of the information that could be found in each of them.

The next aspect we looked at was graphics. The link from the Greenpeace USA main page to the genetic engineering page contained four different pictures, which changed every five

seconds (see Appendix C). We considered these very important because this was the first idea that the reader had about genetic engineering. These pictures were analyzed separately to see how they relate to Greenpeace USA and genetic engineering.

The last section we looked at was the press releases section. This required more effort to obtain the titles of the press releases from the last four years than for the Greenpeace International page. The articles were not all together so we first had to search for articles pertaining to genetic engineering. This search turned up thirty-four matches from the media center. The titles of these articles and the dates they were published were not given in the search so we then had to click on each of the individual thirty-four links for this information. From this, we were able to obtain the article's title and the year it was published. We then realized that the search contained articles from 1996-1999. To get the titles from the year 2000, we had to return to the genetic engineering page to the section on recent news. There were twelve articles in this section and the same process of clicking on each link was performed to obtain the titles and dates.

We first read the titles a few times to familiarize ourselves with things that were common to multiple titles. We realized that we neglected to count other important aspects in the titles when we analyzed the Greenpeace International web page. In addition to counting verbs and adjectives surrounding the key words that we searched for, we also needed to count characters, concepts, and themes. After completing the analysis of the Greenpeace USA web page, we returned to the Greenpeace International page to analyze the missing information. The rest of the analysis of the press releases was done the same as for the Greenpeace International page.

The final page that was analyzed was the Greenpeace Germany web page. The difficulty in analyzing this web page was that it was entirely in German. To overcome this obstacle, we used the site http://translator.go.com. This site allowed us to enter the URL of the web page and translate it to the desired language. Once the translation was completed, we proceeded in the

same manner as in the previous two Greenpeace web pages. To get to the genetic engineering page, we first had to go to the "Themen & Kampagnen" (themes & campaigns) page and go to the link for "Gentechnik" (genetic engineering). Like the Greenpeace USA page, the headings and sub-headings described the information to be found in each section. There was a large picture at the top of the page showing disapproval of patents on life. This was an important issue so we decided to add this aspect of genetic engineering into our counts of the press releases.

After we completed the same counts for Greenpeace Germany that had been conducted for Greenpeace International and Greenpeace USA we returned to the Greenpeace International and Greenpeace USA web pages to count the number of articles dealing with patents. The press releases from Greenpeace Germany were the last to be analyzed. To obtain the titles of the publications from 1996-the present, we needed to look at three different links: news, up-to-date, and the homepage about genetic engineering (located under the title "current ones background"). These publications were put into a word document with the most recent titles first. The same information was analyzed for this page as for the other two.

Once the pertinent information was extracted from the three pages, we started our comparison. The counts from each of the pages were placed in a chart. The chart contained the words, themes, concepts, and characters, the frequency they were used in the titles, and the percentage of use in the press releases section as a whole. In looking at the percentages for each of the three pages separately and then together, we were able to compare the data. The reason for doing this was to see if the percentages for each of the counts for each of the pages were similar. To make the comparison between the three pages, we first made conclusions about the individual page and then compared them to each other.

Chapter 4-Results

The following chapter presents the results that were obtained through the completion of the methods put forth in the previous chapter. First, an analysis of the raw data taken directly from the interviews, case study, and web page analysis is given. This is followed by a comparison between the variables that provide the framework for starting biotechnology companies in the US and Germany. The comparison is based on the data obtained from the use of the methods and the literature review.

4.1 Interviews

These interviews served to provide us with information from a government official involved in biotechnology start-up initiatives, a university professor who has released biotech start-up companies from his lab, a financial expert who deals with biotechnology financing, and a person opposed to biotechnology. Since our project focus is on the variables that provide the best possible framework for start-up biotechnology companies, we used these variables as our concepts when analyzing these interviews. Three of the concepts we looked for were the roles of university, government, and industry in aiding and developing biotechnology start-ups. The two other concepts we looked for were the business aspects of start-ups and the public perception and cultural attitudes that influence the starting of a biotechnology company.

When analyzing the role that the German government plays in funding biotech start-ups it was mentioned twice that government aid differs from state to state in Germany. For example, the Bavarian government provides start-ups with initial seed funding but in Hessen, the government does not provide this type of funding. This seemed to be a downside to starting biotech companies in Hessen and the respondent seemed very unhappy with this fact. Due to the absence of seed funding, young companies must search for financing elsewhere. Some forms of financing that were mentioned included private financing from friends, family, private investors,

and venture capital. If a company has an extraordinary idea then they can receive venture capital on their idea in the early stage. It was explained that as one obtains more funds and their idea develops, their ability to create credit or obtain loans increases.

A second theme we came across was the aims of government start-up initiative programs in Germany. The German government now sponsors a number of biotechnology competitions. These include the Science4Life business plan competition, the BioRegio, BioChance, BioFuture, and BioProfile competitions. The one program we gained first hand knowledge of attempts to bring business and science experts together to form a personal network of contacts. The aim of the competition is to provide skills and knowledge for small companies in order to provide a better biotechnology network in Hessen. This program provides start-ups with seminars on how to write business plans and experts give comments and advice on them as well.

We were told that the government hopes to create new jobs through these initiative programs. Another aim of the government is to teach scientists in universities that they are allowed to create ideas and found new companies. The success rate of the program we learned about is very high. Of the forty-six entries that were submitted in the program last year, twenty-three of them were turned into companies. Because the competition was recent, we were unable to determine how many of these companies are still in business.

One theme we came upon regarding the concept of the industry role was how heavily the pharmaceutical industry relies on start-up biotechnology companies. We were told that fifty to sixty percent of pipeline products are coming from the biotechnology industry. Pipeline products are described as products that are waiting for approval and have a good chance of being developed into a marketable product. The cooperation between university and industry was stressed and was compared to the relationship that the automobile industry has with its producers. Small biotechnology companies are producing patents and products, while the big pharmaceutical

companies are putting the pieces together and selling them. This is becoming a more intensive way to cooperate, with the early research and development being done in small start-up companies.

When analyzing the role that universities play in promoting start-ups we learned that universities provide a variety of sources of aid to start-ups. The start-ups we analyzed were allowed to use university laboratories and equipment for their first two years. They also received legal advice, access to computers and advice from professors. Being in the university also allows Ph.D. candidates to help in research projects for the company. According to one respondent, having personnel that do not need to be trained is a big advantage for a young company, should these students choose to work for the company after graduation.

The benefit that the university receives from promoting biotechnology start-ups was a second theme found within the concept of the university role. Since German universities are government funded, their situation regarding start-ups is very complicated. The benefit of these start-ups is the reputation the university receives from them. Start-ups also help in finding jobs for students leaving the university, and help widen the overall scope of education by allowing for students to work in their labs. The respondent felt that eventually German universities are going to become bankrupt and will eventually have to hold shares in biotech start-up companies coming from their laboratories. As the cost of education rises, the German government will eventually no longer be able to provide German universities with the funding they need. Because of this, he felt that German universities will become privately funded and will adapt the US system with regards to taking shares in biotech start-ups and reaping the financial benefits that they provide to the university.

The first theme we came across when analyzing the concept of business strategies was the role and aims of venture capital in Germany. By looking at the adjectives to describe venture

capital, we found that the role of venture capital in the biotechnology industry is important and there is more money available than there are good investments. If someone has a good idea, there is no problem with getting funding for it. DWS, the venture capital division of Deutsche Bank, had a biotechnology fund that they had to close because they did not have enough companies or ideas to invest in.

It was also explained that the aim of venture capitalists in Germany is much the same as it is in the US. They look for high returns and have a portfolio with about twenty percent of their money invested in high-risk investments like biotechnology. They usually expect a fifty to one hundred percent return per share and focus on the exit strategy of the company. In Germany, we were told that the exit strategy influences the venture capital seed funding. The creation of the Neuer Markt (New Market) has allowed venture capitalists to generate the returns they expect and has provided the general conditions for a booming venture capital market in Germany. Two of our respondents told us that Germany now has the largest market regarding seed phase investments in Europe, second to the US worldwide.

From our interview with the financial expert we found that banks in Germany do not invest in the seed or start-up phase of a company or idea. Almost every German bank grants loans in the production or marketing phase of a company. They offer public subsidized loans as well as capital transfer, management transfer, technical transfer and help with a company's business plan. Deutsche Bank has a division of innovation teams that consist of bankers and experts from the pharmaceutical industry. One problem that was mentioned is that bankers have trouble understanding the technology that is trying to be financed. Having an expert from the industry is very important in order to get a better understanding of the technology.

Another theme relating to the business consideration concept was the importance of The Business Angels Network in Germany. This network was mentioned repeatedly by all of our

respondents. This is a network of experts in the fields of science, law, and business, who provide crucial advice to young companies free of charge. This free advice is given to the company in its first year and is important to the company since it can not afford the high costs of such advice from outside sources. Business Angels also grant private equity to a company. However, their knowledge and their network of contacts was stressed as more important than their investment because often times companies fail not because of a lack of money but because of a lack of management, knowledge of the industry, and contacts. Business Angels provide the desired combination of these factors.

The final theme that we found relating to the concept of business considerations was what investors look for when financing a start-up company. The financial expert that was interviewed told us that the most important aspect of the business plan is having a market potential or a special niche. He mentioned that it is also good if a start-up is able to generate parts of an existing market or if their idea is better than the existing one. Another very important aspect is the management team. The importance of the management team of a start-up company was mentioned by all of the respondents. There are a few important positions that we were told of in the company's management team. First the CEO, or person who is in charge of the technology needs to be on the management team. The CEO provides the knowledge to prove the technology is worthy of receiving funding. The team should also consist of the chief financial officer (CFO), and someone involved in the market analysis or the marketing of the products the company is focussing on. The investor told us that most management teams just focus on the technology and neglect the financial and marketing aspects, which is what investors are looking for in a company or idea.

In our interview with the university professor, we came across the process of forming a team to start up a biotechnology company within the university. The university professor

stressed the importance of building up a scientific competence in an area that has a potential market in the pharmaceutical industry. The team, which was mentioned to be the most important aspect three times, starts with the CEO, who is usually the scientist. From here the company is started. He mentioned that lawyers or business experts sometimes join the team. However, it was explained to us that unlike some US entrepreneurs, German entrepreneurs have the desire to become independent and do not usually like to form partnerships with members outside the university. The reason given for this was that the entrepreneurs all wanted to maintain their companies' independence.

Our respondents also discussed cultural differences between the US and Germany. Two of them mentioned that if you fail trying to start your first company than you are marked a "loser" in the German business world. They then explained that it is virtually impossible to start another company. This phenomenon is a common reason that Germans are hesitant or cautious to start companies. They claimed that this seems to be slowly changing but is still a big problem in Germany.

We were also told that Germany has historically not been a stock market culture. We found that, unlike Americans, Germans receive about eighty percent of their last year's salary as social security payment after retirement and do not need to bother with investing in stocks to ensure their future finances. One of our respondents told us that this seems to be changing with the Neuer Markt now in place. He mentioned that Germans between the ages of twenty-five and forty-five have started investing in start-up companies, resulting in a boom of the stock market over the last three months.

Public perception of biotechnology was the last concept that we focussed on. These issues are important in understanding why the German biotech sector was slower to start than in the US. To verify that the information on this topic in the literature review was accurate, an

interview was conducted with an expert in the field of animal welfare and human to animal relationships pertaining to the law. The topics covered in this interview were the differences in public opinion in the US and in Germany, the effect of educating the public on the subject of genetic engineering, and initiatives that have been developed to restrict the biotech industry.

The main point of looking at this aspect of biotechnology was to see what the differences are in public perception and ethical concerns about genetic engineering in the US and Germany. In the literature that we read, the author often made comparisons between the US and Europe, therefore the assumption was that European countries could be grouped together when talking about this subject. During this interview, we learned that European countries are divided in their perception of biotechnology. The countries where the majority of negative public perception was observed were Great Britain, Germany, Austria, and Switzerland. To make comparisons in this interview it was necessary to focus on these countries.

Opinions about genetic engineering are not the same for all facets of the industry. The primary concern that has been shown is about genetically engineered foods. This application of genetic engineering has received a great deal of criticism in Germany and it is becoming a concern in the US. A respondent from one of the companies we interviewed also offered this information.

The respondent acknowledged that public awareness and criticism in Germany is greater than in the US. Possible reasons for this difference were discussed. The first potential cause that he mentioned was the cultural differences in the way of thinking about this subject. In Germany, the concept of good and bad has been instilled in students such that they have considerable concerns about ethical issues. Another possible reason why the German public is more critical and cautions was historical factors. Due to the sensitive nature of this subject, he was somewhat hesitant to offer this rationale. Poor decisions made between the years of 1933 and 1945 have

caused Germans to be sensitive about giving worth to life. The question of creating new life that is supposed to be "better" in some way worries many Germans. The public is skeptical about their scientists deciding what life is good and what life is bad. The concept of good and bad and how it relates to the US culture was not discussed.

One idea that was proposed was whether or not it was only the biotechnology sector that took longer to develop. The respondent mentioned that if statistics had been looked at from other fields of technology, we might have found that all the fields were behind the US in the their developments. This would cause one to think that there really was no special reason for the biotechnology industry to be slower to start. It could be that the technological growth as a whole started slower in Germany.

A main issue that critics find it difficult to agree on is the correlation between public awareness and public acceptance. In the literature we read, some say that the more educated a person is, the more likely they are to accept genetic engineering. Others disagree and say that persons more educated on the subject become more critical. The opinion given in this interview was that, as people become more educated, they become more critical. The rationale is that less educated people are easier to manipulate. The genetic engineering companies can easily tell an uneducated person that there are not risks associated with their products. An educated person on the subject will be able to question what they are being told.

The main themes that were evident in the interview were the relationships between the government, public, industry, and organizations opposed to genetic engineering. Differences in their perceptions of the role of genetic engineering in society has fueled arguments and also caused them all to drift into different directions. Ideally, all of these parties could develop a common bond and work together to satisfy everyone involved. The problem stems from the fact that they are all interested in their own needs and will only unite when it will benefit them.

After reading through the transcription of the interview, we performed content analysis to determine the applicable information from the interview. The relationship of the various groups involved in genetic engineering was counted to see how often each was mentioned. The group that was mentioned the most was the law. This is most likely because the person being interviewed has a background in the law. The government, public and industry were all mentioned approximately the same amount of times. The majority of the time the relationship between two or more of the groups was the topic being discussed.

Characters were counted next to see in what context they were being talked about. The most obvious characters discussed were US, Germany and Switzerland. These countries are being treated as characters because the discussion was based on what the country was doing or what was being done to the country. Germany and the US are used frequently because these were the two being compared. Switzerland was an important character because the respondent in the interview works on this subject in Switzerland. One other reason for the large number of times Switzerland was spoken of is that the ethical issues and public opinions are very similar with Germany.

Animals and creatures were also frequently mentioned. These were mostly used in describing the concepts of animal rights and the dignity of the creature. The respondent's specialty is animal rights in the law. This was an issue repeated throughout the interview. The words used to describe the way animals are treated were pain, suffer, kill and fear. These words are often used to evoke sympathy to whatever cause is being discussed. The dignity of the creature is a concept that people and organizations working to protect life want the government and industry to consider.

Two characters who did not have a direct relationship to genetic engineering in either of the countries were "friends" and "brother." Much to our surprise, people from other groups

involved with genetic engineering were referred to as friends. The importance of this issue in countries smaller than the US, such as Germany or Switzerland, is that people are always in contact with people outside of their field. He mentioned that this is unlike the US, where it is too large to frequently interact with people who are not involved in the same things. When talking about his brother, the respondent used him as a source of knowledge of what is going on in the US. As a person who has lived in both cultures, his brother has been able to relay the differences in culture and the way of thinking.

The primary item that was discussed was the gene-protection initiative that was developed in Switzerland. This initiative was created to restrict genetic engineering for the sake of animals and plants. There were many organizations involved directly with this initiative and others that worked on it indirectly. Despite the efforts of the group, the public did not support the initiative and a change was never made to the Swiss constitution.

Words used to describe the actions that have taken place between groups were also counted. When talking about the initiative that was written to protect animals and humans from genetic engineering, it was often said that the battle was lost. This "battle" was between the group who wanted to implement the initiative and change the constitution and the public who was against it. In the end of this "battle," the initiative was not implemented so the supporters felt as though they lost. During the time where the decision to change the constitution was going on, there were often debates and arguments between the two sides. These words are important because they show that the two sides were aggressive in conveying their opinions.

During the interview, the respondent also discussed the relationship between the government, industry, and public. In his opinion, the public does not feel respected by the government who is working with the industry. This situation has caused the public to be on one side and the government and industry on the other side. From the way this relationship was

described, it was clear that the respondent had strong feelings about the government not respecting public concerns.

When talking about the attitudes the public has about genetic engineering, the following words were used: criticism, skeptical, concern, perception, and awareness. These were grouped together because all of them cause a person to think that a negative opinion is being conveyed. When a person is critical or skeptical about a certain issue, they do not trust it and question it. The perception of the public in Germany is that concern must be shown because this is a delicate issue and should not be taken lightly. Public awareness from all sides was also discussed. The idea here is that the public should make themselves aware of what the facts are and what each group represents.

The last concept that was looked at was the relationship between risk and culture. This concept was important to look at when trying to understand the differences in ethical concerns and public perception in the two countries. The information on this concept in the literature review was used to make comparisons with this interview. This comparison is discussed in section 4.4.

4.2 Case Study interviews

The focus of the case study interviews was on the actual bioentrepreneurs or individuals that were closely associated with the target company from its beginning. The fundamental questions asked during the interview were standardized, meaning that the same basic questions were asked of each respondent. When new or interesting topics arose, the interviewer was free to explore with un-standardized questions. The fundamental concepts used in analyzing these interviews were the five variables consisting of the university, government and industry role in aiding start-ups, the business aspects of starting a company, and the public perceptions and cultural attitudes surrounding a start-up.

The first section of questions was intended to obtain background information on the company that was being interviewed and on the respondent. From these questions, we learned that all of the respondents that we talked to had a University or Technical University background. The backgrounds of the respondents were diverse, with backgrounds in the PR field and the science field being present. All of the respondents were with the companies for at least two years and either had close contacts with or were one of the founders.

Once the background of the interviewer was established, the initial steps taken by the company were discussed. During these discussions, the concept of the university's role in a biotechnology start-up came up many times. The most common theme that surfaced was that of the university providing low cost lab space, equipment, and in some cases, office space. The theme was mentioned eight times and all of the respondents exhibited signs of being pleased by this fact. In one of the interviews, the respondent mentioned that without the low cost lab space and equipment from the university the company would not have been able to start due to the high overhead costs. In another interview, the respondent mentioned that the university setting offers the young entrepreneurs a comfortable, familiar setting while they start to get a feel for the business before they grow independent.

Another theme related to the role that the universities play in helping to form new companies that appeared quite often was that access to the university network is extremely important. The reason that the respondents gave for this is that the professors have access to industrial or other scientific sources that young entrepreneurs do not. These networks allow the entrepreneurs to get advice, find industry or university collaborations, and help them get a feel for their market niche and the plausibility of both their company and their ideas.

The third common theme that appeared in our interviews was actual aid given to the young companies by the university. The type of aid that was mentioned came in two forms,

direct monetary help or university collaborations. Monthly stipends were given to one of the respondents as a form of project funding to cover the monthly expenses. Another of the respondents indicated that they received aid in the form of a university contract when they first started. This contract was extremely important to the young company. It was stated that this contract is what allowed the company to start doing practical research in the first place.

Another theme that came up was that unlike earlier in the industry's history, university professors will have two or three start-ups working in their labs. The respondent mentioned that when the company he represented started, this was not the case. This statement was said in a manner that conveyed the impression the respondent was disappointed that he did not have this advantage when the company first started off, indicating that it is an important and necessary change that the university has undergone. After mentioning this, the respondent began to discuss the history behind universities aiding start-ups. At first the universities did not offer any aid or help to those looking to start their own company. However, there came a time when more students were graduating than the industry could accommodate. The response to this by both professors and the universities was to encourage the young graduates to start their own companies and make a need for themselves.

One of the less mentioned themes in some of the interviews was the theme of universities acting as incubators. This topic came up in one interview and was mentioned several times. The respondent stated that the university incubator was common in start-ups today and was prevalent at the time that several of the older, more established companies started-up. The incubators offer an environment where different entrepreneurs and professors can meet and discuss the industry, what they are doing, and even offer advice to one another. Also commonly discussed in these incubators is the science that is being done. The respondent was quick to point out that the actual core sciences for the different companies were not discussed, but rather the general ideas and

trends that the companies were working on. This allows the members of the incubator to stay up to date and current on different aspects of new scientific developments.

Not all of the themes related to the concept of the university's role were positive. It was mentioned in all of the interviews that at the time of conception for all of the represented companies the universities were in their early phases of giving aid. All of the respondents mentioned that more aid from the university would have made the process easier. One of the youngest companies mentioned that it was still trying to obtain aid from the university but was having a hard time. Another common theme was that the university did not offer aid or advice on the intricacies of starting a company. For example, one respondent mentioned that frequently the science-oriented entrepreneurs do not have the necessary business knowledge at the onset to start their company. Two other complaints about the university that the respondents had were that the university did not aid in the obtaining of patents, legally or financially, and that no aid was offered during the construction of the business plan. Although two of the respondents indicated that learning to construct the business plan independently was important, they would have liked a little more help from the university.

The second concept that was commonly mentioned when discussing the initial start-up processes of the companies in all the interviews was the role of the government in each of the different start-ups. Two of the companies mentioned that at the time of their formation there was no government aid available to start-ups. One of the respondents used the term "unheard of" when describing government aid to young biotech companies at the time of the creation of the company. A second interviewer also mentioned that government aid was unavailable to the represented company at the time of its start. This was a few years after the previously mentioned company.

One of the companies mentioned that during the second round of financing the government had begun to offer more aid to start-up companies. The respondent gave the example of project funding provided by the BMBF. This type of aid comes from the government and is given to companies and individuals to aid them in the development of the submitted project. This aid pays for half of the cost of the project and the business must pay the other half. The respondent was enthusiastic when mentioning that they hoped to receive this aid, indicating it would be very helpful to their company. A second respondent also mentioned this project funding stating that they too had applied for project aid.

In contrast to some of the other companies, one of the respondents indicated that at the start of their company he had received both project funding and seed money from the government. This is interesting because this was one of the older companies. One of the reasons given for this is that this company chose to locate in an area known as a "bio-valley." These are areas where the local and state governments try to entice biotech companies into by offering subsidized rent or extra aid.

The other type of government aid that was mentioned was contracts from the government given to the companies. Two of the companies mentioned that they received government contracts. Only one of the companies directly stated they received government contracts at the beginning of their company.

Another interesting theme about the role of the government that surfaced was that one of the respondents felt that the government needed to avoid interfering with the development of the biotechnology industry, especially in the agricultural sector. The reason that the respondent gave for this was that if the government does get involved and pass laws or stricter regulations, industries and investors would either turn to or leave for other countries.

The third concept that was discussed in the interviews was the business aspects of starting a company. The most prevalent and usually the first business aspect discussed was that the founders of the companies are still the directors in all of the companies. In one case, one of the co-founders had left to pursue other areas of interest. However, none of the companies have relinquished control of the company to an outsider. All of the companies were also created as a Gesellschaft mit beschränker Haftung (GmbH), which is the equivalent to limited (Ltd) in the US. The reason for this was that all of the founders wanted to start businesses that allowed them the freedom to expand and make the choices that they wanted. All of them chose GmbH for this reason.

Another commonly mentioned aspect was that being the CEO of a young company requires a good deal of business knowledge. Two of the companies mentioned several times that scientists often do not have the necessary business know how before they start their companies. One of the companies avoided this obstacle because one of the founders came from a business background. Relevant experience was described as being contract management experience, general management experience, and experience in dealing with banks. The other company mentioned that they received business expertise from an outside source. When discussing this, the respondent made it very clear that one needs this business experience from the onset and that the entrepreneur usually does not have this experience and thus needs to seek it from elsewhere.

The management team of two of the companies exhibited the need for business experience. One company's management team is composed of the bioentrepreneur as the head of the company, several professors as scientific consultants, and another partner that is very experienced in business. The second company was composed of the biologist, the university professor, and an individual that had previous experience in the business field. Both of these

companies stressed the importance of having good knowledge of business and were proud to talk about their management teams.

The next theme relating to business that appeared frequently was the importance of business plans. One of the companies stated that it was "crucial" to develop a sound business plan. Another mentioned that it was the most important step to starting a company and that from start to finish the entire process took about one year. One of the companies offers business plan consulting as one of its services. One of the respondents said that a company vision was necessary to create a good business plan. Also discussed when mentioning a business plan was that the process of learning how to create a business plan is an extremely important experience. The respondent mentioned that as you learn to do the business plan, you are forced to learn about all the aspects of your company, including doing the market analysis.

The market analysis is an important part of starting the company because it gives both the entrepreneur and the financiers an idea of how the company will fair in the future. If the market analysis for a company looks bleak, several of the companies stated that it is at this time that a young company needs to change its idea or its focus so that it may have a more successful future. One of the companies stated that the market analysis can be greatly improved if the business's customers are consulted as the analysis is completed.

Another theme that arose was that of intellectual property protection. Three of the four companies mentioned that they have some sort of patent. Two of the companies stated that it is crucial to the future success of the companies to get more. One of these companies brought up the topic on two separate occasions because it was thought to be so important. One of the respondents mentioned that getting a patent can be expensive and difficult. For this reason, they sought outside help.

An important part of the business aspects of starting a company is obtaining funds. All of the companies talked about funding in one way or another. One of the more common references to funding dealt with venture capitalists. All of the companies were functioning independently of venture capitalists. Two of the companies stated adamantly that they did not want venture capitalists involved with their company at this time. It was also mentioned that the primary goal of a venture capitalist is to get more out of a company than they put into it. In the US, companies are often looking to make money and enter the market fast. In order to help them do this, companies are willing to take on venture capital. The respondents all mentioned that having an independent company was more important in the beginning than was taking on venture capital with the hopes of entering the market quickly.

There were several reasons given by the respondents as to why they did not want venture capitalists involved in their company. The first reason was that often times, venture capitalists want too much in return for their investment. In order for them to invest in the company, the business must accept certain changes or milestones and goals set by the venture capitalist. If these goals are not met, the venture capital firm often has specific penalties in the contract that are to the disadvantage of the start-up. In addition, one respondent indicated that working under these time constraints can be a nuisance.

Another reason that was given by a respondent for not wanting to approach venture capitalists was that his company was still too young. The respondent said that the earlier in the life of the company that a venture capitalist is contacted, the more shares of the company they will want in return for their investment. Not only do they want more shares, but also they often give less money. The reason for this is that a young company has no worth. It has not established itself in the market place yet and often the company has little ability to generate revenue. To counter this, the respondent mentioned that the company should wait a few years.

At this point, if the company has done well and wishes to grow more, the deal offered by the venture capital firms will be much more beneficial to the company.

Another option to getting funds from venture capitalists is to get funds from banks or other conventional sources of finance. The problem with getting money from these institutions as described by one respondent, is that like venture capitalists, banks see little worth in young companies. Since young companies have little in the way of securities, banks are often reluctant to offer the loan. However, if it can be accomplished, the respondent indicated that funds from banks are more optimal than funds from venture capitalists because banks do not interfere with the company or set milestones for that company to achieve. One of the respondents said that the greater access one has to the financial business networks, the easier it is to obtain the necessary funds.

The last major business theme that was discussed in two of the interviews was the importance of the first two years of the new business. Great care should be taken during this time to ensure the company does not fail. One of the respondents mentioned twice that it was extremely important not to burn out the company funds too quickly. The reason for these concerns were that once you were out of money it was almost impossible to get more funding, and if the company fails it will be very difficult for the founder to get a second chance.

Another concept that was focused on during our interviews was the role of the industry. This was not a common topic, and was only mentioned a few times. No specific information was given about direct, intentional aid from the industry. Some of the indirect aid that was offered by industry members, such as large pharmaceutical companies, that aided start-ups was the co-operatives with the young companies. However, these co-operatives were not always viewed positively. One of the respondents said that the industry saw these co-operations with the universities and the companies as "one-way" streets. Indeed, there was a technology transfer, but

it was in one direction. The example of the industry wanting to get a lot out of the co-operatives while at the same time putting little money or technology into them was given. The respondent said that this was an unacceptable arrangement because the industry gets to make money and learn of the technology from the co-operatives but does not give a lot of money or technological aid to the university or the start-up. The reason that this is so bad is that the cost of the technology and the equipment needed in some of the research arrangements is often very expensive.

The last of the concepts that came up in these interviews was the influence of cultural attitudes. In one of the interviews, the respondent stated that there was a different attitude in Germany than in the US. Instead of the get rich quick attitude that is common in the US, the Germans are more concerned with the social ramifications of starting a company. For example, if that individual should fail in the new business, there will be a negative stigma attached to that person forever. Because of this stigma, the business community as a whole will lose faith in the individual that failed. This fear of failure is a strong deterrent to some young entrepreneurs who fear that their company may not be able to make it. A social implication of the fear of failure is that it hinders Germany's ability to adapt to new change. Individuals will be unwilling to engage in new, untested technologies or markets because they do not want to be seen as failures should their company not succeed.

4.3 Analysis of Greenpeace Web Pages

To complete the analysis of public concerns surrounding biotechnology in the US and Germany, we examined three Greenpeace web pages: International (http://www.greenpeace.org), USA (http://www.greenpeaceusa.org), and Germany (http://www.greenpeace.de). The content of each of these pages was analyzed separately and then compared to each other. The analysis was done to determine the main concerns shown by Greenpeace in each of the countries. These

included concerns they have about their own country and about the other country. The International page was used as an objective look at biotechnology worldwide, with particular focus on Germany and the US. The comparison of these three allowed us to logically conclude the main concerns Greenpeace has about biotechnology. The other aspect that was investigated was if the concerns are portrayed differently in each country.

To begin, we looked at the headings present on the Greenpeace International page. The sub-heading after the general "genetic engineering" heading was "**No** genetic **manipulation** of nature!" The organization made it clear that they were against manipulating nature by emphasizing the "No" and the "manipulation" in the heading by making them larger and bolder than the rest of the words in the heading and on the page. The next part that was analyzed was the links to four individual categories: genetically engineered food, artificial organisms, patents on life and bio-safety protocol.

The genetically engineered food's page has the sub-heading "We want **natural** food!" Here, the word "natural" is highlighted indicating a condemnation of any food that is produced by unnatural means. The caption describing this section stated "Consumers want real food and the right to know and to choose. Genetically engineered food must be segregated and labeled." Greenpeace is not in favor of genetically engineered foods and feel that the public should be aware of the differences between the products being sold.

The sub-heading for the artificial organism's page is "**Prevent** genetic **pollution!**" Greenpeace is concerned that by altering organisms now it will taint the environment and never be organic again. This point is further made in the description of this section. "Genetically modified organisms must not be released into the environment, as the consequences for the environment and evolution are unpredictable and irreversible".

The sub-heading on the next page is "**No patents** on life!" This sub-heading stresses the fact that life is not something that an individual can declare as their own for personal gain. "The natural diversity of all creatures is our global heritage. Living organisms and their genes must not be subject to private property claims."

In the section on bio-safety protocol, Greenpeace is calling for worldwide regulations to mandate genetic engineering. The sub-heading is titled "**Protect** global **biodiversity!**" This description shows that this organization feels regulations can not be controlled differently by each country because possible problems have a worldwide effect. "Genetic pollution is a global threat that must be addressed by international regulations, based on the precautionary principle."

The four sub-headings on the Greenpeace USA page were "recent news," "take action," "consumer network," and "publications." These were larger than the normal text but there was nothing else unique to their appearance on this page. The assumption that was made is that the organization is relying on the pictures and text to persuade the reader.

The Greenpeace Germany web page did not have any other heading aside from the general heading of "Gentechnik" which is the German equivalent for genetic engineering. A picture and caption made up the top of the page. Like the Greenpeace USA page, it was assumed that they were emphasizing the graphics and text. If the graphics and text were what the organization was representing their ideas in, then it was important to understand the use and meaning of them.

The next component on the International page that was analyzed was the graphic. The picture that was on the main genetic engineering page did not immediately cause the reader to know what was being opposed. There was a picture of a holding tank with a large "X" on it that indicates disapproval of whatever was being contained (see Appendix C). When looking at the

picture more closely, it shows Greenpeace acting against genetically engineered soy, so the original interpretation of the picture is correct.

The link to the Greenpeace USA genetic engineering page was a graphic that changed between four different pictures: a worker fully covered in white with a mask on and holding soybeans, a genetically engineered tomato, genetically modified corn and tofu (see Appendix C). From this picture, it seemed that Greenpeace opposed these products. The only picture that directly caused the reader to see the product as harmful was the picture of the worker with the soybeans. The mask and gloves that he was wearing show that the soybeans can not be handled without concern for one's personal health. A person usually wears a mask to avoid harmful toxins in the air. Gloves are usually worn to protect a person's hands and forearms from contamination that could cause adverse effects to skin.

The first item on the Greenpeace Germany page was a picture of a baby with a patent number clipped onto its ear (see Appendix C). The image of a baby evokes various emotions from the reader. These include sympathy, innocence, and purity. To add to this effect, a picture of a sad baby was chosen. Another important aspect to this picture was that the patent number was tagged to the baby's ear as is often done in the cattle industry. This strips away the baby's humanness as though it was a product. Next to the picture was the heading "Because they do not know what they do." With this picture and heading was a very brief caption explaining the opposition Greenpeace has to patenting life science. In addition, they mentioned their concerns about genetically manipulated agriculture in this caption.

The last and most important section of the web pages that we analyzed was the press releases section. This included the dates and titles of press releases from the past four years. By looking at these, it was possible to get a general feeling of how Greenpeace views genetic engineering. To do so it was necessary to systematically count important subject matter in the

titles. The titles from the press releases section were all examined separately before being compared. The process of putting the titles in a word document with the most recent publications first was done three separate times. To begin the analysis of the press releases, we first had to determine what subjects were important to investigate. Preliminary ideas were developed when analyzing the headings and graphics. The remainder of the issues were found by reading through the titles and looking for repeated information.

The first search we made was for articles where Greenpeace was mentioned. We first counted the amount of times that they were used in the titles and then looked at in what context Greenpeace was being used. To determine the context, we searched for the surrounding verbs and adjectives. The International page had the largest percent of use in the titles. In the one hundred thirty six titles, verbs that describe actions that Greenpeace has done against genetic engineering were in eighty-four of the titles. Therefore, the standard verbs that were counted in the press releases for all three pages came from these titles. With the exception of the verb "welcome", all of the other verbs describe aggressive actions that Greenpeace has displayed.

Greenpeace describes its actions using strong, illustrative words in their titles. This means that they were actively showing disapproval. Some verbs that were found throughout all of the articles were call, force, stop, threat and warn. These were being used when talking about genetic engineering companies and the products that they produce. The two topics that Greenpeace has welcomed are global steps to get out of genetically modified organisms and European rulings to regulate genetic engineering. We used the word welcomes as an aggressive verb because its use was often followed by restrictions on genetic engineering. From these results, we can see that most of the articles linked on Greenpeace are actively against genetic engineering. In the USA titles, the majority of the suppression is being placed on genetically

modified foods such as soy products and corn. Unlike Greenpeace International and Greenpeace USA, the actions of Greenpeace Germany were not as prevalent in these publications.

The amount of times that the companies and products were talked about in the titles was approximately the same for all three pages. The companies that were most frequently used were Monsanto, Novartis, and Nestle. Monsanto is a US company and the other two are worldwide companies. These companies produce products that contain genetically engineered soybeans and corn. These are the two main crops that have been mentioned in all three pages. Products that were opposed contained corn and soy so these were the two key words we looked for in the titles to analyze the products.

We then looked at descriptive words to learn how Greenpeace feels about these companies. One of the most prevalent themes surrounding Monsanto was one of ineptitude. Some of the phrases that indicated this were "by mistake," "apologizes" and "incomplete risk study." The next company that we looked at was Novartis. In these articles, the company was described as being deceptive. Words that led us to determine this were "illegal imports" and "false." Nestle was the last company to be analyzed. The two main themes that were stressed about this company were that their products are "manipulated" and that there has been some success is getting these products "off the market."

After this we looked at the concerns Greenpeace had about genetically modified foods. The two most important crops that have been opposed are corn and soy. To get a better idea of why Greenpeace is against these crops, we looked at the words surrounding them. The corn was most typically described as genetically modified, Bt corn. Bt is a chemical that is found in the pesticide added to the corn. Descriptive words associated with corn and soy in the titles were dangerous, illegal, killer, risky and unwanted. The words used when talking about soy are very

similar. One additional topic that is talked about is how farmers and consumers do not want this genetically modified soy to be mixed with the animal fodder.

All of the pages portrayed the companies and products in a negative manner. Verbs used to describe genetically engineered foods and companies are threaten, betray, and refuse. Greenpeace describes these products as threatening society and that the companies are betraying the public. The word refuse is used to show that the genetic engineering companies are not making efforts to decrease the amount of GMOs or improved safety for the public.

Next, we looked for articles that talked about the US and ones that talked about Germany. The first reason for doing so was to see the frequency in which the countries' names were used. The second reason was to see how genetic engineering in the two countries is portrayed. Some of the articles talk negatively about the lack of US regulation. Titles stating that Greenpeace has called for tough GMO rules for US exports, the US has continued to obstruct progress in UN sponsored talks to set international rules on GMOs, and the US EPA has failed to protect public health and the environment and is inadequate as a basis for international rules, all show contempt for the lack of regulations in the US.

The articles having to do with genetic engineering in the US show a strong disapproval of the industry. The articles about the US were mostly about the "illegal, manipulated" corn that is being exported by the US. Other titles pertained to soy exports and the US threatening with transatlantic economic war. At least five of the titles in the International press releases section indicate that Greenpeace does not welcome US genetically engineered exports. This is known because the titles tell that Greenpeace has repeatedly protested to stop US exports from arriving in various countries.

The main page began by showing opposition to patents on life. Therefore, we looked for titles pertaining to this topic. Patents were only discussed in articles from April 1999 to the

present, which gives the impression that this is a new concern. These articles stressed the fact that life is not an invention and patenting is wrong. A key word that was repeatedly used in these titles is against. This word was used to describe the feelings Greenpeace has about these patents.

The difficulty in looking at only the title of the article is that information can be perceived incorrectly. The advantage of looking at the title of the article is that it is the only information the reader has to make the decision to read or not to read the article. If the reader decides to not read the article then this is the only information that will be gained. The authors of these publications have to provide a title that will both intrigue the reader and offer the main points that the article discusses. In doing so, the reader will either go on to learn more about the contents or walk away with a primary idea that the author wrote about.

4.4 Comparison of Variables

The following section is a comparison between the variables that provide the best overall framework for biotech start-ups in the US and Germany. The background research that was completed on biotech start-ups in the US is compared to the results that were obtained through the research methods that were done in Germany. Included as Appendix D is a table comparing these variable between the US and Germany.

The US and German governments played two different roles in promoting the biotechnology industry as well as start-ups. Findings from the literature show that Germany was one of the first countries to acknowledge biotechnology as one of the essential technologies for the future. Germany's first governmental program to promote biotechnology dates back to 1972. The German government pursued a direct interventionist technology policy on the biotech sector through its Ministry of Science and Technology.

Unlike the German approach, the US government rejected technology-specific regulations and took a less direct approach to promoting biotechnology. Instead, it worked to help enhance

the current framework of innovation that already existed in the US. The US government collaborated with both the pharmaceutical industry and universities in order to establish communication channels between the three institutions. However, the German government, until recently, had minimal contact with the pharmaceutical industry and university and failed to establish this network of cooperation.

From our research in Germany, we learned that the German government currently sponsors a number of start-up initiative programs and business plan competitions nation wide. These programs are sponsored by both the German government and pharmaceutical industry in hope of providing skills and knowledge for young companies, to create jobs and economic growth, and to provide a network for start-ups by bringing together business and science experts.

Through our interviews in Germany, we discovered that the availability of funds from the government differs from state to state. Our background research showed that these different types of state regulations do not exist in the US. Instead, the US has the same type of grant and regulation policies nationwide.

The role the pharmaceutical industry plays in supporting biotechnology start-ups was another variable we focussed on in our literature review. The literature revealed that during the beginning of biotechnology industry development, US biotech companies were interested in forming strategic alliances with domestic pharmaceutical companies. Foreign pharmaceutical companies, including German ones, also began to form alliances with US biotech start-ups in the early stages of development. German pharmaceutical companies lacked in-house biotech innovation and needed to turn to US start-ups to maintain their share of the market.

Today, the role of industry in the US is still very important to biotech start-ups and there continues to be a great deal of cooperation between the two. Historically, the communication between biotech start-ups and pharmaceutical companies in Germany was very low and start-up

companies lacked trust in the industry. One of our respondents mentioned how collaborations with pharmaceutical companies were like one-way streets. We learned that the pharmaceutical industry in Germany wants to reap the benefits of start-ups while providing them with as little help as possible.

Each country's industry relies heavily on biotech start-ups to supply them with patents or products that they can then market and sell for profits. Start-ups in both countries also rely heavily on these collaborations because most start-ups do not have the capacity to produce actual products. We learned from background research and our interviews that this collaboration is crucial to the success of a start-up in both countries.

The business aspects of starting a biotechnology company in the US and Germany are alike in practically every way. In both countries, the scientist is usually the CEO of the start-up and continues to be throughout the life of the company. This was revealed from the literature and from the respondents we interviewed.

Business plans and the crucial aspects that must be included in them are also the same in both countries. First, the existence of intellectual property is an absolute must for a biotech start-up in both the US and Germany in order to prove that what you are trying to accomplish is real. Two important aspects in both countries are the company having a vision for its future and a timeline of milestones that will be reached. Investors in both countries also stress that the company has a planned exit strategy. From the literature, we found that an IPO is common for US biotech start-ups. However, none of the companies we talked to currently seek this type of exit strategy and want to continue to function as a private company.

As mentioned before, partnerships with pharmaceutical companies are regarded highly in both countries as well as having a market potential or special niche. A strong management team was also found to be one of the most important aspects to have as a start-up. In both countries,

investors look for members of the team that are experts in marketing, finance, and technology. Investors in Germany revealed that they invest in people, not in ideas. This was also found the same in the US according to the literature.

The role and aims of venture capitalists are also the same in the US and Germany. We found that raising venture capital for biotech start-ups in both countries is an absolute necessity. From the literature, we found that the first US venture capital company was created in 1946 and that the amount of venture capital invested in biotechnology in the US in 1997 was seven times the venture capital invested in German biotechnology.

From one interview, we learned that there is enough seed finance money available in Germany but there is a lack of ideas to invest in. Bioentrepreneurs in Germany told us that they preferred to not receive venture capital at an early phase of their company because it is too risky and venture capitalists ask for such a high return on investment. Instead, we found that German bioentrepreneurs prefer conventional financing. The type of financing that was mentioned the most was bank loans because of their low risk. However, we were also told that banks usually do not finance in the start-up phase of a company in Germany and that they only give out loans during the production phase of a company. One respondent told us that seed financing in Germany is from friends, family and personal savings. From our literature, we found that US bioentrepreneurs favored venture capital over any other source of financing but it is also common to receive initial funding from friends, family and personal savings.

Like the US, we found from interviewing a financial expert that venture capitalists in Germany expect a fifty to one hundred percent return per share and focus on the exit strategy of the company. The type of exit strategy influences the amount of seed funding that a start-up receives in both countries.

Another common business aspect in both countries is the importance of business angels and the services they provide to biotech start-ups. In the US and Germany business angels are experts in the field of science, law and business, who provide crucial advice to start-ups free of charge. Business angels also grant private equity to start-ups in both countries. However, in both countries, we found that the knowledge and network of contacts they provide is far more valuable than their money.

In the US and Germany we found that the university acts as the main technology transfer mechanism for a biotech start-up. Some of the type of aid that is provided to biotech start-ups is the same in both countries. Both US and German universities provide start-ups with low cost labs, equipment, and office space and also offer a comfortable and familiar setting for the company to grow in. We found that faculty members in the US are given incentives and aid in the patenting or licensing of their research and are also given help in constructing their business plans. The bioentrepreneurs we interviewed told us this is not the case in Germany.

According to the literature, there are a small number of committed entrepreneurs in Germany compared to that of the US. Professors and universities in the US look to help start-ups form contracts with industry and usually act as advisors to the company for the first few years. This is seen very rarely in Germany but is becoming more common according to one of our sources.

The first assessment of public perception was through reading literature on the subject. From the information that was acquired, we were able to form a theory of the situation in the US and Germany. To further investigate the subject, an interview was conducted with an expert in the area of ethical issues.

The primary reason for analyzing this aspect of biotechnology was to see if a negative public perception was a reason that the biotechnology sector was slow to start in Germany. The

literature stated that this was one of the reasons that the German biotech sector was slower to start than the US biotech sector. As seen in the literature, historical events in Germany caused the public opinion to be negative about biotech applications. The public was weary of any science that involved manipulation of life. This topic was also discussed in the interview. The respondent also gave this as one of the possible reasons Germany was slower to start. He also suggested that students in Germany are taught to have significant concerns on ethical issues while the US is not as interested in teaching this. Both of these sources state that differences in opinion can be attributed to cultural differences.

The next topic that was important was the correlation of public awareness to public perception. The content of the literature varied on this subject. Literature has shown that the public is more likely to be supportive of biotechnology if they are better informed of it's applications. This is derived from the belief that knowledge is a crucially important determinant of support for science and technology. Surveys done in Germany to determine public perception of biotechnology detected that the public's knowledge of relevant basic biology has increased slightly, but optimism about the contribution of biotechnology and genetic engineering to improving our way of life has actually declined. The survey showed that knowledge is poorly correlated with support for biotechnology applications. The interviewee's opinion on this subject was that the more educated a person is, the more critical they are on the subject.

In the interview and literature review, the importance of the relationship the public has with various groups was recognized. Surveys have shown that Europeans view consumer organizations as the most trusted source. Respondents also stated that they have the least confidence in companies and political parties. Results from the interview also show that the public does not trust the government as a source of information. This is because the government is viewed as have a lack of respect for the public.

The final information that was important in understanding the differences in public opinion was the relationship between risk and culture. This topic can be divided into two sections: government risk and public risk. According to Douglas and Wildavsky (1982), risk is a politically defined term. The regulations that the governments make are based on what risks they are trying to protect the public from. The risk in question is a culturally dependent assessment. The public sees other risks aside from these that the government does not evaluate. The government has shown concern for risk and safety. The public is also interested in questioning the morality of the issue. Information from the interview confirmed that the government evaluates risk to create regulations and the public relies on the evaluation.

Chapter 5-Conclusions and Recommendations

The final chapter of this report is a detailed list of conclusions and recommendations based on the results and literature review. The recommendations are for how the German biotechnology industry can keep improving and for further research topics that arose from completing this project.

5.1 Conclusions

As these findings indicate, the best overall framework for the development of biotechnology start-ups depends on the interaction of a specific set of variables. These variables consist of the role that university, government, and industry plays in developing biotech start-ups. The framework also includes the business aspects of starting a company and finally, the influence that public perception and cultural attitudes have on biotech start-ups. This framework has provided many opportunities for biotech start-ups in the US and has helped create a strong biotechnology industry. We conclude that despite needing further improvements, these variables have created a favorable environment for biotech start-ups in Germany.

Several of the people interviewed commented that although the university provided some aid in the start-up, they would have liked more help. This led to the conclusion that German universities are not doing everything possible to aid biotech start-ups. It was mentioned in all of the interviews that at the time of conception for all of the represented companies, the universities were in their early phases of giving aid. All of the respondents mentioned that more aid from the university would have made the process easier. One of the youngest companies mentioned that it was still trying to obtain aid from the university but was having a hard time. However, this does not mean that German universities are not providing aid to biotech start-ups. The university does provide the much needed lab space, equipment and personnel at a reduced rate but it was found that they should attempt to provide more in order to promote biotech start-ups.

Two other complaints about the university that showed up were that the university did not aid in the obtaining of patents, legally or financially, and that no aid was offered during the construction of the business plan. Although two of the respondents indicated that learning to construct the business plan on your own was important, they would have liked a little more help from the university.

We feel that there is not enough education for entrepreneurs interested in starting their own companies in Germany. We found that most of these entrepreneurs have a scientific background and sometimes do not have enough knowledge of business and legal aspects associated with starting a biotech company. For example, during one of the interviews we conducted, a respondent mentioned that frequently the science-oriented entrepreneurs do not have the necessary business knowledge at the beginning to start their company. When discussing this, the respondent made it very clear that one needs this business experience from the onset and that the entrepreneur usually does not have this and thus needs to seek it from elsewhere.

With respect to the government role in biotechnology, we have concluded that the complicated manner in which the government operates has caused problems for entrepreneurs in Germany. Unlike the US, Germany has many strict regulations on the biotechnology sector. In addition, these regulations are not the same throughout the nation. Government regulations differ from state to state, which makes it difficult for some companies to start in regions that have stricter regulations. We have also found that the government does not involve the public in the creation of these regulations, which causes the public to be resentful. However, the German government has created a number of start-up initiative programs to provide entrepreneurs with the much needed business and legal advice but the actual success of these programs is unknown due to the fact that these programs have taken place over the last few years.

We also found that the pharmaceutical industry in Germany has not provided biotech start-ups with enough aid. This topic was not concentrated on during the interviews, but those who did share their experiences had strong opinions on this topic. No specific information was given about direct, intentional aid from the industry. The indirect aid that was offered by large pharmaceutical companies was the co-operatives and contracts made with start-ups. These co-operatives and contracts were not always viewed positively. One of the respondents said the industry saw these co-operatives with universities and start-ups as "one-way" streets. Indeed there was a technology transfer, but it was in one direction. The example of the industry wanting to benefit from these co-operatives while at the same time putting little money or technology into them was given. The respondent said that this was an unacceptable arrangement because the industry gets to make money and gain knowledge of new technology from the co-operatives but does not give a lot of money or technological aid to the university or the start-up. The reason that this is so inadequate is that the cost of technology and equipment needed in some of the research arrangements is often very expensive.

The next conclusion that we made is that the business involved in starting a biotech company is of equal or greater importance than the science. Having a strong business sense is one of the most important aspects of starting a biotech company and a good business plan and market analysis can make a start-up more successful. By writing an in-depth business plan, the entrepreneur gains complete knowledge about the company that they are trying to start. A complete market analysis can inform an entrepreneur if the product in question is going to succeed or fail. Knowing this in the early stage helps the entrepreneur decide if it would be better to work on a different product or not start the company at all.

Another important factor in considering the business aspects of a start-up company is the management team. The importance of the management team to a start-up company was

mentioned in all interviews. There are a few important positions that we were told of in the company's management team. The CEO or person in charge of the technology needs to be there since the technology needs to be proven in order to receive funding. The team should also consist of the chief financial officer (CFO), and someone involved in the market analysis or the marketing of the products the company is focussing on. The investor told us that most management teams focus on the technology and neglect the financial and marketing aspects. This is problematic because financiers are looking specifically at the management of a company and how they have set up their marketing and financial strategies.

The last factor that we were able to make conclusions about was the timing of taking venture capital into a company. Two respondents mentioned that they did not want venture capitalists involved into their company. The reason that was stated was the companies wanted to remain independent. We concluded that there is a difference in views on venture capital between the US and Germany. In the US, venture capital is typically taken into the company at an early time.

We have concluded that aspects of the German culture have hindered biotech start-ups. One of the concepts that came up in the interviews was the influence of cultural attitudes. Some cultural differences between the US and Germany were told to us by our respondents. In one of the interviews, the respondent stated that there was a different attitude in Germany than in the US. Instead of the "get rich quick" attitude that is common in the US, the Germans are more concerned with the social ramifications of starting a company. This fear of failure is a strong deterrent to some entrepreneurs who fear that their company may not be able to survive. It was noted in Germany, that if an individual failed in starting a new business, a negative stigma is attached to that person forever. The concept of failing is considered a drop in social status in Germany, which is considered very important in the German culture. Because of this stigma, the

business community as a whole will lose faith in the individual that failed. They then explained that it is then virtually impossible to start another company. This phenomenon is a common reason that Germans are hesitant or cautious to start their own companies. Although this seems to be slowly changing, it is still problematic in Germany.

All of the data collected during this study has led to the conclusion that public perception has a large bearing on the biotechnology industry. The US and German industry must consider public concerns. The pharmaceutical industry lost a lot of the public's support due to their earlier policies and because they did not inform the public of the products that were being produced. The first information that led to this conclusion is the impact negative public perception had on the promotion of biotechnology in Germany.

Historical events were one of the main reasons that the public was opposed to biotech applications. The decisions that the government and science community made during World War II caused people to become wary. The public did not look highly on the manipulation of life. The lack of trust in the government also caused people to turn to consumer organizations for their information. The variation in the opinions in the US and Germany are due to cultural differences. The concept of different cultures having effects on the people in the culture is still a factor in opinions of biotechnology.

The information on the gene protection initiative that was obtained by interviewing the expert in the field of animal welfare and human to animal relationships pertaining to the law led to the conclusion that public support is essential for success. The initiative was never implemented because the public was against it. In describing this situation as a "battle," the respondent showed that the group supporting the initiative considered this both a political and personal issue. We believe that the public may not have supported the initiative because it was not in favor of the group who wanted to implement it.

The question of the relationship between public awareness and public acceptance is not easy to answer. The difference in opinion from experts leaves a person thinking that this is an issue with no one solution. The public most likely cannot agree on how they feel about biotechnology and this could be a reason that critics disagree. With the rapid changes occurring in biotechnology, new information is always being offered so it would be impossible for people not involved in the field to keep up with the changes. Another possible reason for this is that public opinion of biotechnology varies within the applications. For instance, a person may not have a problem with medical applications but are opposed to genetically modified foods. The Eurobarometer shows that the public agrees that it is morally acceptable to use genetic tests to produce medicine or vaccines. Genetically modifying agricultural products is accepted less by the public. This modification is viewed as being immoral. However, the public shows support for applications that directly benefits them such as using genetic tests to detect inherited diseases, introducing human genes in bacteria to produce medicine or vaccines and genetically modifying bacteria to clean pollution.

Public perception and ethical issues will continue to be a factor the biotech industry must be concerned about. Without public support, the production of genetically modified organisms will not flourish. The public will be the ones to purchase the products and invest in the companies so it is important to involve them in the decision making process

5.2 Recommendations

The data that we gathered from the use of interviews and the case study has led to the formation of recommendations for entrepreneurs, the German government, German universities, and the German pharmaceutical industry. In this section, the recommendations for all but the entrepreneurs will be set forth. The recommendations for bioentrepreneurs can be found in

Appendix E, the manual that was created to aid new bioentrepreneurs in starting their own company.

The government in both countries can play a major role in promoting or hindering the development of the biotechnology sector. In the US, the government has maintained a hands-off policy that has allowed the industry to flourish. In several of the interviews, the respondents explain that the German government needs to stay away from regulations on biotechnology. This was also a common theme in much of the literature that we read. For this reason, we recommend that the large number of regulations governing the field of biotechnology be simplified and standardized with the intention of creating more flexible rules and regulations. In addition, great care should be taken when decisions on agricultural biotechnology are made. If too many restrictions are placed, companies and investors could start looking to foreign markets.

However, reducing the regulations alone will not be enough to remedy the problem. To successfully promote biotechnology in Germany, the public image of biotechnology needs to be enhanced. Improving the public perception of biotechnology not only includes improving the technological and economic potential presented by biotechnology, but also of the ethical and social challenges associated with biotechnology. To accomplish this goal, the government should create a shadow organization that will be responsible for promoting biotechnology in Germany.

A shadow organization is a government funded body that is not publicized as being a part of the government and the funding is done without drawing a lot of attention. The focus of this organization should be on illustrating the overall framework and conditions in which biotechnology is going to be used. This includes the kind and scope of safety analysis, ethical limits, indicating possible applications and describing the consequences of using or failing to use biotechnology. Some of the consequences of not using biotechnology are lack of competitiveness, lack of jobs in research, development and production, and less international

trade. We feel that the known economic benefits created by biotechnology, such as the creation of new jobs and an increase in revenue generation, currently outweigh the unknowns associated with biotechnology and will ultimately benefit society as a whole.

To help accomplish these goals, the Government should arrange suitable events for a broader public discussion on the opportunities and risks of biotechnology and genetic engineering. This includes promoting discussions between various social groups, establishing contacts to facilitate an exchange of opinions between the institutions and establishments involved, and the organization of genetic engineering conferences for an exchange of information and for educating the public. An example of a benefit taken from this change would be that projects funded by the BMBF could be improved or aided by appropriate suggestions that come from these events. Industry and science should also be called upon to make information, experience, and assessments from the industry available to the general public. By bringing all of this information into a public light, the public could see the actual benefits and applications of new biotech developments, and allow them to hear both sides of the current discussions on biotechnology.

The public perception of independence and failure act as another obstacle to biotechnology. For this reason, we recommend that the government implement programs that address several essential areas. One goal of these programs should serve to create a more positive image of entrepreneurship. Included in this is trying to improve the general negative impression of self-reliance. By showing individuals who set out to start their own companies in a positive, public manner, the image of entrepreneurs will gradually start to improve. This will aid in the encouragement of entrepreneurship for all industries in Germany, not just biotechnology.

A second goal should be to minimize the effects of society's risk aversion. From our interview with the member of the finance committee we learned that Germany is starting to

become less risk averse. He mentioned that with the creation of the Neuer Markt, people were starting to explore more risk-oriented investments. The government can aid in the reduction of risk aversion by offering incentives to individuals who take risks. Tax cuts or benefits to individuals who invest in the stock market would be one example of a way the government could try to promote these activities.

A third goal should be to lessen the stigma that is placed on individuals who do not succeed in their start-up. If an individual fails in his or her first venture and has another new idea, the government should offer funds to allow this person to take a second chance. Since the finance community will often shun the entrepreneur who did not succeed, this aid will help the entrepreneur to start again. If these second-chance companies become successful, the government should try to distribute this information to the business and the finance communities to show them that one failure does not mean that an entrepreneur can or will not be successful at a second attempt.

Another recommendation that we have is for the creation of an organization that will be closely associated to the Government, and will provide on-going support for the continuing development of modern biotechnology. The main tasks of this organization should include regularly monitoring and evaluating research, development and application, including the associated social issues, elaboration of further recommendations for the Government, and regular reports on basic developments taking place in biotechnology. This relationship would enable the government to stay up to date on the current state of biotechnology, which would allow them to make more precise, focused decisions.

From the literature and the results that were obtained, it is apparent that the universities, despite having made significant progress, still need to make some changes. The first recommended change is that the universities should try to intensify the cooperation between itself

and the industry, either by creating joint research areas or by founding institutes associated to the university.

Another recommendation for the universities is that not only should they try to provide more aid for pure research, but they should also include funds for a German patent application and the patenting of the research findings. This would greatly aid the entrepreneurs by offering them monetary aid for the often-expensive patent process. In order to aid the entrepreneurs with the legal aspects of obtaining a patent, German universities should provide courses of studies for science and engineering that include instruction in the legal and commercial aspects of formulating patent applications. Another area that should be included in these programs is information on patent strategies to protect an invention and to utilize patent information. This will aid the entrepreneurs in getting their patents and will reduce the cost of getting the patent by reducing the need to pay for external advice.

5.3 Recommendations for Further Research

One recommendation for future study is to evaluate if the cultural differences that hinder the success of biotech start-ups are unique to the industry or if they hinder start-ups in other industries as well. A second recommendation would be to focus on the whole of Germany. Our interviews were based in the state of Hessen and we feel that this does not give an accurate representation of biotech in Germany. A third recommendation is to repeat this project in five years to see if the German biotech industry has continued to improve. The final recommendation for further research is to investigate the benefits and drawbacks of having a public or private university with regard to technology transfer. It would be interesting to compare the ability of each type of university in promoting start-ups.

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Appendix B – Glossary of Terms

Biotechnology: The application of the principles of engineering and technology to the life sciences; bioengineering.

Biotechnology Incubator: A place or situation that permits or encourages the formation and development of biotechnology, as of new ideas.

Department of Health and Human Services (DHHS): Executive department of the United States federal government charged with administering a wide range of programs in the fields of health care and social services.

Entrepreneur: A person who organizes, operates, and assumes the risk for a business venture.

EuroBarometer: System of public opinion measurement used to gauge public response to a carefully chosen range of questions on biotechnology.

European Commission (EC): Concerned with research and development of biotechnology and public understanding of the surrounding issues.

European Union (EU): European supranational organization, dedicated to increasing economic integration and strengthening cooperation among its member states.

Extramural: outside or additional to the usual courses of study at a university, college, or other educational institution, though usually connected with them

Federal Ministry of Science and Technology (BMBF): German government agency in charge of the pharmaceutical sector.

Genetics: The branch of biology that deals with heredity, especially the mechanisms of hereditary transmission and the variation of inherited characteristics among similar or related organisms.

Initial Public Offering (IPO): first offering of stock to the public by a company.

Innovation: the introduction of something new; a new idea, method or device.

Intellectual Property: original creative works that can be protected by law. All original works, whether they are artistic creations, commercial designs, or scientific inventions, are considered intellectual property.

Misappropriation: Having taken something dishonestly using for one's own use.

NASDAQ: National Association of Securities Dealers Automated Quotation System.

National Institutes of Health (NIH): agency of the U.S. Department of Health and Human Services, established in 1930. Part of the PublicHealth Service, the NIH seeks to improve the health of the American people.

Niche: a specialized market.

Patent: Document conferring or securing a right.

Regulation: A law or rule to regulate conduct.

Sector: A part or division, as of a city or a national economy. The public sector is connected with or acting on behalf of the people, community, or government. The private sector is conducted and supported primarily by private individuals or by a non-governmental agency or corporation.

Seed Finance: Financing provided to research, assess, and develop an initial concept before a business has reached the start-up phase.

Start-up: A business or an undertaking that has recently begun operation

Start-up Finance: Financing provided to companies for product development and initial marketing. Companies may be in the process of being set up or may have been in business for a short time, but have not sold their product commercially.

Trade secret: Any information that can be used in the operation of a business or other Enterprise and that is sufficiently valuable and secret to afford an actual or potential economic advantage over others.

Transgenic animals: those having chromosomes manipulated by artificially introducing genes.

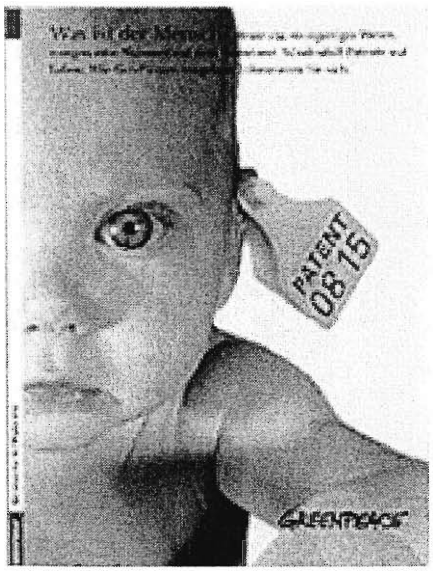
Venture Capital: Money made available for investment in innovative enterprises or research, especially in high technology, in which both the risk of loss and the potential for profit may be considerable.

Appendix C – Greenpeace Graphics

1. Graphic from Greenpeace International.

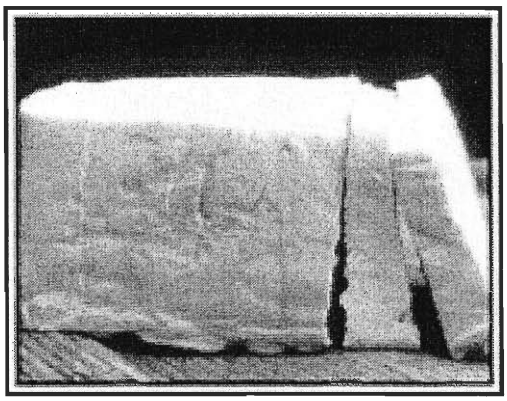
14 April 1998 Corinth, Greece
Greenpeace action against genetically engineered soya at soya mill.
© Greenpeace/Karayannis

2. Graphic from Greenpeace Germany.

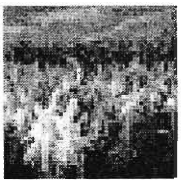


3. Graphics from Greenpeace USA (genetically modified tomato not included).

Worker holding soybeans.

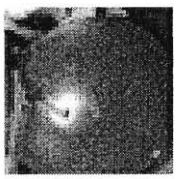


Genetically modified tofu.



genetic engineering

Field of genetically modified corn.



consumer network

Genetically modified tomato.

Appendix D - Comparison of Variables

Variable	US	Germany
University Role	Low cost labs & equipment. Incentives for patenting. Professors willing to provide aid to start-ups.	Low cost labs & equipment No incentives for patenting. Professors starting to provide aid to start-ups.
Government Role	Less direct approach to promote biotechnology. Nationwide regulations and policies regarding biotech.	Direct interventionist technology policies. Number of start-up initiative programs with industry collaboration. Differing state to state regulations and policies.
Industry Role	Strong industry-university co-operatives. Early partnerships were formed between both German and US start-ups. Strong pharmaceutical industry.	Industry-university co-operatives are seen as one-way streets. Industry is out for it's own benefit. Collaboration with government initiatives. Lack of in house-competence.
Business Aspects	Scientist acts as CEO. Importance of Intellectual Property and Vision. IPO is common exit strategy. Partnerships with industry looked highly upon. Venture Capital is preferred and is usually a seed investment. Business Angels and their services are vital to the success of start-ups. Strong management team is important as well as market analysis.	Scientist acts as CEO. Importance of Intellectual Property and Vision. Willing to remain independent. Partnerships with industry looked highly upon. Conventional finance is preferred such as bank loans and equity. Business Angels and their services are vital to the success of start-ups Strong management team is important as well as market analysis.
Public Perception and Cultural Issues	Get rich quick attitude. Opposition to GMOs. Lack of trust in government. Biotech as a whole is seen as beneficial.	Aversion to risk & fear of failure. Morality plays role in decision making. Opposition to GMOs. Lack of trust in government. Medical & Environmental applications are seen as beneficial.

Appendix E – Manual of Recommendations

Introduction

Starting a new business is a difficult, yet rewarding challenge. Taking an idea developed as a student or professor and creating a new business is a way for the individual to express not only creativity, but also to reap the benefits of their discovery. Success, however, is not guaranteed. The process will be difficult, time consuming, and sometimes overwhelming. Some of this can be attributed by the often-lacking knowledge of scientists and professors on how the business world works.

This manual has been created in order to aid the entrepreneur in his or her new venture. The first two years are critical to the future success of a company. It is often the case that lack of knowledge on the business aspects of starting a company contribute to the troubles that arise during this time period. This manual should not be used as a sole source of information. The purpose of this manual is to serve as a guide to the entrepreneur by offering advice and recommendations on certain aspects of starting a new biotechnology company. Some of the more important topics will be reviewed in this manual, but the scope of the discussion will only scratch the surface of the knowledge that needs to be obtained. Therefore, this manual will mention some of the key points that need to be considered at the start of a company and will also recommend people or organizations that the entrepreneur can contact for further information.

Intellectual Property Protection

Most biotechnology businesses start with an idea. This idea is the initial corner stone of the business and thus needs to be protected as much as possible. To guard the idea, the entrepreneur should obtain a means of intellectual property protection. The most common form of intellectual property, and the most useful to the scientist, is the patent.

The patent is often the best choice because it offers the longest term for protection. Most frequently, the best way to approach obtaining a patent is to apply in the country of origin. Getting a patent in Germany is currently cheaper than obtaining one from an international or US provider. If the entrepreneur or the patent holder then feels that procuring an international or US patent is necessary, the priority date that was assigned by the German patent office can be used when applying for the other types of patents. By applying for the German patent first, the entrepreneur saves money, yet still gets the same priority date internationally. The process of getting a patent typically lasts two to two and a half years. The German patent can last up to 20 years, if, after the third year, the holder of the patent pays an annual fee. The fee increases each year that the patent is extended.

Obtaining a patent is a legal affair. Neither the German nor the US patent offices require the applicant to have legal consultation. It is, however, recommended. Typically the scientist or professor does not have the necessary background to file the best possible application. Applications are reviewed, and the patent is given to only what is stated in the application. Therefore, if the wording is faulty, or does not cover all of the idea that is being patented, the holder of the patent will not receive the best possible protection. For this reason, consultation with an individual or firm with a very good reputation for handling patents is recommended. Within the university, there are often professors or other individuals that have already undergone this process. Asking around is a good place to start to get an idea for selecting a representative.

Obtaining both the patent and the necessary legal advice can be a costly process. To help alleviate some of these costs, entrepreneurs can contact business angels. Business angels are typically experienced individuals that aid entrepreneurs by offering them free advice for the first two years of their company. This free advice is a way to get consultation for the patent application without having to pay a large fee. To help reduce the cost of the actual patent, the

applicant can contact institutions that help to fund the procedure. One such institution is the Fraunhofer Institute. The Fraunhofer Institute will share the costs of the patent and offer some advice on the application procedure, easing the burden on the applicant. Care should be taken whenever engaging in a partnership to fully understand the agreement and terms of the partnership that is being offered by the outside party.

University

The university plays an extremely important part in aiding in the development of a company. Starting a new company is very expensive. The cost of lab space and equipment is often far too much for the entrepreneur to fund on their own. For this reason, the entrepreneur should look into the possibility of getting a lab at the university. A lab offered by the university provides the entrepreneur with low starting costs because there is already equipment there, it is already set up, and the appropriate permissions and paper work for running a lab has already been obtained. Usually, the start-up has to only pay rent and the cost of the chemicals or materials that they are using.

Another advantage to starting in the university is that the entrepreneur has access to its networks. This network is composed of other researchers and professors. There are several benefits to the university network. One benefit is that ideas and discoveries can be discussed with other individuals that are up to date on the current state of biotechnology. Suggestions can be made and opinions sought. Another benefit is access to the university's professors. Professors often have good contacts with important individuals in government and in the industry. Entrepreneurs can use these contacts to help get their business off of the ground.

Starting in the university also provides a comfortable, familiar environment to the entrepreneur. Since the researcher most likely started working on the idea within the university, they are familiar with the setting and the way things work. Many entrepreneurs comment that the

comfortable environment is a good place to work and then slowly grow more independent over time.

Business Advice

During the patent procedure or after the patent has been obtained, the next step in creating the business is to start designing the business plan. Most scientists have not had any training or formal education in composing or creating a business plan. The business plan, however, is one of the most important first steps in starting the company. This is where the entrepreneur puts forth the ideas for the company. Some of the ideas to be included in a business plan are the vision of the business, how it is going to accomplish it, where it is going to do it, how it is going to fund itself, how it will grow, and where it stands in the market place. The business plan is the first piece of information that potential inventors read about your company, therefore, it is necessary to be as concise and do as good a job as possible.

In creating the business, the entrepreneur needs to have a vision. This vision is essentially, what the entrepreneur thinks the company can become. With this vision established, the entrepreneur can begin to describe how he or she would like to achieve the desired goals. This is important for two reasons. First, it creates a document that is to be read by investors and other supporters. Second, it really helps the entrepreneur to focus on what it is they want and what it is that they need. The business plan must be a readable and understandable document and must contain clear visions of growth. The vision of the growth of the company needs to be realistic and needs to be based on a sound strategy to achieve these ends.

The desired outcome and the fate of the company need to be included in the business plan as well. There are currently several options. One option for a company is to make an IPO (initial public offering). This is the process of opening a private company to the private sector in order to raise more financing. This option is becoming increasingly common, especially since the

creation of the Neuer-Markt. Another option for a company is to be bought out or bought into by a larger pharmaceutical company. A buy-out is when the owners of the business sell the company. A buy-in is when a larger company pays for the start-up company, but the smaller company is not assimilated into the larger company. The purchased company remains on its own, but the larger company, in return for their money, gets to place their own people into the management positions and get to dictate the course of future research.

This goal needs to be discussed between the various founders so that when the time comes everyone knows where the company stands. An agreement should be made when the company is started in order to prevent fallout between the founding members, should one or more decide that they no longer like the predetermined option. This agreement should set forth the terms and conditions of the departure of a founder. Included in this is who is allowed and how they are allowed to buy the leaving founders shares. In some cases, business have fallen apart because one of the founders does not agree with the course the company is taking and wants to get out. This agreement will allow for this to happen while preserving the company from tearing itself apart.

Another aspect of the business plan is the market analysis for the company. This is one of the more important aspects of the business plan because aside from the management team, this is what interests potential investors the most. The entrepreneur should do the market analysis with aid from potential or current customers so that the realistic needs of the market are assessed. Today, this analysis needs to show that the core idea can yield many products. Companies that only have one potential product or service in today's market typically will not receive funding. The market analysis should also take into account the size of the potential niche. If a company has a product that addresses a problem that no one else does or that there are not nearly enough

companies to fill, they will be in a prime position to receive funding. Companies that are trying to release a product into a saturated market will find it much harder to obtain the necessary funds.

The entrepreneur should take care when deciding how much money will be needed in the business plan. Too much capital is not as bad as not having enough capital. Often overseen or unpredictable cost will arise. To help handle these occurrences the entrepreneur should multiply the initial estimate by a safety factor that he or she deems fit. This will help the entrepreneur from running out of money, which often leads to loans or financing with less-than-desirable terms and conditions.

Writing a business plan needs to be done by the entrepreneur of the company. By doing the research and learning to write the business plan, the entrepreneur is forced to analyze each little detail of the company. This helps to focus ideas and from this, the entrepreneur can learn the things that he or she needs to do. While it is good to do the business plan on their own, entrepreneurs have several places that they can turn to for assistance. The business angel network, for example, offers support on the creation of business plans. Another form of assistance can come from government programs such as Science4Life.

Science4Life is a business plan competition, sponsored by the government, with the intention of promoting the creation of new companies by offering them advice on their business plan. This advice comes from free analyzing of the business plan by members of the industry, finance community, and from the field of science. The competition sponsors conferences and meetings where different topics of writing a business plan are covered. This program greatly aids entrepreneurs by giving them advice on the business plan, the feasibility of the company that has been, or is currently being formed and gives them access to the network of individuals that is already associated with biotechnology.

Another important aspect of starting up a company is creating the core team. This is the group of individuals who get together and form the company. The most gifted individual should be designated as the CEO or managing director of the new company. The new CEO will be have both science and business responsibilities. Another individual needs to take on the responsibility of handling the marketing of the new company. Marketing is very important because it is through marketing that the company will earn its business. Another area that is also important is the financing of the company. This entails getting outside funds, and managing the existing funds of the company. The company needs to have strong ties to experienced firms or individuals in the field of business. The advice obtained from these contacts is needed to aid the entrepreneurs in their learning of what it takes to run a company.

In some cases, the management team can contain outside individuals or firms. This is often the case when there is a lone entrepreneur. The contacts with these outside sources serve the entrepreneur by giving him or her access to knowledgeable players in the business world. Early on, the single entrepreneur can act as the CEO, handling all of the business aspects alone with the advice from the external contacts. Typical members of this management team would include science advisors who aid in determining the scientific course to be taken, and business advisors who lend expertise and advice to the business decisions that need to be made.

Financing

Once an idea for a management team has been devised, the next problem the company faces is funding. Biotechnology research often requires a lot of money. It is at this time that financing needs to be taken into consideration. Typical first round financing is done by raising money from friends, relatives, or other sources close to the entrepreneur. In some cases, venture capitalists are approached. Care should be taken at this time when approaching venture capitalists. The earlier a venture capitalist enters into an agreement with a new start-up, the more

beneficial it will be for the venture capitalists and not the entrepreneur. The reason for this is that companies have no real value. The idea is untested and the ability of the company to operate successfully has not been proven. Often the venture capitalists will ask for larger shares in the company and give less money at this time. If the company can be financed without out the aid from venture capitalists until it has reached a point where it has proved the worth of its product and its ability to operate successfully, the venture capitalists will offer more money and request less stock.

Another form of funding that the entrepreneur can try to obtain is funding from traditional sources like banks. Loans from banks can be more desirable than venture capital because the bank does not require you to give them stocks and does not get involved with trying to guide the company as is often done with venture capitalists. The problem with funding from sources like banks is that the company has little to offer the banks in the way of securities. If the entrepreneur can convince the bank that the idea will be successful and that the future of the company is bright, the likelihood of obtaining the funds increases.

As the company grows larger, more funding will eventually be needed. When this time comes, the best method to procure more funds is to have a well-rounded network of individuals associated with the company. The entrepreneur should keep this in mind as the company develops and should attempt to create this network of contacts over time. Working to establish this network as the business grows will be a lot easier for the entrepreneur than scrambling when the money is desperately needed. A well-rounded network most commonly consists of the bioentrepreneur, the venture capitalist, the senior management team, and the investment banker. Because most bioentrepreneurs come from a research-based background, the networks that they have access to are commonly limited to their scientific and technical expertise.

The venture capitalist joins the team and takes on the challenge of financing and guiding the bioentrepreneur in order to reap financial returns. The venture capitalist focuses on making money so that they can pay themselves and the individuals and institutions that they represent. The venture capitalist must work to obtain the trust of the bioentrepreneur so that the transition into the commercial market is as smooth as possible. When the venture capitalist joins the team, care should be taken to define the needs and wants of the venture capitalist.

More often than not, the venture capitalist is not invested in the company for the long run. The goal for most venture capitalists is to grow the company to a point where it can find an exit strategy. Most commonly, exit strategies are public offerings or the sale of the company. It is at this point that the venture capitalist recoups their investment and can move onto another company. Because the venture capitalist usually intends to leave the company, the bioentrepreneur needs to understand the objectives and the time frame that the venture capitalist wants to work within. Another concern that the bioentrepreneur should keep in mind when picking from venture capitalists is their background. Because there is a lot of venture capital money chasing a few great ideas, the competition between venture capitalists can be fierce. Choosing a seed venture capitalist that has a history of co-investing with the investment bank's venture capital group can have a beneficial effect at the time of the companies IPO due to the close relations with an investment bank.

The senior management team typically consists of a strategist, a tactician, and a financier. The strategist's primary responsibility is to identify commercial opportunities and position the company to participate in them. Strategists are typically experienced managers from the pharmaceutical industry, often with a research or marketing background. A good strategist will not only know the products and technology but will also know the competitive landscape and the network of people who are associated with them.

The tactician is needed to ensure the day to day operations go smoothly. Along with that, the tactician is responsible for ensuring that the necessary milestones are reached in accordance with the commercial strategy. Tacticians are usually experienced managers and have expertise in product and project management relevant to the company's platform. Good tacticians will have prior experience in bringing products to market, and as a result, knows the ins and outs of such an event.

A financier is familiar with the workings of the venture and public investment communities. This allows the company to have access to more capital. Also, the financier is required to do everything possible to assure a rising stock price. In the initial phases, most biotechnology companies lose money. Because of this, the financier must have strategic financial skills as well as operational ones. Because of these requirements, most financiers come from the venture or investment banking sectors. A good financier will have a good working knowledge and understanding of how the real world works along with the strategic and operating needs of the company.

Also important to the long-term success of the company is an investment banker. Typically, the investment banker tries to deliver cheap capital and impact research coverage. The investor is like the venture capitalist in that he or she works under a specified set of objectives and rules. For example, different firms have very different policies about whether they will participate in a deal. Being acquainted with this inner circle of bankers is crucial to the bioentrepreneur who is looking for an exit strategy.

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European Patent Office
http://www.european-patent-office.org

BMBF: comprehensive information on the subject of inventions and patent law.
http://www.patente.bmbf.de/titel.html

Patent server of the German Patent and Trademark Office
http://www.deutsches-patentamt.de

Home page of the Patent Agents Society
http://www.patentanwalt.de

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