BRIDGING THE ACADEMIC BIOTECHNOLOGY COMMERCIALIZATION GAP: CAN THE MISSION OF THE PUBLIC RESEARCH UNIVERSITY BE PRESERVED?

A Dissertation

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DEDICATION

This dissertation is dedicated to my son, Aaron Keith Jarrett, who supported and encouraged me throughout this entire process, even while he was in the same household with me while he successfully pursued his MBA degree and passed his CPA exams. His unending faith in me, even when I doubted myself, encouraged me more than he will ever realize. His encouragement was matched only by his sense of humor, which made me get on with it all, no matter what incidents or setbacks occurred.

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ABSTRACT

The primary purpose of this exploratory study was to determine if there is a best model available for public research universities to use when they are implementing or revising a mechanism to commercialize early-stage academic biotechnology inventions and discoveries. Unintended consequences, including conflicts of interest, faculty roles, and the mission of the public research university were also studied in order to determine if these issues could be managed or removed when academic biotechnology commercialization occurred.

This study compared the best practices biotechnology commercialization model at the University of California San Diego (UCSD) with biotechnology commercialization mechanisms in place in three different public university settings: Georgia Research Alliance (University of Georgia), University of North Carolina Chapel Hill (MBA Entrepreneurial program and Carolina Challenge), and Pennington Biomedical Research Center - Louisiana State University System.

The UCSD model included five key components declared essential for commercialization success including: 1) small size of the institution, 2) higher than normal research dollars for faculty, 3) extremely entrepreneurial community, 4) integrated life sciences curriculum, and 5) integrated commercialization track (funding, R&D expertise, springboard for new companies).

The study found that not all five components which were deemed essential for success at UCSD were necessary in designing a successful model in the other three organizations. Five new components also emerged as important to consider when creating a commercialization model, including: 1) highly-focused program, 2) critical mass of faculty who commercialize, 3) workforce development, 4) research cross-collaborations, and 5) faculty incentives for commercialization.

The study also found several options for managing or removing unintended consequences associated with commercializing early-stage technologies, including: 1) channeling of commercialization revenues to support academic programs, 2) developing university foundation programs for arms-length activities including equity in new companies, and 3) developing specific allowances for faculty engaged in start-up company activities.

The researcher recommended that further study be conducted for two of the original five components (higher than normal research dollars for faculty and integrated life sciences curriculum) because they were under-represented or did not exist in the models analyzed.

CHAPTER 1.

INTRODUCTION

Rationale

A growing issue facing universities is the lack of research and development funding and expertise available for the successful commercialization of early-stage academic biotechnology inventions and discoveries (Association of University Technology Managers (AUTM), 2006; Friedl, 2006; Pisano, 2006; Powers, 2006). Without finding a viable commercialization solution, many university technologies may never have a chance to become drugs, medical devices, diagnostics or other important treatments or tools for the life sciences. To address this issue, academic institutions have forged closer relationships with industry and have also entered the biotechnology business much more directly. Some of academia's commercialization activities have resulted in unintended consequences, such as conflicts of interest, concerns over faculty roles, and questions regarding the overall mission of the university.

Despite these consequences, missing out on the opportunities to produce biotechnology successes could have significant negative consequences for universities and for the public good. More than $25 billion in revenue from U.S. university-based businesses and technology licenses has been infused into the academic community since the early 1980s, with $1.38 billion dollars in licensing income reported during fiscal year 2004 and nearly one billion dollars calculated for the previous fiscal year, 2003 (AUTM, 2006). As a result, many communities, regions, and states are increasing their economic development expectations in relation to academe, seeing universities as the key to successfully revitalizing and expanding their underperforming economies.

To drive this economic engine, several large states are making significant investments in bioscience research and development. For example, seven universities in North Carolina are partnering with Dole Foods owner, David H. Murdock, to build a $1.5 billion biotechnology research complex 30 miles northeast of Charlotte (Fischer, 2007).

Recently, other states have begun to invest heavily in biotechnology development, with the goal of solidifying partnerships between higher education and business and industry. A few years ago, the state of Washington created a $350 million program, the Life Sciences Discovery Fund. A new proposal to spend $1 billion over the next ten years has been proposed by the Governor of Massachusetts, Deval Patrick (Fischer, 2007).

California has committed $3 billion to regenerative medicine, while nearly $600 million for Scripps Research and more than $200 million for the Burnham Institute have been generated in Florida. Pennsylvania has pledged $500 million for the Jonas Salk Legacy Fund, and $350 million has been gathered for bioscience research in the state of Washington. Not only are the larger states looking to create bioscience partnerships, but also smaller states such as Alabama and North and South Dakota have committed investments in these areas (Fischer, 2007; Schwartz, 2006).

> Others, however, have urged caution, noting that building a biotech hub is a risky venture and one that might not pay off for years, if ever. As greater numbers of civic leaders …look to higher-education institutions to create jobs and revitalize local economies, development experts worry that the expectation that university-generated research will lead to an economic renaissance may be overly idealistic… (Fischer, 2007, p. A-1).

These activities have resulted in an escalation in the formation of closer relationships between academia and communities. Some argue that higher education institutions are more important to a community's economic development than tax cuts or other incentives (Fischer, 2006). Such economic development projects can augment transformation in a local or regional

economy, but do not act as the core for economic transition. Instead, they can become "a good way to diversify your region and your economy, but, by themselves, they are not going to replace your steel industry, or your textile industry," reiterates Walter H. Plosila, Vice President at Battelle Memorial Institute (Fischer, 2007).

Washburn (2005) discusses the danger of universities marketing themselves as engines of economic growth, which could create false expectations, especially in the so-called "catch-up" schools. One of the concerns Washburn explores is that if these universities are unable to deliver on the promises they have made to their legislatures and communities, this failure could jeopardize their requests for future funding. This opinion is shared by James J. Duderstadt, University of Michigan President Emeritus and University of Rochester President Joel Seligman, among others (Powers, 2006).

In support of this point of view, many faculty and others are concerned that the expectations being placed on academia are out of proportion, especially in economically depressed regions, as argued by Sean Stafford of the University of Chicago, who believes that universities play an important role but cannot shoulder the entire responsibility for economic development (Fischer, 2006). He and others warn there is a limit to the extent of the economic returns and promises any single academic institution can bring to its local community, region, and state (Washburn, 2005).

Those who push this economic platform know that academic-based blockbuster biotechnology hits, which have grossed millions of dollars for universities, faculty, related institutions, academic teaching hospitals and other affiliated centers, are central to this success. Such noteworthy biotechnology license deals include more than $200 million to Florida State University from Bristol-Meyers Squibb for Taxol, $80 million to date to the University of

Florida for Gatorade (Powers, 2006), $46 million to Memorial Sloan Kettering from Amgen for Neupogen, and $16 million to Massachusetts General Hospital from Immunex for Embrel (Edwards, Murray & Yu, 2003).

A 2002 survey by Feldman, Feller, Bercovitz and Burton reinforced that these blockbuster successes are not the rule for academic biotechnology commercialization.

> The distribution of licensing revenues is highly skewed with a few big commercial successes generating large returns for a small number of universities. Well-known licenses, such as the Cohen Boyer gene splicing technique (University of California and Stanford), Gatorade (University of Florida), Cisplatin (Michigan State)…or Taxol (Florida State University) are the exceptions rather than the rule (p. 108).

Nevertheless, such successes have prompted greater pressure to encourage academic institutions, including public universities, to form market-driven partnerships with business and industry (Angell, 2000; Edwards, Murray & Yu, 2003; Gordon, 2004; Spack, 2005; Vallance, 2001) and encourage faculty to commit more time and effort to research leading to commercialization (Etzkowitz, Webster & Healey, 1998; Newman, Couturier & Scurry, 2004; and Slaughter & Leslie, 1997).

> Such admonitions, though, have done little to dampen the trend of looking to research, and, in particular, to biotechnology, to jump-start regional economies. Nationwide, state and local governments, universities, and private companies are spending millions of dollars to build new facilities and attract top-flight researchers (Fischer, 2007, p. A-1).

This economic push, which gained momentum in the 1990s and continues today, has been defined by Slaughter and Leslie (1997) as academic capitalism. The term, academic capitalism, relates specifically to higher education research activities, realizing that academic institutions contain some of the most scarce and valuable human capital that "nations possess capital that is valuable because it is essential to the development of the high technology and technoscience necessary for competing successfully in the global economy" (Slaughter & Leslie, p.11). The majority of this capital rests in the knowledge and information possessed by faculty

and other academic staff. When this capital applies to work that "yields a benefit to the individual academic, to the public university they serve, to the corporations which with they work, and to the larger society" (p. 11) and moves toward or enters the marketplace, this becomes academic capitalism (Slaughter & Leslie).

Even though the nation's universities are the largest source of such academic capital, transforming this raw resource into successful market bioscience products and treatments, is a complex process with a low success rate. For example, although impressive, some of the biotechnology commercialization revenue successes presented above may be misleading. In the new annual report from the Association of Technology Managers (AUTM, 2006), the actual return on investment that universities received for their support of technology transfer in fiscal year 2004 was only 15 cents on the dollar. Also decreasing was the number of institutions reporting annual royalties of more than $20 million. In 2000, 14 institutions fell into this category, while only 11 did in 2001.

Contrasting these data, the volume of technology transfer activity grew during that same reporting period. The number of inventions rose from 10,802 in 2000 to 11,259 in 2001 and to 16,871 in 2004. Patent filings also increased by approximately 1,000 for fiscal year 2001 over fiscal year 2000 and have continued to increase each fiscal year since (AUTM, 2006; Blumenstyk, 2003b).

Looking deeper, the story appears mixed. "The relationship between the number of issued patents and the number of new licenses is largely coincidental; despite our fondest hopes, we are not able to license 97 percent (97%) of patents as soon as they issue" (Wheaton, 2006, p.1). A recent survey reported that only 12 percent (12%) of university licensed technologies are ready for commercialization (Feldman, et al., 2002). The report describes the small success rate

related to discoveries, citing that of all invention disclosures, only a small number resulted in interest from potential licensees, with an even smaller number generating any license income. "The rule of thumb in university technology transfer is that for every 100 invention disclosures, 10 patents and 1 commercially successful product results" (p. 108). "Despite the controversy, universities are forging ahead with their technology transfer activities in a quest for new sources of revenue and new-found legitimacy as important sources of innovation in a competitive global marketplace" (Powers, 2003, p. 26).

Academic Biotechnology Commercialization

The prognosis for biotechnology success is quite risky, which is of notable concern for research universities, because a sizeable share of academic inventions and discoveries are biomedical. These technologies require extensive U.S. Food and Drug Administration (FDA) approvals which include expensive, long-range research and corresponding comprehensive data. Most FDA approvals take an average of 10 years and can cost upwards of $800 million to $1 billion dollars to reach commercialization. "Current estimates of development times for small-molecule drugs are 10-15 years with an estimated average cost of $802 million per approved drug" (Friedman, 2006, p. 36). As a result, the lag time for any royalty milestone payments going back to a university can be substantial (Feldman et al., 2002).

The Milken Report on university biotechnology commercialization released in September, 2006, concludes that very few universities account for the majority of revenue associated with biotechnology-based economic development (Milken, 2006). According to this study, related revenues and the location of successful commercialization programs in the U.S. are concentrated in very few geographic regions. A Milken Report from 2004 reports that the San Diego area is ranked as the best geographic location for biotechnology startup company

commercialization in the U.S., followed by Boston, and then Raleigh-Durham, but the number of highly developed geographic clusters is small (Milken, 2004; 2006).

A Brookings Institution Report conducted by the Institute of Portland Metropolitan Studies (Portland State University, 2001) concluded similar findings. In a survey of 51 of the largest U.S. metropolitan areas, the report concluded that only nine areas contained the capacity to generate and sustain significant biotechnology industry development.

Harvard Business School Professor Gary Pisano (2006) goes even further, concluding that after being in existence for 30 years, the biotechnology industry has still not come of age. He describes the current status, noting that "despite the commercial success of companies such as Amgen and Genentech and the stunning growth in revenues for the industry as a whole, most biotechnology firms earn no profit" (p. 114). In fact, Pisano points out that a very small percentage of entities generate positive cash flows and the overall industry has lost money. In addition, he adds there is no evidence that small biotechnology companies are "significantly more productive at [research and development] R&D than the much maligned behemoths of the pharmaceutical industry" (p 115).

Several experts argue that academia's fascination with the technology industry and with the commercialization of its own inventions and discoveries is not based on extensive review of the process and the realistic probably of success, nor on comprehensive strategic planning in order to maximize opportunities (Pisano, 2006; Powers, 2006). Those who are skeptical declare that the shift from more traditional revenue sources to this new model, which focuses on commercial returns and economic impact, was implemented hastily, without enough time and effort given to assess how this relatively new, potentially strong revenue stream would actually play out over a broad range of academic institutions located across the country (Newman,

Couturier & Scurry, 2004). This lack of vision, Pisano points out, has contributed to the lackluster overall performance of the biotechnology industry.

As reinforcement for this argument, Washburn (2005) reports that the biotechnology commercialization problem may go back as far as the late 1970s. At that time, data presented to the U.S. Congress in support of the Bayh-Dole Act of 1980 was somewhat misleading. The Bayh-Dole Act, a watershed piece of federal legislation which marked a significant change in the federal science and technology policy, became a catalyst for commercialization of academic-based inventions and discoveries. Proponents of the Act argued that federally-licensed patents, including those from academia, were sitting dormant and not being commercialized. What was not disclosed in the data presented to Congress, according to Washburn, was the fact that the majority of the patents held by the federal government had been offered to industry but turned down because they were too early-stage and needed further developmental research funding which those in industry were unwilling to provide.

Ironically, even after more than 25 years since the passage of the Bayh-Dole Act (1980), this same problem of how to develop and fund early-stage inventions and discoveries remains a major issue for universities (Friedl, 2006; Kouri, 2006; Nowak, 2006). Yet, the fact that many academic technologies are too early, or even inappropriate, to commercialize is often overshadowed by the assumption that success for early-stage technologies is all but assured with just more time and money. Even today in academia, approximately one technology in 100 brings in license revenue (Feldman, et al., 2002). The return on investment for technology transfer is 15 cents on the dollar (AUTM, 2006) and 12 percent of licensed technologies are ready for commercialization (Feldman, et al.).

The revelation that most university-generated technologies were not commercialized prior to Bayh-Dole because they were too early-stage or not appropriate to market, begs the question as posed by Washburn (2005), "what share of the university-based inventions generated since 1980 were commercialized *because* of the institutions created under Bayh-Dole, and what share *would have been commercialized anyway*?" (p.143).

The Valley of Death

Powers (2006) and Pisano (2006) suggest that university leaders need to rethink the technology transfer model in order for these institutions to reach their true commercial potential. Powers notes "…the current technology transfer process has done a better job of raising universities' financial hopes than it has of realizing them" (p. B-18). One of the most important pieces too often absent from the current commercialization paradigm is a reliable mechanism for bridging the gap between early-stage academic biomedical inventions and discoveries and venture fund investment interest. This funding gap exists today despite three decades of increasingly commercialization mechanisms (Friedl, 2006).

As described below by Colonel Karl E. Friedl, Ph.D., (2006) of the U.S. Army Research Institute of Environmental Medicine, this growing issue has been referred to as the "valley of death" by himself and others.

> Between these two fundamentally different cultures of researchers and developers is the so-called "valley of death," where discoveries fall into a technology purgatory instead of smoothly transforming into new building blocks accessible to the problem solvers. This cultural divide is reinforced by the existing organizational structures that want to fund only the most innovative mechanistically based projects and investors who want reasonable feet-on-the-ground indicators of likely success (p. 413).

Others are recognizing the importance of this growing problem, including the Association of University Technology Managers (AUTM), the professional organization for academic technology transfer managers, which has recently added a new category to its annual survey to

specifically address this commercialization issue (AUTM, 2006). AUTM describes "gap" as "the discontinuity in funding between federal funding for research – which typically drops sharply as technologies approach commercialization – and commercialization, which can be very difficult to obtain in the very earliest, highest-risk stages of technology commercialization" (p. 2).

The survey results indicate that inventors and technology transfer officers have found it necessary to turn to alternative funding sources at this early state, such as friends and family. Individuals provided approximately half of the earliest stage funding for university start-up companies, according the 2004 fiscal year AUTM survey (AUTM, 2006).

As noted above, this problem with commercializing early-stage academic inventions is not a new one, but was present before the passing of the Bayh-Dole Act. The difference is that, initially, this early-stage funding problem was not discussed but kept quiet during the Congressional hearings in the late 1970s regarding the Bayh-Dole Act. This silence has, in some ways, mistakenly led some to assume that the early-stage commercialization problem is a very recent one (Friedl, 2006; Kouri, 2006; Nowak, 2006; Washburn, 2005).

Commercializing biotechnologies which may not be ready or appropriate for further development can result in efforts that lead to increases in the rates of 1) start-up companies, 2) inventor involvement in technology development, and 3) equity ownership by the academic institution. Such expansion of technology development activities might be based on the need to commercialize at all costs and might not revolve around sound business practices (Fischer, 2007; Powers, 2006; Rubin, 2005).

The gap between academic technology transfer offices and the venture community is especially large, as noted by Eric Nicolaides, a Chicago-based venture management form partner

(Technology Transfer Tactics, 2007). He points out that if a new start-up company is formed around an academic inventor, but not much more, then that is not really forming a new company in the sense of economic development.

Conversely, recognizing that a significant number of academic biotechnologies are and will continue to be very early-stage, the solution is not always as simplistic as deciding "go" or "no go," but actually involves a more sophisticated assessment mechanism. Not all technologies which find themselves in the valley of death should be commercialized, but, not all of them should be abandoned. Universities must choose which technologies are non-rival goods as described by Washburn (2005) and disseminate them into the public domain while promoting the remaining promising technologies through additional research and development. "The best way to guarantee that a technology will reach commercialization is to take an active role in bringing entrepreneurs, venture capitalists and scientists together at the time a license is granted and a strategy is formed for a new product" (Pounds, 2007).

Yet, there may be other incentives working in tandem with those related to developing promising technologies. Economist Jerry Thursby conducted a large survey of university technology transfer officers in which he reported that revenue was considered their highest priority, even if it challenged the need for effective commercialization (Washburn, 2005). Such incentives may cloud the decision-making process and may influence how much time and attention is paid to commercializing the technologies, whether or not they deserve to be developed.

Presently, viable options for such gap-filling commercialization measures are scarce at universities, with the few available opportunities often plagued by conflicts of interest and replete with unintended consequences. As a result, many promising yet nascent biomedical

technologies sit undeveloped because current investment strategies are not structured to include such early-stage, high-risk research in their portfolios (Spack, 2005). Using current practices, such as creating university-based start-up companies to commercialize these early-stage technologies often results in conflicts of interest, concern over faculty roles, issues related to whether such technologies are viable for commercialization, and other unintended consequences (Powers, 2006; Technology Transfer Tactics, 2007).

According to a study on university-based start-up companies, the market returns and success rates for academically-generated technologies is not attractive to investors (Chukumba & Jensen, 2005). In studying why industry is reluctant to fund university-based start-up companies, the authors discussed that, according to those in industry, academic inventions and discoveries are often considered extremely embryonic. "If an established firm is unwilling to take a license, then it is very difficult to find the funding for a start-up because even the venture capitalists who specialize in start-ups come to university inventions only as a last resort" (p. 4).

Contributing to this problem has been a change in the climate surrounding biotechnology investment options. In recent years, the value in early-stage biotechnology stock has fallen dramatically. The University of California, San Francisco (UCSF) reported that the university had a record-breaking 125 deals with biotechnology investors in 2000 but that number dropped sharply to 70 the next year (2001) and only 39 in the first ten months of 2002 (Knight, 2002). One reason for this change can be attributed to the fact that investors are now more interested in technologies that will get to market quicker and turn a profit in less time than university inventions typically can.

The AUTM survey editors also report that start-up companies created by these biotech investors have dropped off dramatically (AUTM, 2006). Although angel investing has begun to

rebound since the dot com downturn of 2002, current biotechnology angel investors have become more like early-stage investors, moving their funds toward later-stage technologies, according to Jeffrey Sohl, Director of the Center for Venture Research at the University of New Hampshire (AUTM).

Ashley Stevens, who was a co-editor of the 2002 AUTM survey and Director of Technology Transfer at Boston University that same year, explains.

> Over the past few years, investors have been more interested in starting up companies based around products in late-stage development…Universities don't have nearly as many phase 2 compounds in their licensing baskets…and my guess would be that many of the recent university startups are stuck at seed stage, hoping for venture [capital investment] (Bouchie, 2005, p. 843).

This downturn, which began in 2000, led to a buyer's market for early-stage biotechnologies, many of which had their origins in university-based inventions. The result was that venture funds began investing in later-stage technologies at lower, early-stage prices. This reduced even further the value of early-stage technologies and pushed investors to increasingly show interest in late-stage technologies that are already in the clinic or have a short time frame before submission to the FDA for drug or device approval (Kling, 2005).

Some companies which are focused on funding biotechnologies explain how they are now structuring their early-stage investments, while acknowledging that the research they are looking for lies within universities. In targeting very early-stage academic-based technologies, these companies only expect to pay bargain prices for such university-based inventions. They have discovered a new bargain price niche along with secured rights to academic discoveries. One investor described that this new strategy was developed after his company had miscalculated the time and investments they would need to provide for a technology that took longer to develop than anticipated. Because the company had originally paid a large sum for the

rights to the technology, they later opted not to put another $16 million into developing it further but chose to shut down its overall technology development instead (Forman, 2006).

Looking abroad for successful academic commercialization models to emulate has been difficult as well. It appears that this commercialization gap problem is not confined to the United States. A recent study in the United Kingdom (UK) found that biotechnology venture capitalists are not attracted to invest in university-based spinout or startup companies based on academic inventions. This increased risk-aversion by traditional biotechnology investors has resulted in the need for UK academic technology transfer offices to look for other sources of early-stage funding and other support (Dorey, 2004). As a result, in parts of Europe as well as in the United States, it is becoming more apparent that creating new, early-stage technology development strategies are paramount in order to secure maximum long-range returns from academic intellectual capital (Friedl, 2006; Kouri, 2006; Nowak, 2006).

But will these strategies work? Even proponents of the new economy, such as University of North Carolina System's Leslie Boney, recognize the transformation into the knowledge economy will contain some difficult moments. "On some level, there is a disconnect between the old economy and the new economy," he says, "and in the short term, that could be painful for people in the community" (Fischer, 2007, p. A-1).

The presumptions that there would be a high success rate for academic inventions and discoveries after implementation of the Bayh-Dole Act and related legislation did not take into account that prior to the passage of Bayh-Dole, the majority of university-generated inventions and discoveries were too early or inappropriate to commercialize (Washburn, 2005). How accurate is the assumption now that the funding gap is a recent phenomenon, which needs solutions based solely on recent events?

Also missing from the present equation for closing this funding gap is the acknowledgement that some biomedical research inventions and discoveries have been and remain non-rival goods, which should become part of the public domain, with the ability to be used and shared simultaneously by many researchers (Washburn, 2005). As discussed earlier by Nicolaides, not all university-based technologies are appropriate for the marketplace (Technology Transfer Tactics, 2007).

The National Institutes of Health (NIH) has voiced this same opinion and has increased its demand that research tools and other appropriate biomedical technologies that have been invented or discovered using NIH research funds should be shared by academic researchers, even if there is the ability to commercialize the technologies. NIH provides a mechanism for protecting the technologies for commercialization while ensuring that the tools or biomaterials are also shared (NIH, 2007).

One recent option for addressing this overall academic commercialization problem involves universities creating their own start-up companies, as pointed out in the 2005 study by Chukumba and Jensen. Even so, using this new commercialization strategy has not always provided a viable solution, the authors point out, "as is well-known by now, university inventions are typically embryonic. Their commercial potential is uncertain and the likelihood of their success is very small" (p.6).

Statement of the Problem

The lack of research and development funding and expertise available for the successful commercialization of early-stage academic biotechnology inventions and discoveries leaves many potential drugs, treatments, diagnostics, and other life science solutions undeveloped (AUTM, 2006; Friedl, 2006; Pisano, 2006; Powers, 2006). To address this issue, academic

institutions have entered into and increased their commercialization activities, including the formation of start-up companies, resulting in unintended consequences, such as conflicts of interest, concerns over faculty roles, and questions regarding the overall mission of the university. Despite these consequences, missing out on opportunities to produce biotechnology successes could have significant negative consequences for universities and for the public good.

Many academic research institutions have encouraged faculty and other employees to commercialize their inventions and discoveries, and have set up offices of technology transfer to oversee these activities, but these initiatives alone are not enough to ensure success for transfer of university-based technologies into the marketplace (Slaughter & Rhoades, 2004). A very low percentage of academic inventions and discoveries ever become successfully commercialized (AUTM, 2006; Chukumba & Jensen, 2005; Milken, 2004; Pisano, 2006; Powers, 2006).

One way to increase the rate of success associated with academic biotechnology transfer is to provide a new, broadly-applied mechanism to provide a more comprehensive way to bridge the gap between early-stage inventions and venture capital funds. At the same time, such mechanisms should ensure the university's mission and address the concerns raised, such as unintended consequences, concerns over faculty roles, and questions regarding the overall mission of the university.

This was an exploratory study focused on analyzing the following: 1) the mechanisms for commercializing early-stage academic inventions and discoveries with success defined as the formation of a new company or the license to an existing entity, and 2) the resulting unintended consequences and the processes implemented to minimize or remove these unintended consequences resulting from such commercialization activities. Both issues were analyzed around creation of a viable start-up company as the measure of success regarding early-stage

academic technologies. The goal of the study was to present possible mechanisms, models, and best practices that other public universities could use to successfully commercialize their early-stage biotechnologies while preserving the overall mission of the university and minimizing or eliminating related unintended consequences.

Initially, this study was planned to analyze two different university-based mechanisms to develop early-stage, academic biomedical inventions and discoveries with the goal being the formation of a start-up company or licensing to an existing company. One model, that of the Louisiana State University System Pennington Biomedical Research Center (PBRC), is based on the creation and implementation of an early-stage research and development investment platform, while the second at the University of North Carolina at Chapel Hill is focused around a specialized entrepreneurial curriculum program in the graduate school MBA program.

The PBRC model is a comprehensive program still being developed, involving several key players in the university, including faculty and administrators. This program also includes other academic components, a research foundation, and an early-stage investment fund, among others. The goals of the program include commercialization of early-stage inventions and discoveries through the formation of start-up companies and the elimination or management of related conflicts of interest and other unintended consequences, while preserving the mission of PBRC and the Louisiana State University System.

The UNC MBA biotechnology entrepreneurship model is a program that reinforces the core missions of education and training and also increases the chance of commercialization success for academic biotechnologies with the goal of starting new companies around technologies. This recently created curriculum-based mechanism at the University of North Carolina has been established to commercialize early-stage academic biotechnology inventions

and discoveries and promote technology transfer success (Kouri, 2006). This model also helps to grow the number of local biotechnology industry experts in finance, management, and regulatory areas. Graduate students, inventors, and industry experts develop business plans and create start-up companies. Even with such a history of biotechnology success in the Research Triangle, the funding gap also exists and is growing in North Carolina.

During the initial phase of studying the PBRC model, an opportunity arose to include the Georgia Research Alliance (GRA) program as a third bioscience commercialization model to analyze. Due to the ongoing success of the GRA program, access to key informants participating in the GRA program, and the focus on the GRA model by the State of Louisiana Board of Regents, the model was added to this study.

As a first step, the three models were reviewed individually and then compared to each other. The second step of the analysis continued when the three mechanisms were compared to the University of California at San Diego (UCSD) model. The Milken Report (2004; 2006) ranks the San Diego region and UCSD first in biotechnology start-up company formation and continued operations, which the report considered essential in early-stage commercialization success. The UCSD model includes the following five key components for success. This study looked at the presence or absence in the GRA, UNC, and PBRC models of each of the five key research commercialization components listed below:

1) Organizational efficiency based on a flat hierarchy and the relative small size of the institution,
2) A high ratio of research dollars to faculty,
3) A highly entrepreneurial culture and community,
4) An integrated academic life sciences curriculum program, and

5) A specialized biotechnology commercialization program which includes:

   a. Funding for new technology development

   b. Research and development expertise, and

   c. A springboard for new company development

   (Holmes, 2006; Milken, 2004; 2006).

This study also addressed the following questions:

1) What is the individual process by which:

   a. the GRA model works?

   b. the PBRC model works?

   c. the UNC model works?

2) How do the five key components play out in each setting (GRA, UNC, and PBRC) in terms of organization, implementation, and in relation to commercialization?

3) What are the similarities and differences among the three models and how do they compare to the UCSD model?

4) Are there additional key components considered essential for commercialization success?

5) How do the three models address the issues related to unintended consequences such as conflicts of interest, faculty roles, and the overall mission of the university? and

6) Which findings can be applied to other public research universities?

Academic Locations for Start-Up Companies

According to experts (Holmes, 2006; Milken, 2004; 2006; Pisano, 2006), the success of biotechnology start up companies is very dependent on geographic culture, the availability of start up funds, and qualified, seasoned management (Blumenstyk, 2006). A large number of research universities are often situated in economically depressed or risk-averse geographic areas which are away from major population centers containing potential employees who possess the necessary highly-specialized skills. Therefore, it seems even more important for universities located in less populated areas which are economically depressed or less entrepreneurial, to focus an even greater effort on what can be done to help ensure commercialization success for their biotechnologies since the odds do not appear to be in their favor.

Since the issues of geographic region, a revamped biotechnology commercialization model, and management of conflicts of interest are of central focus, this study addressed these key issues. The 2006 Milken Report concludes that university intellectual property "…is absorbed more readily in regions with an existing technology industry base. A high concentration, or clustering, of technology firms in a region assists in creating an environment of linkages and opportunities for university commercialization efforts" (Milken, 2006, p. 55). This study looked at which of these elements might be crucial to commercial success in other regions or locations in the U.S and whether successful models elsewhere could be developed which only contain a subset of all of the key elements.

Wu (2005) points out that the overall success for industry clusters is enhanced by the concept of collective efficiency, where proximity provides benefits for many players in the geographic area. The author further explains "as creative industries concentrate in a city, new business formation also becomes more likely through startups and spin-offs. Barriers to entry

are lower than elsewhere as needed assets, financial support, skills, inputs and employees are often available locally" (p. 3). But Pisano (2006) indicates that such initiatives based on focused strategic planning have not taken place at the majority of academic institutions.

By contrast, success has been notable in the geographic locations where decades of planning and implementation as well as great emphasis on education and training have occurred to support the development of the local biotechnology industry. Wu (2005) describes the role of universities in the overall success of biotechnology clusters.

> A scan of nearly all of the clusters, particularly biotech R&D, points to the critical role played by local universities and research institutions in bridging technology and industries. Most creative communities seem to spring up near universities where learning and industrial activity are woven into the local culture. Universities can become incubators for startup firms, as places where knowledge is patented, where specialized research is housed, and where scientists and industry work together on product commercialization (p. 8).

According to the February, 2007, Louisiana Board of Regents and Louisiana Recovery Authority report issued by Regional Technology Strategies, Inc., the majority of biotechnology research and development takes place in only nine U.S. metropolitan areas, including Boston, Los Angeles, New York, Philadelphia, Raleigh-Durham-Chapel Hill, San Francisco, San Diego, Seattle, and Washington, D.C. (BOR, 2007). The report continues,

> The gap between the top nine life science regions and the rest of the nation is considerable. Compared to the other 42 largest metropolitan areas in the U.S., these nine cities have eight times as much biotech research activity, ten times as many large and newly established biotech firms, and thirty times more venture capital funding (p. 34.).

In the top three biotechnology geographic clusters ranked by the Milken reports (2004; 2006) - 1) San Diego, 2) Boston; and 3) Raleigh-Durham) - the local academic research institutions have played key roles for decades in terms of economic development and overall success. All three communities began their biotechnology push more than 20 years ago, have

continued to invest in the ongoing development in their regions, and look to the universities as key strategic partners in these comprehensive models.

A note of caution accompanies these data. Despite the successes in terms of economic development, none of the nine U.S. metropolitan areas which are home to the most successful biotechnology hubs rank within the top 25 largest employers in their regions (Fischer, 2007). Brookings Institution biotechnology cluster expert, Joseph Cortright, comments that it takes luck and time to turn a promising technology through the commercialization continuum, and for drug products, this process can take several years, or decades, and in the end, the technologies produce very few new jobs (Fischer).

Even with such proactive measures, these three successful clusters took years to develop. Until the late 1970s, the San Diego area was primarily a Navy town which was home to a nascent University of California campus with little comprehensive biomedical research. Then, dependence on the federal government for its economic well-being began to change when the military downsized its presence in the area. As the focus shifted away from federal military and related economic support, community leaders chose to find other areas of fiscal promise in order to maintain and hopefully grow its economic development (Milken 2004; Milken, 2006).

One mechanism was to expand the University of California San Diego (UCSD) and increase its focus on research activities related to the biosciences. According to the Milken reports (2004; 2006), the investments and talent needed to expand UCSD's research infrastructure and provide a basis for overall economic development had their origins in the success of the Silicon Valley information technology (IT) industry. Identifying new opportunities to recreate biotechnology success in the San Diego area, experienced Silicon

Valley industry personnel and available funds were invested in San Diego, which jumpstarted the economic transformation in this area of Southern California (Milken).

The economic development in the Boston area has been somewhat different. The region, with a very strong history of biomedical research in its universities, contains two of the most notable academic institutions, Harvard and the Massachusetts Institute of Technology (MIT), both of which are private. Substantial research funds; an abundance of research faculty; the presence of expertise in the financial, legal, and management areas; and access to East Coast venture funds have all contributed to the successful development of Boston-based technologies both in information technology (IT) and biotechnology. Like the San Diego model, the strategic planning and support of this Northeast industry began in the late 1970s and early 1980s (Milken, 2004; 2006).

The Raleigh-Durham, North Carolina area, also known as the Research Triangle, has many similarities to the San Diego history, with its focus primarily on biotechnology development and not IT. The origins of its planning and support mechanisms also date back more than three decades. Although the Research Triangle Park (RTP) is home to the University of North Carolina at Chapel Hill (public), North Carolina State (public), and Duke University (private), it is important to note that they were not the principle entities which spearheaded the RTP development (Washburn, 2005). The main forces behind the initial planning and the ongoing push to keep the project on focus were the bankers, industrialists, and land developers. Al Link, who has written two books on the development of the RTP, explains that the universities were focused on keeping themselves focused on their research priorities and not becoming an extension of industry. "The universities saw themselves as magnets to attract

research companies to the area, not as participants in those companies' research efforts" (Washburn, p. 177).

In the 1950s, North Carolina suffered from brain drain and a declining economy. Markets for the state's primary industries – textiles, furniture, and tobacco – were declining and college graduates typically left the state to seek work elsewhere. Looking to capitalize on the three local universities, Duke, North Carolina State, and the University of North Carolina, local politicians and businesspeople sought to create local opportunities to stem the brain drain. Research Triangle Park was founded in 1959 on 450,000 acres of worn-out farmland.

> Today Research Triangle Park exceeds 7,000 acres, is host to 136 organizations, and its 38,000 employees draw $2.7 billion in salaries, making it the largest planned research center in the world. Roughly one third of the resident firms and organizations are biotechnology and pharmaceutical companies (Friedman, 2006, p. 208).

One of the differences in the Raleigh-Durham model is that a major pharmaceutical company, Glaxo Smith Kline, located its North American headquarters in the Research Triangle, which created a natural springboard for spin-off biotechnology companies (Friedman, 2006). Very recently, the state of North Carolina announced a partnership with Duke University, six public universities (University of North Carolina at Chapel Hill, Charlotte and Greensboro; North Carolina State University, North Carolina A&T State University, North Carolina Central University), and Dole Foods owner David Murdock to create a $1.5 billion biotechnology research campus in Kannapolis, a small town 30 miles northeast of Charlotte (Fischer, 2007).

Yet, these geographic examples are the exception in terms of how the overall U.S. biotechnology industry has been modeled. In all three cases described above, biotechnology activities have been in existence for three decades, having evolved and adapted over time and having customized themselves to meet the changing needs of their respective communities. Wu (2005) describes how venture capital has focused around five key biotechnology hubs in the

U.S., with a tendency to localize around technology clusters. For example, Wu notes that 75% of new venture capital is focused in five American metropolitan areas, including "Boston, San Francisco, San Diego, Seattle and Raleigh-Durham. In Boston, venture capital flowed more to software and biotech, while in San Diego it went disproportionately to medical and biotech R&D" (pp. 10-11).

Pisano (2006) notes that in studying the structure of the biotechnology industry for the past 20 years, he has learned that much of its infrastructure or "anatomy," as he describes it, was borrowed directly from Silicon Valley IT models. Noting that these models are flawed when applied to biotechnology commercialization, Pisano believes that a radical departure in structure must take place in order for success to prevail in the overall biotechnology arena.

In his description of the anatomy of biotechnology, Pisano (2006) includes universities, start-up companies, not-for-profit laboratories, established companies and investors, as well as the infrastructures linking them together, such as capital markets and intellectual property. He concludes that the different sectors and players in the biotechnology industry work at cross purposes, creating "islands of expertise that impede the integration of critical knowledge" (p. 116). Wu (2005) continues by explaining the special role that the new, small biotechnology firms play in this industry.

> The large basic research establishments in universities, government, and private firms serve as important incubators for the development of innovation. Individuals then establish firms, often small startups, to commercialize them. This pattern has been particularly significant in the biotech, microelectronics, and computer industries (p. 6).

Adding to the controversies, a new consensus is emerging even among those in higher education who had embraced this economic pathway, recognizing that the existing version of the commercialization model needs to be revamped in order to ensure success for a broader range of academic biomedical research institutions. Two major reasons for restructuring the paradigm

have been suggested: 1) many academic universities with a focus on biotechnology are located outside of progressive, highly populated geographic clusters; and 2) numerous conflicts of interest associated with such academic/industry/ investment partnerships are emerging and have not yet been adequately addressed (Association of Academic Health Centers, 2005; Newman, Couturier, & Scurry 2004; Spack, 2005).

Conflicts of Interest

As discussed by Powers (2006), ethical issues are creating conflicts of interest in academe related to economic development which have yet to be resolved.

> Financial interests at times cloud institutional or faculty judgment: Universities have allowed businesses that support research to control its publication…And although federal regulations require faculty members to disclose potential financial conflicts of interest, colleges and universities vary in how thoroughly they enforce such requirements and are under no obligation to report their own possible conflicts of interest (p. B-18).

In 2003 and 2004, public interest groups questioned the high price of a drug from Abbott Laboratories that had been developed and sponsored in part through federal funds, questioning the rights and responsibilities of the use of public funds for such bioscience research and development (Rubin, 2005). To add to these concerns over conflicts, the retrenchment of venture funding has forced universities to begin to take equity ownership in new start up companies which are cash-strapped and which have had little or no support from biotechnology venture capitalists. A patent report found that 66% of businesses had not entered into license agreements with academic institutions. The top two reasons for the lack of collaboration were that 1) university technologies were too early to commercialize, and 2) academic research is very seldom in areas where the companies conducted business (Thursby & Thursby, 2000).

Recently, the biotechnology industry has begun to voice its dissatisfaction in dealing with universities. Several industry representatives concur, citing a shift in the mission from the public

good to returns on investments (ROIs). Thomas Berger, Vice President of Genta, Incorporated, explains that money seems to be the main concern, yet he points out, these universities want that revenue stream without taking the corresponding risk (Wahsburn, 2005).

A related danger was pointed out by Hewlett Packard's (HP) Jim Duly. He commented that HP spent approximately $20 million annually on academic sponsored research, but university terms were becoming increasingly unreasonable (Washburn, 2005). He added, "tech transfer officers have become so focused on short-term revenue….they are destroying long-term sponsored research relationships with industry" (p. 192).

These areas of tension between universities and industry have resulted in the development of new tactics to promote opportunities for licensing. One such mechanism has been for universities to be more directly involved in the formation of startup companies. Since such newly formed entities are in search of start-up capital, academic institutions have bypassed traditional royalty payments for equity ownership (Feldman, et al., 2002). Such company ownership is new for academia, which now finds itself in situations in which it has little or no prior experience.

Despite the drawbacks, the trend is projected to continue. Part of the reluctance to limit equity ownership may be due to the fact that traditional licensing mechanisms are not always the best solution for academic biotechnologies. Over time, it has become more apparent that traditional licensing mechanisms cannot fulfill all situations. "This has resulted in a greater understanding of the limitations of this transfer mechanism in terms of a downward revision in expectation about licensing's revenue-generating potential" (Feldman, et al., p. 109).

At the same time, despite the push toward closer relationships in controlling research activities and commercialization discoveries, young biotechnology companies have pulled back

from cutting-edge science, and have, instead, increased their focus on pursuing refinements (new formulations) with an eye toward increasing the breadth of treatment possibilities. Friedman (2006) discusses that small companies usually do not have the capital necessary to pursue more than one project at a time.

From an investor's point of view, this can be seen as increasing the risk of failure, since the company has not spread the risk over several projects, which can, thus, turn away potential investment. "Larger companies can at least prioritize their goals, giving investors a relative appreciation of potential success. Therefore, small size combines the problems of increased risk due to lack of diversification with exclusion from consideration by investors…" (Friedman, 2006, p. 211). Pisano (2006) warns that this leaves gaps with little focus paid to high-risk projects and wonders where the new breakthroughs will come from and how the industry will reduce the possibility of a breakdown.

Many involved in biotechnology believe that, eventually, the sector will be successful but it will take more time. James A. Severenson, Ph.D. (2006), Vice Provost at the University of Washington in Seattle, believes technology transfer actually enhances the public service mission of the university through the creation of partnerships between academia and industry. In supporting this belief, he discusses that, as a result, there is an increase in sponsored research, development projects, and teaching programs, among others.

Others, such as Pisano (2006), Powers (2006), and Newman, Couturier and Scurry (2004), wonder when that day marking success will actually come. As described by Pisano, the belief that this industry will turn the corner may not be plausible unless more emphasis is placed on reassessing the overall biotechnology strategic model.

> Such optimism assumes that the underlying structure of the sector is healthy and the strategies of the players make sense. My research suggests otherwise. This structure and

> these strategies cannot solve the fundamental business and scientific challenges facing the sector (p. 118).

Failures in Existing Translational Research

Contributing to the concern regarding commercialization success are those related to the underperformance of clinical translational research. Recent scrutiny about the National Institutes of Health (NIH) regarding its overall vision and clinical outcomes research, has led to a massive new restructuring of the NIH clinical research initiative. NIH has weighed in on its own flawed overall clinical research model, including technology transfer, and developed a new strategy to transform academic clinical developments. In the first major overhaul in 50 years regarding how it funds biomedical research, the NIH has launched a comprehensive project to reduce the time from discovery to treatment, with a major component of its restructuring focused on decreasing the time and effort needed to translate discoveries into treatments and technologies for patients. Some of the widespread criticism of its past research model has included the assessment that NIH-funded research at universities has been very successful in theoretically curing disease, treating illnesses, and making strides in the mouse model, but has not been able to translate such advances to humans (NIH News, 2006).

> 'The NIH doesn't impose any plan or measure the impact,' contends Stephen Johnson, head of the Center for Innovations in Medicine…at Arizona State University…'The metric used to tell if a researcher is successful is by his or her publication record…more than anything, researchers need to come up with a coherent plan to battle diseases like AIDS and cancer. We haven't done that' (Littlehales, p. 28).

The new NIH plan to advance biomedicine, which has been named the Clinical Translational Science Awards (CTSA), calls for the development of 60 academic health center sites across the U.S. which will be linked to form a national consortium. Twelve sites have already been funded for a five year period at approximately $700 million. Additional sites will

be funded beginning in 2007, with the NIH goal of having all 60 sites up and running by 2012 (NIH funds, 2006; NIH, 2007).

In another comprehensive plan to revamp academic training and education for biotechnology, 13 of the most prestigious graduate schools in the country are revamping their Ph.D. programs in order to speed translational research. The Howard Hughes Medical Institute has committed $10 million in training grants for the program, which is just being launched (Kuehn, 2006).

In support of the philosophy outlined in the NIH perspective, Pisano (2006) has declared that a comprehensive change will be required, which he defined as one that will have long-range and significant impacts on universities, government-funded research, the pharmaceutical industry, and others involved in the biotechnology industry. A key component to the overall success of this new academic commercialization model is a redesigned group of mechanisms for bridging the gap between inventions and resultant treatments (NIH, 2007).

University administrators and inventors, on the other hand, are not typically seasoned in the business of early-stage biotechnology commercialization, which often requires the ability to take an academic technology, create a complex business plan for continued research and development, form a new start-up company around it, secure adequate investment funding, and put into place a capable management team to develop the technology into a viable marketable product (Fischer, 2007; Kouri, 2006).

> Universities are not usually viewed as leaders in entrepreneurship. In fact, there is often a tendency to distinguish between the search for truth in science, considered a legitimate function of the university, and the search for invention, which is considered an inappropriate focus on ideas that have potential commercial or practical applicability" (Louis, Blumenthal, Gluck, & Stoto,1989, p. 110).

Unintended Consequences

In the past, providing researchers with more flexible policies to encourage their involvement in commercialization has resulted in some successes, but also in some highly controversial collaborations with industry (Olivierei, 2003). As previously mentioned above, industrial collaborations can result in unintended consequences for universities. Such unintended consequences have left some university faculty and administrators skeptical about the entire technology transfer process. They question how this new commercialization focus affects the overall purpose of higher education institutions, especially public universities, and they caution academic administrators about the lack of experience of academe in this relatively unknown business climate (Newman, Couturier, & Scurry, 2004; Schmidt, 2002).

Higher education may be particularly vulnerable to issues surrounding technology commercialization. Nadler, Hibino, and Farrell (1999) have studied the consequences of conventional thinking, which reduces a complex problem into independent parts prior to solution-finding. As a result, the authors conclude, the wholeness of the problem is not considered as each problem is being analyzed and solutions formulated. More often than not, each resultant solution provides only a partial fix, while also creating new, unintended consequences when applied to the whole. To add to the complexity, the overall, more universal problem or issue may still remain and contain new or additional difficulties.

This collapse of the thinking paradigm, in which there is extensive analysis of the parts but not the whole, is based in the scientific research model (Nadler, Hibino & Farrell, 1999). Where but in academe is the scientific research approach more prevalent? This research approach stands as the cornerstone of scientific inquiry, where it has proven successful for

hundreds of years. Such solutions are most successful when the problems are based in natural phenomena.

Inherent in this analysis design is the belief that there is a single, correct solution to a problem. Unfortunately, when this fragmented scrutiny is applied to broader, more obtuse issues involving human behavior, market influences, and other unpredictable variables, the research model is less successful. In their research of how market forces influence academe, Newman, Couturier and Scurry (2004) indicate that historically, many higher education institutions either do not address the marketplace in their problem-solving processes or are inexperienced when including these forces in their analyses.

According to Slaughter, Archard, and Campbell (2004), there are two popular strands describing the norms and values of science. The Mertonian theory sees science as distinct and separate from the marketplace and considered value-free. This interpretation is related to that proposed by Vannevar Bush (1945), which is called the linear model of science-based innovation, and is described in more detail in Chapter 2. The other major strand, entrepreneurialism, purports that science recognizes both academic and market components. Consequently, no one consensus exists regarding the value of or even the appropriateness of academic commercializing of inventions and discoveries.

For example, Mendoza and Berger (2005) state that the results in academe have been both positive and negative.

> Industry-university partnerships have provided university administrators, faculty members, and businesspersons with new relationships that are changing the nature of academic roles and rewards…some…viewed quite positively- such as the generation of new sources of revenue…while…other unintended consequences may be having a negative impact on the academic profession (pp. 3-4).

Dr. Wesley Cohen (2001), of Carnegie Mellon University, states that the majority of public research conducted in universities and government laboratories in such areas as drug development and biotechnology, becomes available to industry through public avenues. He does not infer that privatization is not appropriate for such research, but, rather, that academic leaders and researchers need to take into consideration the mechanisms for transferring these technologies to best practices.

Naiveté also plays a role in how higher education has dealt with technology transfer, according to Van Der Werf and Blumenstyk (2001). Public universities do not have the same market influences as their for-profit scientific counterparts and are less savvy as to how to participate in the business climate (Schmidt, 2002). Academic inventors are not familiar with the world of business management and development nor do they typically acknowledge that such expertise requires training and experience. According to Kouri (2006) and Nowak (2006), a researcher who remains involved in the development of the new company will typically fail at any attempt at management. Often, the researcher will want to maintain control even though the success of the new company may be irreparably damaged. Whether or not the researcher is involved in the new company management, universities themselves are not very experienced in business development.

On the other hand, pharmaceutical companies and other commercial biomedical organizations employ the scientific method but also function according to market pressures. Management of academic-based intellectual property should be viewed "as a necessary administrative service and expense, and not as a university profit center," according to David Pramer (1998, p.448), who has been professor and administrator for research policy at Rutgers University.

But experts say that the commercialization trend also reflects a growing appreciation for the value that universities can have in developmental research and "in assisting start-up companies. Universities have deeper pockets and are more patient and stable than easily spooked venture capitalists. They also often have the best-equipped laboratories, the fastest, most robust computer systems, and the most extensive libraries" (Van Der Werf & Blumenstyk, 2001, p. A28). Conflicts also arise over the traditional view of knowledge as a public good under the stewardship of academic versus the growing belief that such knowledge is academic capital, subject to monetary valuation (Slaughter & Rhoades, 2004).

The potential commercialization value of such academic riches were first realized more than two decades ago, when the federal government passed the Bayh-Dole Act, the first in a series of legislative acts to encourage large, research universities to commercialize their federally-funded inventions and discoveries. Much has changed since then in the landscape of academia. Now, even regional universities boast of having technology transfer offices while many administrators and researchers expect their institution's next technology will be one that will bring in millions of dollars in royalties.

But, the process is not always smooth. Universities and industry are suing each other over patent rights (Nadis, 2000), government and peer-reviewed research journals are claiming academic research is besieged with conflicts of interest (Mangan & Blulmenstyk, 2000; Olivieri, 2003), state governments are demanding more public/private partnerships despite these conflicts (Newman, Couturier, & Scurry, 2004), and critics claim the return on investment from academic technology transfer is skewed and misleading (Schmidt, 2002). Yet, the push to involve public funds, public universities, and state dollars in biotechnology commercialization continues, with an expectation that faculty researchers will play a major role.

Faculty Roles

Critical to the success of biotechnology commercialization is intellectual capital, which is uniquely concentrated in research universities. As a result, faculty who are expert in research areas ripe for commercialization now find themselves in the middle regarding where their loyalties and responsibilities lie (Bok, 2003). On the one hand, they are valued for their academic contributions, including teaching and research; on the other hand, they are pressured to commercialize any inventions and discoveries they have made. Such dual participation creates conflicts of interest, resulting in regulations and limits on their time and effort (Gelijins & Thier 2002; Newman, Couturier & Scurry; 2004).

Most of the university-industry pressures are focused on its researchers, who struggle to balance the need for academic freedom and scholarship with industry-sponsor obligations. "This question needs national attention by both academia and industry, with the goal of defining broad standards…the standards should be clear, easily understood and easily explained to the general public" (Hall & Scott, 2001, p. 553). The authors continue by pointing out recent cases of apparent conflicts of interest only strengthen the questions surrounding these relationships.

In the new North Carolina Research Campus project, the state has committed nearly $30 million annually, focused on hiring academic researchers. The participating universities are preparing to hire for new faculty members, UNC is looking to fill 18 faculty positions while North Carolina State is slated to hire 13 new faculty (Fischer, 2007).

According to Mendoza and Berger (2005) "other issues fostered by faculty partnerships with industry representatives include conflict of interests, restriction of information flow, shift power to non-academic personnel, universities' fragmentation into entrepreneurial fiefdoms,

shifts of research priorities toward more marketable areas with the consequent distortion of traditional academic missions…" (p. 3). Often at the center of discussion is money.

Currently, 77% of NIH's research budget is committed to funding ongoing projects. As a result, many new programs or grants are not being funded (Couzin & Miller, 2007). The authors continue,

> Many scientists complain that the tough funding climate is exacerbated by an excessive focus at NIH on costly "big science," such as the Cancer Genome Atlas, which is using large-scale genetic sequencing to decipher the molecular basis of cancer and whose 3-year pilot phase is budgeted at $100 million. Projects like this one, many scientists say, are coming at the expense of grants that sustain individual labs and have been the source of much innovation over the years (p. 359).

Trying to adjust to this funding barrier has led some to turn to different financial avenues. One researcher suggests that academic faculty revisit industry sources as one alternative. Mary Hendrix, scientific director of one of Northwestern University's research centers, discusses how researchers can recover their lost government funding by looking elsewhere for support. Her choice is to promote public-private partnerships and form stronger relationships with specific disease foundations (Couzin & Miller, 2007).

For example, Johns Hopkins, one of the nation's leading research universities, has had difficulties in translating its research activities into commercialization success. The university's administration cites politics and a negative faculty attitude regarding technology transfer as the key to the university's problems. To address this problem, a new head of technology transfer has been hired (Johns Hopkins Technology Transfer, 2007).

Many agree that faculty play a critical role in commercialization of technologies and that the culture of buy-in from the faculty is key to this part of economic development.

> The core of this success is a university's ability to build intellectual capacity by recruiting and retaining top-notch faculty. For instance, successful biotech clusters are highly dependent on the quality of medical research and availability of specially trained research

> scientists and technicians. These universities have been a hot bed of technological innovation and entrepreneurs, inventing the gene chips to transform medicine and pushing the boundaries in stem cell research (Wu, 2005, p. 8).

One of the attractions that academia has over industry is that university researchers can share in the royalties generated from the technologies they discover. "Managing faculty cannot be as direct as it is with industry employees, whose behavior is non-voluntary and driven directly by established organizational outcomes" (Mendoza & Berger, 2005, p. 9). Unlike industry, where researchers are typically hired as work-for-hire and revenues from discoveries remain with the employer, the standard position in American universities recognizes that faculty are not work-for-hire, and actually own their own inventions and discoveries. Mendoza and Berger add that the same goals and interests might not be shared by faculty and administration, but that, traditionally, limitations on administrative control have been the result, in part, to faculty self-governance and their ability to maintain professional mobility.

Even so, as part of their employment terms, faculty and others agree to assign the intellectual property they discover or invent while employed to their academic institution, and in return, they are entitled to a percentage of royalties or equity generated from the commercialization of their technologies. Still, an unresolved tension remains between the goals of the faculty and administrators. "The greatest points of conflict for professors were issues that pushed them to make choices between a public service and an academic capitalist knowledge regime. These issues were publishing versus patenting, access versus secrecy, and contested ownership of a wide variety of intellectual property" (Slaughter & Rhoades, 2004, p. 113).

Intellectual capital, the collective expertise and creativity of faculty, is considered one of the cornerstones of academic research institutions. According to Derek Bok (2003), a university's scholarly quality and integrity remain paramount in the eyes of the public and in a

democratic society. He continues by explaining that for generations "universities have long been one of the principal sources of expert knowledge and informed opinion on a wide array of subjects…" (p. 117). Yet, several scholars agree that faculty's role as the major labor force in higher education is undergoing substantial changes (Slaughter & Leslie, 1997). Financial changes have pushed academic institutions to form partnerships with business and industry and have encouraged faculty to commit more time and effort to research instead of teaching (Newman, Couturier, & Scurry, 2004; Slaughter & Rhoades, 2004).

Even with this shift, many higher education institutions do not recognize commercialization success in faculty promotion and tenure considerations. The state of California Council on Science and Technology acknowledges the importance of such recognition in a 2006 report on state funded research. "In considering a set of state IP policies, it is important to understand that the reward system that motivates researchers depends in large part upon their ability to share some or all of their research, in order to obtain recognition" (p. 11).

Bok (2003) points out that "research universities are rarely, if ever, any better than their faculties" (p. 117). To continue making their greatest contribution, which he believes is their intellectual capital, "…it is imperative that they guard the integrity of their procedures for appointing and promoting professors…" (p.117). Bok goes on to caution administrators, legislators, and others not to reward or advance faculty for work conducted solely on the basis of commercial viability, regardless of its inherent research interest or value.

On the other hand, recent levels of funding at NIH have not kept up with the cost of living.

> Even though the budget for…NIH doubled between 1998 and 2003, to $26 billion, it has hardly kept pace with inflation since. During the boom, academic and research labs built up capacity and talent, and thousands of long-term projects

> got funding – but now new projects struggle to secure support (Littlehales, 2007, p. 26).

"Compounding the problem is that most universities and medical institutions rely on NIH money for the bulk of scientists' salaries and overhead costs and are not set up to support faculty members long-term" (Couzin & Miller, 2007, p. 358). Presently, the funding percentage at NIH is lower than it has been in several years, and has dropped dramatically in just a few years. For example, at one of the NIH agencies, proposal funding has dropped from 27% in 2001 to 11% in 2006. To add to the difficulties, more scientists than ever are having to resubmit their grant applications prior to securing funding, which can be a wait of up to eight months (Couzin & Miller).

Consequently, the reality of the current financial situation in public universities does not allow for a total disregard for academic researchers in their role as inventors and creators of products and technologies. Dr. Cohen (2001) explains "…universities place different weights on how founding a company is credited…In many universities, commercial activities are still regarded as "second tier"…Universities also vary in the amount of funding delay they will tolerate as a consequence of working with industry" (p. 180). As evidence of the growing support of the importance of technology transfer in terms of faculty roles, the Texas A&M University Board of Regents has recently voted unanimously to include technology commercialization of inventions as part of faculty tenure evaluation (Lipka, 2006).

The promise of substantial commercial revenue streams is important to acknowledge because the majority of these inventors are research faculty. In addition, one needs to acknowledge the power and influence that such a promising financial return from commercialization has on research universities (Kirp, 2003; Newman, Couturier, & Scurry; 2004). As explained above, the lack of experience that faculty researchers have in business

development and management presents its own problems. At the same time as faculty inventors are encouraged to commercialize their inventions by their university administrations, government, and others, few avenues exist to help them learn how to become well-versed in business matters. Kouri (2006) explains that one solution is to develop a business management and development curriculum in which the faculty researchers take part. Nowak (2006) demonstrates that another alternative is to establish early-stage developmental funds, and Holmes (2006) demonstrates that at UCSD there is a successful combination of both, at least in part.

Mission of the Public Research University

Universities can play an integral role in local, regional, and state economic development. In some geographic locations, the university is one of the largest employers. The traditional expectation of a university regarding economic impact was measured in the number of individuals employed by the institution of higher education and its affiliate organizations, the students who entered as consumers into the local economy, and university-related special events which brought in additional local revenue. But the expectations related to economic impact in the modern sense goes beyond these traditional avenues. The twenty-first century view of academic economic impact often includes characteristics that resemble that of a company town (Fischer, 2007).

At the same time, research universities have the responsibility of meeting their core mission of teaching, research, and community service. How can these institutions of higher education balance their long-standing obligations and also look to including new ones? Richard K. Lester, a center director at Massachusetts Institute of Technology, cautions that a real danger exists if academic institutions promise more return than is possible and reiterates that universities are primarily educational institutions (Fischer, 2007).

Despite these warnings, academic institutions continue to move forward with regard to economic development. The UNC System is one example of a statewide institution of higher education putting into motion several projects and programs focused on commercialization and economic development. System President Erskine B. Bowles, the former director of the federal Small Business Administration and a venture capitalist, has acknowledged that the UNC System "has made economic development transformation a central part of its mission. That objective is playing out in different ways on different campuses…and the university has started a fund to reward grants…that focus on local economic-development needs" (Fischer, 2007, p. A-1). This new role is seen as an important obligation by the UNC System. "Now we have the opportunity, and the obligation, to help the state figure out what the new economy looks like" (p. A-1).

This exploratory study analyzed each of the three models, compared them, and then looked at them in relation to the UCSD best model for academic-based commercialization and start-up company formation. Even though the models contain only some of the five key components, all of these mechanisms which were studied, aimed at moving early-stage academic-based technologies further along the commercialization continuum in order to increase the possibility of market success.

As a result of this study, five additional key components were identified as important in developing a successful commercialization model. In addition, the study explored ways to diminish the unintended consequences associated with commercializing early-stage technologies, especially in terms of conflicts of interest, faculty roles, and the mission and uses of the public university.

CHAPTER 2.

REVIEW OF RELATED LITERATURE

"An embedded assumption of the theory of academic capitalism is that shifting revenue streams, whether contracting or expanding, shape strategic initiatives" (Slaughter & Rhoades, 2004, p. 182). As noted above, the impact has been less than anticipated regarding fiscal and economic returns (Dueker, 1997; Edwards, Murray & Yu, 2003; Pisano, 2006; Powers, 2006) and as explained below, more than expected in terms of unintended consequences for administrations and faculty (Dueker; Olivieri, 2003).

With such a complicated background of how and why technology transfer developed in academia, it helps to outline how we got to where we are presently, and how we can move forward while implementing best practices and planning for the future in terms of academic biomedical research commercialization.

Background

During World War I, the federal government hired university researchers by placing them at federal laboratories where they conducted research for governmental projects. By World War II, the United States government had changed it tactics, opting instead to develop partnerships with universities by contracting with higher education institutions in order to preserve the control by civilian scientists over their own research projects (Geiger, 1990). Vannevar Bush issued a report on the future of science in America to President Franklin Roosevelt in 1945 in which he emphasized that medical advances and new products depended directly on continued advances in basic research, which were only available through universities and their expert scientists (Bush, 1945).

Recognizing the tremendous contribution academic scientists made during World War II, the federal government deliberately chose to increase science research support beginning in the late 1940s (Bok, 2003). Central to this growth were countless faculty researchers who opted to pursue their careers in academia instead of industry. Their intellectual capital and expertise were paramount in the unprecedented successes and advances made in science during the decades between 1940 and 1970 (Geiger, 1990). By the start of the 1970s, the United States was the undisputed world leader in science and technology with research faculty at the core of this scientific revolution (Bok). This three-decade increase in federal funding expanded concentrations of academic scientists, boosted graduate school education, paid the salaries of laboratory technicians and support staff, and purchased complex, expensive research equipment (Geiger).

> A major change in the postwar U.S. national innovation system is the immense expansion of research in institutions of higher learning. By simultaneously providing funds for university research and education, the federal government has strengthened the university commitment to research (Wu, 2005, p. 6).

In 1940, for example, the total dollar amount spent on organized research in universities, regardless of funding source, totaled $27 million. By the end of the decade, the federal government alone provided academic centers with more than $130 million annually (Geiger, 1990). As a result, allocations to science faculty through research grants and contracts rose 25-fold from 1948 to 1968, exceeding even the expectations of those individuals who were instrumental in initiating these changes (Bok, 2003). Central to this exponential growth in federally sponsored research was the increase in basic sciences, biomedical and nuclear research (Geiger).

Due to the sheer enormity of higher education research and the expertise of faculty during these three decades, the number of academic researchers grew exponentially (Geiger, 1990).

University-based researchers housed in the most advanced scientific laboratories, developed technologies that accomplished everything from putting a man on the moon to inventing gene splicing techniques. During this time, academic clinical scientists sparked the beginning of the new biotechnology industry (Bok, 2003).

Del Favero (2003) discusses how a focus on one's discipline provides faculty with competing allegiances. She explains

> [faculty members'] primary connections with peers in their discipline go beyond the boundaries of the institution that employs them…Achieving success in one's discipline...consumes the energy and attention of most faculty...and recognition and career advancement, especially at universities that place a high priority on research, consumes the energy and attention of most faculty...Allegiance is first to their discipline and second to their institution (p. 905).

In contrast, focus on a sponsor's needs instead of on a researcher's interest will, at some point in time, even if only in the long-run, benefit the sponsor (Geiger, 1990). If one follows the same logic that Del Favero (2003) discussed above, a researcher will then form a new allegiance with the sponsoring agency. With the ability to secure multi-million dollar grants and contracts from such sponsors, researchers' work has often gravitated toward satisfying the interests and needs of these funding sponsors, especially in tight financial times.

Kerr (2001) points out that over the past 20 to 40 years, there has been a dramatic increase in federal and private grants and in industry contracts to university researchers and also in the influence these governmental and private external funding entities have had on these researchers. At the same time as these external funding amounts increased, there also was a shift from funding only sponsor-created programmatic research areas to a more detached approach in which faculty, once again, often were able to choose their areas of research focus (Stahler & Tash, 1994). Researcher allegiance shifted once again, only this time, it created a

researcher's allegiance to oneself. As a result, well-funded researchers became even more independent.

External funding often provides a substantial percentage of salary and laboratory support for the faculty member and staff, based on research topics developed on his or her own terms, with the university itself usually exercising little control over the focus of the research projects its faculty are awarded. As such, these research projects are typically created and negotiated outside the purview of the academic administration for the most part (Kerr, 2001). As a result, faculty academic freedom, at least in terms of university administration control, has remained healthy.

Recently, we have seen another shift in funding source direction, with state-generated public funds and industry-based sources taking center stage. Administrators and external entities, such as state legislatures and economic development consortiums, are calling for more oversight of research direction and focus in order to secure funds from the available coffers and also allow for more control by these financial sponsors (Newman, Couturier, & Scurry, 2004).

Gumport (2000) recognized that at times of consolidation and restructuring, faculty and institutions are required to turn to alternative sources and methods of funding and operation. Many academic medical and health sciences centers have done just that beginning in the 1990s, when a series of catastrophic financial events caused them to find immediate solutions to fiscal crises. The downward financial spiral began with the onset of managed care, which brought with it an immediate decrease in revenues of nearly 50% (Van Der Werf, 1999). To offset such drastic funding deficits, academic centers turned to whatever revenue streams they could establish, without immediate regard for unintended, long-term consequences.

The tensions and conflicts facing faculty go beyond those related to financial conflicts of interest regarding independence in research. These tensions also include the desire for administrations to maximize revenue streams through faculty-awarded grants and contracts, while faculty question how this requirement allows for shared governance (Gumport, 2000). To complicate matters even more, the increase in desire to commercialize academic-based technologies has added sponsors to the mix of players in shared governance. As a result, new, shared governance alliances and oppositions have formed among faculty, administrators, legislators, sponsors, and industry.

Research vs. Technology

Since academic departments were first and foremost teaching units, the exponential growth of research funding along with the accompanying rise in stature of faculty receiving these funds resulted in increased tensions within departments for control of finances and of the faculty members themselves. These extramural research funds did not typically include revenues to cover teaching expenses (Geiger, 1990). In addition, it became necessary for faculty who had secured such large research grants and contracts to spend a substantial amount of time on their research at the expense of teaching. Tensions over research and teaching requirements heightened as both departments and funded faculty vied for limited resources (Stahler & Tash, 1994).

Some of this heightened tension was due to the fact that federally-funded research grants are typically awarded to an individual, known as a Principal Investigator (PI), not directly to an academic institution, although the academic institution recovers an indirect cost percentage or overhead that is a pre-determined percentage over and above the direct dollars awarded to a PI.

The same is seen at the state level, at least as reported in California's science and technology committee to the state government.

> The state also is a stakeholder in the intellectual property generated by its funding of public universities and other research institutions. Clearly, consistency with federal statutes and policy suggests that ownership of IP resulting from state sponsored research also should reside with the grantee (California Council on Science and Technology, 2006, p. 9).

In other words, if a university's federal indirect cost rate is 50%, then the university will receive $500,000 over and above the $1,000,000 a PI is awarded, for a total of $1,500,000 given to the institution. With indirect cost rates at most research universities typically ranging from 40-60% of the total direct research grant award, bringing in a "star" PI also means bringing in substantial amounts of additional money, which requires an institution to do nothing more than hire that "star" researcher (NIH, 2007).

Yet, if a PI leaves the university and moves to another academic institution, typically, the research grant moves with the researcher, and the added overhead dollars also leave that former institution and move to the new one. This portability gives the individual researcher great power and clout within his or her current institution, as well as with any potential future university (NIH, 2007). Yet the revenue from such sponsored research rests in university coffers, and includes the attractive percentages of overhead (indirect) costs. Since these overhead dollars sometimes total more than half of what the direct grant or contract dollar amount may be, and are earmarked as discretionary funds for the academic institution, administrations are reluctant to dissuade top researchers from going after such awards even though they recognize that the allegiance of researchers is at best, fragmented (NIH).

This situation is an example of the social exchange theory, which researchers believe is a valuable mechanism for studying the relationship between faculty and administration. By

identifying social rewards and looking into the ongoing process between these two groups, one can determine what factors motivate productive interactions and provide motivation for successful outcomes between them (Del Favero, 2003). The more reciprocal and trusting the relationship is, the more confidence the parties have in the governance process. In addition to this relationship based on sponsored research funds, faculty and administration have seen a growing give and take surrounding academic commercialization.

Commercialization of Academic Research

The seminal activity that began this academic research commercialization movement was the passage of the Bayh-Dole Act of 1980, by the U.S. Congress (Bayh-Dole Act, 1980). The major purpose of this federal legislation was to give universities the right to the intellectual property from their inventions and discoveries that had been funded through federally-sponsored research (Schmidt, 2002).

Prior to the enactment of Bayh-Dole, no organized mechanism of commercialization existed for federally funded technology. In the 1960s and 1970s, government sponsored academic research increased through grants and contracts awarded through the National Institutes of Health (NIH), National Science Foundation (NSF), Department of Defense (DOD), Department of Energy (DOE), and five other federal agencies. "Basic research was considered to be in the public interest, since it led to a dramatic increase in the discovery and development of new knowledge, which, in turn, had the potential to strengthen the country's economy" (Goodwin, 1996, p. 323). At that time, any invention or discovery derived from this sponsored research was owned by the federal government, yet no organized mechanism for licensing and commercializing these technologies existed. As such, few discoveries reached commercial success. By 1980, more than 30,000 patents had been issued but only five percent were for new

or improved products or processes. Fewer than 150 of these patents were issued to the universities that had developed them (Goodwin, 1996).

In order to improve the opportunities for commercializing these technologies, and thus, increasing the overall public good, the Bayh-Dole Act was enacted in December 1980. This law was the first in a series of federal legislation designed to give incentives to universities and their researchers to commercialize their intellectual property by granting them the rights to their inventions and discoveries (Goodwin, 1996). With this legislation in place, the new academic function of technology transfer emerged. Only 25 universities had any ongoing technology transfer activities in 1980, while 200 were engaged in the process by 1992. Bayh-Dole was the first in a series of federal legislative acts that were passed enabling universities to promote industry collaboration and technology commercialization (Slaughter & Leslie, 1997).

As part of this series of legislative acts, the Small Business Innovation Development Act of 1982 mandated that 1.25% of federal expenditures from agencies with more than $100 million dollars be earmarked for research to be performed by small businesses. This act was opposed by large research universities, which argued that this money should be given to them instead for basic research, yet "overall, in the 1980s and 1990s, U.S. policy at the federal level shifted so that colleges and universities were able to engage in academic capitalism" (Slaughter & Leslie, 1997, p. 48). Federal policy supported academic capitalism and commercialization of research. Faculty were encouraged to participate in more commercial research and minimize curiosity-driven projects (Etzkowitz, 1994; Etzkowitz & Leydesdorff, 1997).

Ironically, 20 years later, universities and small businesses have developed quite a sophisticated mechanism for transferring academic-based technologies to small business start-up and spin-off companies, with the universities sharing in the royalties and equity ownership in

these companies. Often these small businesses are created around inventions and discoveries made by academic researchers. Federal technology transfer grants are awarded to small businesses with researchers acting as the Principal Investigators (PIs) and universities as the business partners (Gaither, 2003).

Yet, such relationships, although promoted by the federal government through these agency grants and contracts, have led to financial conflicts of interest (COIs) and eligibility problems for faculty PI's. Recently, small businesses with majority ownership resting within venture capital firms were declared ineligible for federal small business research grants. The impact of this is great considering that, in 2002, the federal government awarded $1.5 billion dollars to 5,000 companies through small business awards (Gaither, 2003).

Emergence of Biotechnology

In recognizing the enormous contributions that U.S. biomedical research had made to scientific progress, the federal budget for academic research in these areas rose from $3 million to $76 million between 1941 and 1951 (Washburn, 2005). When NIH funding grew flat in the mid-1980s, many medical researchers became more entrepreneurial. This timing coincided with the passage of the Bayh-Dole Act and the emergence of new academic-based technology transfer offices. Even in the first decade following the passage of Bayh-Dole and related-commercialization regulations, much of the focus was on the development of biomedical-related academic technologies, due to their potential for financial success (Slaughter & Leslie, 1997).

Although the push to develop university-based technologies is not concentrated in any one area of research, many agree the major academic sector earmarked for success is biotechnology. As the new millennium began, industry's investment in basic biomedical discovery and clinical trials within universities totaled $55 to $60 billion dollars (Moses &

Martin, 2001). A large portion of the discoveries and inventions arising out of biotechnology companies are "often based directly or indirectly on ideas generated by university scientists" (Hall & Scott, 2001, p. 553).

The number of human subject clinical trials, which are sponsored by large pharmaceutical companies, rose from 33,000 in 1990 to 60,000 in 1998 (Martin, 2002). This $97 billion biotechnology industry boasts strong relationships between business and academe. "Private industry is one of the largest sources of funds for university research in these areas, and nascent biotechnology companies often lack the investment capital needed to conduct research on their own" (Schmidt, 2002, p. A-42).

This drastic change in university research focus at academic health centers (AHCs) and teaching hospitals was the direct result of the crisis in the 1990s that removed discretionary funds. AHCs turned to biotechnology commercialization, partnering with pharmaceutical companies and working to create biotechnology companies around university-based discoveries. This push toward development of biomedical technologies coupled with the change in federal legislation to encourage commercialization of academic intellectual property has resulted in tremendous expansion of academic technology transfer activities at most research universities (Association of Academic Health Centers, 2005).

Even so, because the crisis that faced AHCs a decade ago was so sudden and severe, little long-range planning accompanied the universities' move toward commercialization. They had a much more immediate need to stop revenue drains, save jobs and programs, and keep their academic institutions intact. Now, though, these university-based centers are realizing that the entire academic technology transfer model needs to be revisited, improved, and monitored in an ongoing manner (Association of Academic Health Centers, 2005).

Academic Health Centers

Traditionally, health insurance reimbursements for AHCs and their teaching hospitals was 40% higher than the normal reimbursement rate. The additional revenue covered academic biomedical research studies and salaries for residents and interns. But with the onset of managed care, not only did the excess dollars from insurance disappear, but the overall reimbursement rate from health insurance dropped dramatically. Almost overnight, this academic revenue stream was reduced by nearly 50%, leaving AHCs in the red (Van Der Werf, 1999).

In 1993, for example, Loyola of Chicago was the wealthiest of the 28 Jesuit colleges and universities in the nation, with an endowment of $425.2 million, 150 degree programs, new campuses opening in suburban areas, and a financially successful AHC. Just two years later, the university lay in ruins. The medical center was struggling to break even, the endowment value decreased 29%, suburban campuses could not meet expenses, several degree programs had no students, enrollment dropped more than 12%, and tuition rose by 74% (Van Der Werf, 2000).

In the years that followed, AHCs scrambled to find solutions for their shortfalls. Some, like Tulane University, sold interest in their teaching hospitals, with mixed results (Van Der Werf, 1999), while others, like Stanford University and the University of California San Francisco, merged their health systems, lost billions of dollars and parted ways after continued, disastrous results (Mangan & Blumenstyk, 2000). By the late 1990s, AHCs were still searching for a viable solution.

Loyola was blindsided so drastically by this external change in health care reimbursement that it caused a total restructuring of the entire institution. This university was forced to create a wholly-owned subsidiary to protect the AHC from further financial depletion. New campuses and expanded degree programs which were not self-supporting and had been relying on the

health sciences center surplus for funding, were cut. In addition, the endowment, which had counted on its income from surplus AHC revenues, was forced to redirect its efforts toward fundraising (Van Der Werf, 2000).

Loyola was not the only major research university to be dramatically altered by the managed care debacle. Public universities as well as private ones scrambled to find immediate, although less than perfect, solutions to their budget crises. Allegheny University of the Health Sciences declared bankruptcy in 1998. The University of Minnesota, George Washington, Indiana, Tulane, and Saint Louis universities all sold a portion of their entire teaching hospitals as a way to correct the revenue drain (Van Der Werf, 1999). As noted above, Stanford University and the University of California San Francisco took the merger route, but the outcome was still negative. Nearly 2,000 jobs were lost in the California merger. In 1999, the two centers were showing a $37.7 million dollar loss (Mangan & Blumenstyk, 2000). In 1998, the medical center at the University of Pennsylvania lost nearly $90 million, while the losses at Georgetown University neared $120 million.

Even after taking such drastic measures, these academic health centers were still losing revenues. The initial mechanisms they enacted were not viable, long-term solutions to their financial woes. "Often, the impetus for reinvention is some sort of external shock which forces the organization to recognize that it can no longer remain viable with its present mode of thinking and operating. The blow may come suddenly" (Souba, 1998, p. 115) as it did with the onset of managed care, leaving the universities with little time to regroup or plan financial alternatives.

Marcia Angell, MD, past editor of the New England Journal of Medicine, has written that the boundaries between academic biomedical research and industry have blurred in recent years.

She describes the three circumstances that have led to the current overlap. First, new drugs and devices coming out of university inventions and discoveries are the results of technology transfer, which involves close relationships between academics and investors and industry. Second, many academic medical centers have needed significant alternative revenue streams since the reduction of Medicare and third-party payments for patient services. Finally, the percentage of clinical trials being conducted through academic institutions has dropped in recent years from 80% to 40% (Angell, 2000).

Pisano (2006) does not see any indicators that biotechnology has transformed pharmaceutical R&D productivity. Even more worrisome is the continued observation that venture capitalists are still retreating. Since 2001, after the downturn in investment interest in genomics waned, investors have moved further away from risk.

> Rather than forming so-called molecule-to-market companies, whose first product revenues might be more than a decade away, entrepreneurs and investors have begun to look for lower-risk, faster-payback models, such as licensing existing projects and products from other companies and then refining them" (p. 118).

The exuberance over the development of biotechnology commercialization has been labeled irrational by at least one academic researcher in the field. Joshua Powers (2006) reports that more than half of universities consistently lose money on technology transfer while conflicts of interest issues have risen. One reason for this disconnect may be that technology transfer is a much more difficult process than previously acknowledged, according to Everett M. Rogers (2003), and as technology transfer offices become more experienced, they realize that this process is both comprehensive and complex.

State and Federal Funding

This current commercialization situation in research universities has developed over a period of time and has involved many players, both inside academia and outside of it. As

pointed out in the 2005 report from the Association of Academic Health Centers (AHC), the university-based financial climate is still shifting while, at the same time, traditional health services and government avenues of revenue are continuing to grow tighter. The AHC report points out that in the past, state governments supported public higher education with tax dollars but expected no measurable economic return. Now, elected officials no longer solely base their financial support for higher education on the advancement of knowledge. This old scenario has been replaced with a hybrid financial and economic structure in which allocations for future state revenues are assessed on the economic returns from past funding (Newman, Couturier, & Scurry, 2004; Spack, 2005).

As a result, lawmakers' requirements for returns on state revenues have increased, holding public universities more accountable in terms of the economic impact they bring to their respective states. One mechanism of enforcement is to tie the state dollars these public universities receive to the commercialization of academic-based research discoveries and inventions. As Powers (2006) points out

> "…legislators must realize what they now do to stimulate irrational behavior. One problem is that they are offering universities incentives to contribute to economic development—like targeted grant programs or funds available only to institutions that meet certain development goals. One natural response to the incentives is for a university to set up its own technology transfer office, business incubator, or business-development program, all of which require substantial investment of resources" (p. B-18).

Acknowledging that such requirements can cause conflicts for academic institutions, state legislatures "are willing to put universities in the position of having to routinely wrestle with potential conflicts of interest if that is what it takes to give the institutions a larger role in economic development" (Schmidt, 2002, p. A26).

Consequently, academic administrators have declared to faculty that, due to pressures from state legislators and decreases in government support, they are being asked to take

measures to help increase the economic impact that the university has on the state or local community. These new requirements for measurable economic returns have caused tension between those who believe that the university stands for the free exchange of ideas and those who now believe that commercialization success better measures the worth of academe (Gordon, 2004; Slaughter & Leslie, 1997).

> Throughout the institutions there was a belief that more competitive market processes for allocating state monies to academic departments were being introduced and a view that departments and faculty were being pressured to find external resources to supplement institutional funds. That sense of scarcity and increased pressure was complemented by perceptions of heightened competition for external revenues, particularly with regard to research monies (Slaughter & Rhoades, 2004, p. 183).

Some scholars, researchers, and administrators worry that the existing university research model could actually be at risk, as scientists protect and keep confidential their research findings and discoveries, focusing on transforming their intellectual property into profitable products instead of sharing their results with the public for the greater good (AHC, 2005; Spack, 2005).

While the issues surrounding the role of public universities are debated, the financial and economic changes facing higher education, especially in the biomedical research areas, continue. Simultaneously, a growing focus on promoting the commercialization of academic inventions and discoveries as an alternative revenue generator is developing, despite the fact that some believe the entire infrastructure of academic research may have been irreparably eroded by this commercialization (Newman, Couturier & Scurry, 2004).

According to Slaughter and Leslie (1997), the drive by academic administrations to foster closer relationships with industry can impact many areas including faculty autonomy and academic freedom. Even so, the climate has changed within the last decade (Slaughter & Rhoades, 2004) and several authors suggest that finding an intermediate path or balance between

traditional and newly developing missions is best for the future of research universities (Mendoza & Berger, 2005; and Slaughter & Rhoades, 2004).

Given the current state budget constraints and the expansion of academic focus on technology transfer activities, it seems unrealistic to believe that this promising new revenue stream will be curtailed in order to keep intact the original research model that developed not long after World War II (Tereskerz, 2003). As described by Slaughter and Rhoades (2004), the climate has changed within the last decade.

> We now point to the internal embeddedness of profit-oriented activities as a point of reorganization (and new investment) by higher education institutions to develop their own capacity (and to hire new types of professionals) to market products created by faculty and develop commercializable products outside of (though connected to) conventional academic structures and individual faculty members (p. 11).

Instead of returning to the past model of separating commercialization from academic pursuit, it seems more plausible and attainable to redefine and improve the current university research model by finding a more workable balance between commercialization activities and scholarly endeavors (Newman, Coururier & Scurry, 2004; Spack, 2005).

Following in the footsteps of pioneer states such as Georgia, Minnesota, New Jersey, and New York, a new wave of support for commercialization of academic biotechnology began to take hold at the close of the 20th century. Michigan proposed a "life sciences corridor," Republican Midwestern governors campaigned for substantial increases in support to build biotechnology-industry hubs, California created the "Institutes for Science and Innovation," and Alabama approved $100 million for biomedical research building construction (Schmidt, 2002).

In 1999, American universities collected $641 million in royalties and other license fees for discoveries developed from university technologies. The number in patent applications rose from 6,518 in 1998 to 7,612 just a year later. Total university-based royalties rose 10% while the

number of spin-off companies remained virtually the same (279 in 1998 and 275 in 1999). Three thousand seventy-nine (3,079) patents were issued in the U.S. during 1999, and licenses or options totaled 3,295 (Blumenstyk, 2003b).

In 2001, the American Council on Education and the National Alliance of Businesses issued a report, which concluded that heads of higher education institutions should encourage and support collaborations between academic researchers and private industry. But, the report also noted that not all university leaders and researchers agreed with this advice. Many raised the issues of conflicts of interest and ownership of intellectual property rights stemming from such joint ventures (Basinger, 2001). Nils Hasselmo, president of the Association of American Universities and co-chairman of the panel that wrote the report warned that "the nature of these working relationships can shape the research agenda and environment of a university, and universities have to safeguard against becoming research-and-development arms of companies…" (Basinger, 2001, p. A27).

To help resolve these issues surrounding conflicts of interest and intellectual property rights, the report suggests that universities enter into master agreements with industry when they are creating these partnerships, sign confidential disclosure agreements, retain intellectual property ownership rights, and close licensing deals without prolonged negotiations designed to wear down unsuspecting academic institutions . Critics of the report questioned whether universities should involve themselves more in such partnerships and cautioned against moving the focus from education to entrepreneurism (Basinger, 2001).

Professor Leon Rosenberg, MD (2001), of Princeton University, who had also served as Director of Research at Bristol-Meyers, noted that partnerships in the biotechnology industry.

"…cannot be limited to government-industry collaboration, simply because university research plays such a critical role…" (p. 114).

Even if such precautions are taken, conflicts of interest, bitter power struggles, and fights over patent and other intellectual property rights will still occur. Adding to the mix, which makes these relationships even more complex and prone to difficulties, are two factors: 1) the strong push by state officials and lawmakers to move their public universities into industry-partnering relationships riddled with potential conflicts of interest, and 2) the recent information technology collapse and the overall economic downturn (Fischer, 2006).

A few years ago, states were brimming with high tax revenues, beginning to receive their share of tobacco settlement dollars, and ready to change their investment cultures (Healy, 2002). A study conducted in 2001 by the Maryland Technology Development Corporation (Tedco), directly linked approximately 2,200-6,800 high-paying jobs to the technology incubators in the state. This economic development resulted in tax revenues as high as $96 million and encouraged state lawmakers to continue to support the partnership (Washington Post, 2002). These examples of economic success led to an increase in university venture capital funding in which institutions invested portions of their endowment funds for ownership equity in spin-off and startup companies coming out of campus discoveries and inventions (Desruisseaux, 2000).

Once again, the economic climate has shifted, and universities are now being asked by their own state lawmakers to first show a return on past investments prior to asking for new public funds earmarked for economic development (Newman, Couturier & Scurry, 2004). So-called angel investors are passing on funding early-stage academic technologies (Spack, 2005), and federal funding for small business technology transfer funds has tightened (NIH, 2007). How has this come to pass?

In recent years, the shift of traditional venture capital funds (VC's) away from early-stage biotechnologies has had a negative effect on angel and seed investors. As VC's have moved further down the commercialization continuum, they have also reduced the return on investment they provide to earlier-stage investors (typically angel and seed funds). This has resulted in a decreased amount of available money for the angel and seed funds to use to invest in early-stage, often academic-based biotechnology inventions and discoveries (Bouchie, 2004).

As described by Prem Das, the Director of technology licensing at Harvard Medical School in Boston, academic biotechnologies have been hard hit. Das and the Angel Capital Association professional organization agree that the time and investment is often monumental (Bouchie, 2004). According to them, it typically takes upwards of 8 to 12 years for biotechnology inventions to be comprehensively developed into pharmaceutical drugs or other regulated products, clear the clinical trial and manufacturing requirements set up by the FDA, and be approved for the marketplace. But time is not the only roadblock, the Association points out, because it often takes over $20 million until a seed or angel investor can exit a biotech investment. As a result, angel and seed investors have also reduced their funding of early biotechnologies, exacerbating the early-stage funding gap (Bouchie).

New Commercialization Models

Since academic involvement in biotechnology commercialization is still a young and evolving partnership, few good models exist that address the R&D commercialization gap. Research budget constraints and limitations on the ability of academic institutions to compete in the marketplace serve to inhibit university intellectual property commercialization, which shortchanges the potential value of the technologies that are licensed (Dueker, 1997).

Traditional academic biomedical research funding sources, such as the National Institutes of Health (NIH) do not typically grant awards to fund the early developmental stage of research. Also, the NIH Small Business Innovation Research and Technology Transfer Awards (SBIR/STTR) fund a very small percentage of the academic technologies that sit at this early stage of development (NIH, 2007). As a result, promising inventions and discoveries lie dormant because they are not appropriate for NIH funds, yet are too preliminary to draw interest from early-stage investors without giving away too much of their potential market value (Association of Academic Health Centers 2005; Spack, 2005).

Some new university/industry biomedical commercialization models are being developed to address these issues, but at this time, have not been entirely successful. On the plus side, these new models have improved the technology transfer process and related activities that have blossomed at research universities. As progressive and successful as they have been from an academic technology transfer organizational and operations perspective, they admittedly fall short in two major areas: 1) finding appropriate early-stage funding sources (Kouri, 2006; Nowak, 2006; Olivieri, 2003; Spack, 2005; Tereskerz, 2003) and 2) strategically placing experienced individuals to lead the management teams in these new startup companies formed around these technologies (Kouri, 2006; Nowak, 2006). As a result, it has become even more difficult for an early-stage academic-based invention or discovery to successfully move along the commercialization continuum than in decades past.

As discussed in Chapter 1, there is a growing problem in securing adequate financing for discoveries that have moved beyond the traditional biomedical research funding stage but are still too early for current early-stage investors (Association of Academic Health Centers, 2005; Friedl, 2006; Gordon, 2004; Kouri, 2006; Nowak, 2006; Spack, 2005). This situation is referred

to as the "funding gap" or the “valley of death” by academic commercialization experts (Kouri, 2006; Nowak, 2006) and is acknowledged by investors and academics alike. Currently, few new funding models have been developed to successfully address this problem (Spack, 2005).

Based on past experience, research universities traditionally have been expected to implement the following options to resolve this funding issue:

1) license the early-stage technology to industry or an aggressive early-stage investment fund for a very small financial and/or equity return;
2) rely on "friends, fools, and family" to fund the developmental research;
3) apply for federal NIH grants from the Small Business Innovation and Research Fund (SBIR/STTR), although the wait time is often more than one year and the amount and the number of awards are small; or,
4) implement some combination of the above options (Angell, 2000).

To date, these existing mechanisms have not met with much success. But, these alternatives have developed out of necessity, since even early-stage venture capitalists (VCs) have left a growing number of emerging academic technologies trapped, declaring that more developmental work needs to be completed prior to any investment interest on their part. Yet, turning to industry collaboration is not the best alternative, since such partnerships have led to conflicts of interest and undervaluation of academic biomedical technologies (Gelejins & Thier, 2002; Spack, 2005). The AHC and others are now recognizing that changes are needed in the academic biomedical commercialization process in order to increase the success of commercialization and reduce conflicts of interest and other unintended consequences (Association of Academic Health Centers, 2005; Spack).

Nowak (2006) has described the current funding problems in relation to funding gaps in the commercialization continuum. He explained that there is a growing chasm between the funding given to academic researchers that result in inventions and discoveries, and the place in the commercialization continuum when even the earliest-stage investment funds will consider taking a risk and invest in these inventions and discoveries. This gap in the commercialization continuum is illustrated in Figure 1.

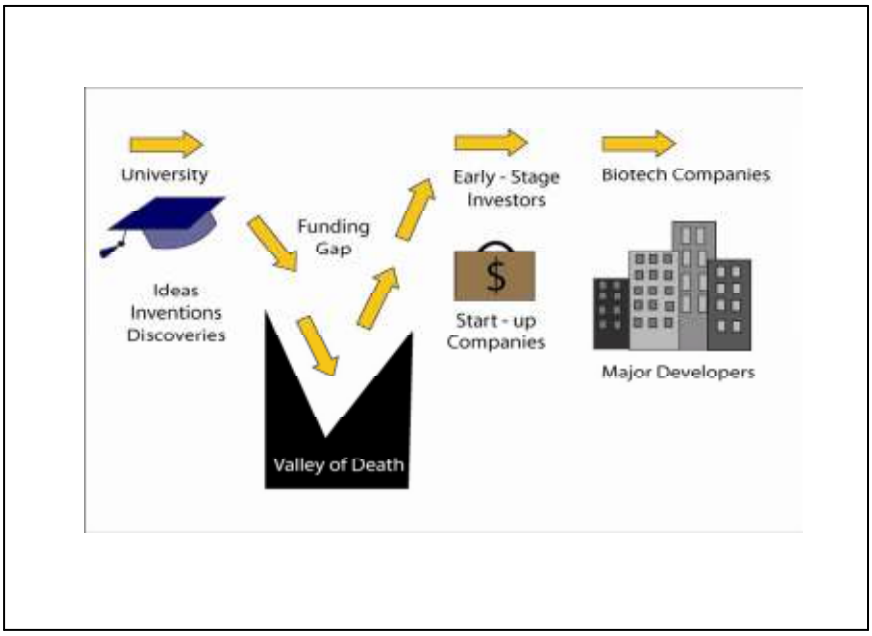


Figure 1. Commercialization Gap for Early-stage Biotechnologies

At the 2006 AUTM national meeting in March, Nowak (2006) described this funding gap as the "valley of death," a term also used by Friedl (2006), indicating it is the place along the continuum where even the most promising invention or discovery coming out of a university will die unless there is a viable mechanism in place to provide for the funding and related business development components necessary to bridge this dangerous gap.

Nowak (2006) discussed that this commercialization gap between research and products is growing and is occurring on a much more regular basis than before. Even so, he declared that few successful strategies to overcome these serious commercialization problems have been developed to date. Several who have recognized this commercialization gap (Friedl, 2006; Kouri, 2006; Nowak, 2006; Spack, 2005) have suggested that funds and expertise are needed in order to move these promising, yet nascent technologies, along the commercialization continuum (Figure 2).

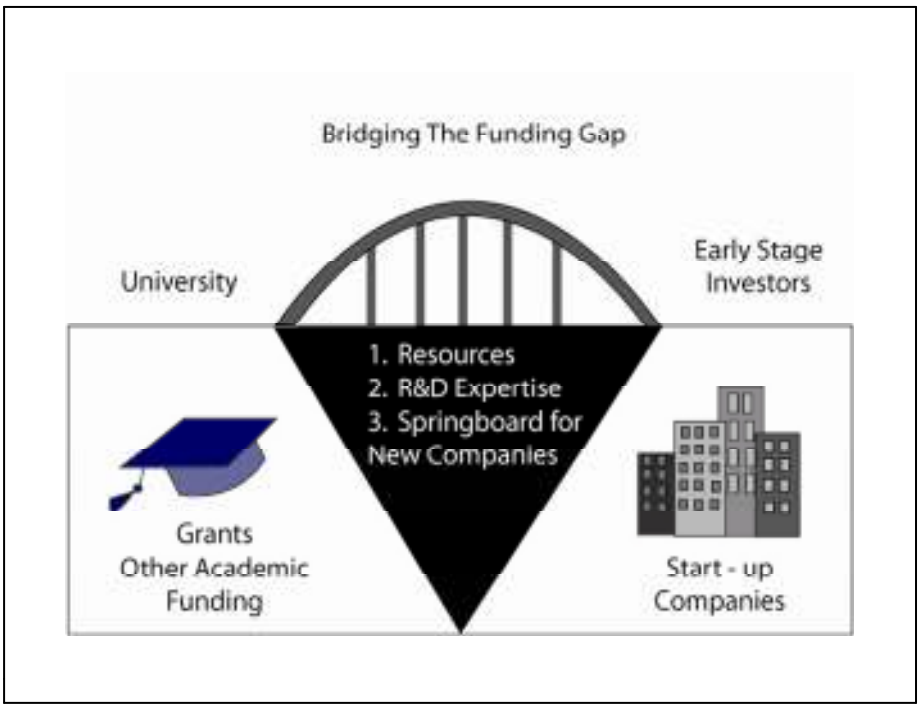


Figure 2. Bridging the Funding Gap

Nowak pointed out that this is an ongoing issue that requires workable solutions, such as the development of academic-based bridge funding and the creation of specialized curriculum-based programs. Although initially, these strategies appear to be very different in their approaches to the commercialization problem, upon further exploration, Nowak pointed out that they have much in common.

Curriculum Development

As part of his 2006 AUTM session, Nowak introduced Richard Kouri, PhD, who was Entrepreneur-in-Residence, Kenan-Flagler Business School at the University of North Carolina at Chapel Hill at that time, Kouri provided an overview of the program begun in the MBA program at UNC. He agreed that there is a growing funding gap facing university-based technologies, but Kouri adds that this gap is not only related to funding, but also in finding the necessary business expertise in order to develop such biotechnologies. Since the inventions and discoveries created at research universities are often made by faculty working in the biomedical fields, these technologies require sophisticated business development expertise in a highly specialized industry (Kouri, 2006).

This situation presents a dilemma because the inventors who understand these technologies most are not experienced in business management or development and traditional business experts do not understand the highly specialized biotechnology industry. UNC's solution has been to establish their biotechnology industry program as a different strategic approach to resolving the commercialization gap.

Recently, others have also voiced the growing need for developing specialized experts who will be able to meet the early-stage biotechnology industry needs for leadership, management, financial analysis, and scientific development. One response has been to create new academic programs, including the PhD/MBA joint degrees at institutions such as the Massachusetts Institute of Technology (MIT) and San Diego State University (Gewin, 2005). A much more comprehensive model combining early stage funding and specialized curriculum programs has been established at the University of San Diego. The School of Medicine SOM/CONNECT solution is part of a comprehensive program that includes an educational

pipeline as well as a an extensive translational medicine and developmental research program (Holmes, 2006).

Educational Entrepreneurship was also researched by Slaughter and Rhoades (2004) who found that many of the leading research institutions have reported that new or expanded focus is being placed on graduate degrees incorporating the mechanisms of entrepreneurship and commercialization. Some master's programs were created or expanded to target individuals who had already earned undergraduate degrees. The original goal was to expand masters degrees into "executive" programs, many without the requirement of writing a thesis. Another, unintended, graduate program began to take hold as well, the entrepreneurial-based degree. As will be researched in this study, the University of North Carolina built its biotechnology commercialization MBA program around an entrepreneurial core, while the University of San Diego has expanded its existing graduate and professional degree programs and has instituted cross-disciplinary research and training programs to add a concentration focused on educational entrepreneurship (Holmes, 2006).

Other new biomedical technology industry programs are being developed or are already in place. The Biodesign Innovation Program, a three-course Biotechnology Track program in the graduate school at the Louisiana State University Health Sciences Center in Shreveport, is based on the premise that graduate schools do not train scientists but educate them, leaving them lacking in the ability to be able to perform in the biotechnology commercialization field. This program also includes an internship in a company or other entity involved in the biotechnology industry (Giordano, 2006).

Responding to alumni and students it has surveyed, Stanford University has announced a new MBA curriculum which will begin in the fall of 2007. This new curriculum is described as

customized and flexible, to reflect the needs of the marketplace and employers (Gloeckner, 2006). Yet, this does not solve the problem of how to provide business management and development education to those faculty who are have already or could some day develop a biomedical invention nor how to give business experts or MBA students the necessary experience and information regarding the biotechnology industry.

Biotechnology industry experts agree that being an expert in the biomedical sciences has no relation to being a successful business entrepreneur (Gewin, 2005). Scientists and business school deans agree that there is a growing need for academic scientists to learn on-the-job biotechnology industry business training to be most effective in assisting in the commercialization process (Powell, 2004). Such approaches are helping to broaden the understanding of the biotechnology industry at universities but they, alone, do not directly resolve the problem of the growing technology transfer chasm. The comprehensive approach taken by the MBA program at UNC addresses the issues related to faculty, business experts, and investors and is therefore, a program that seems quite appropriate to study further.

Conflict over the Mission of the University

There are opposing viewpoints about whether or not academic investment in commercializing inventions and discoveries provides social benefits or not. Some argue that since so much university research is funded from either state or federal taxpayer dollars, at least this shows some initiative in trying to secure a return on that investment. Others argue that universities should not be "distracted from their primary missions of teaching and research, and, in any case, should not behave like big business" (Desruisseaux, 2000, p. A44).

A faction of university faculty are resisting the push for academic institutions to increase their focus on economic development, while some universities are taking even stronger steps to

ensure just such a commitment (Fischer, 2006). Texas A&M University announced earlier this year that a faculty member's involvement in patents and commercialization of technologies will be considered on par with teaching, research, and service in terms of tenure and promotion (Lipka, 2006).

Even though some have frowned upon such investment, several universities have already funded startups. Although the examples described in this discussion include both public and private academic institutions, the focus of this research study is on public universities. That being said, the examples are highly transferable from private to public entities. The Ohio University has joined state money with private funds to form the Appalachian Development Fund, with the university putting up $2 million of the total to provide technical assistance to new companies. Vanderbilt University has invested several million dollars in seven companies that were offshoots from academic research and Boston University pulled $120 million from its endowment fund into one company, Seragen, which is now a subsidiary of Ligand Pharmaceuticals. Unfortunately, the university has only recovered a small portion of that investment (Desruisseaux, 2000).

With the push toward commercialization of research technologies and the encouragement of faculty to increase collaboration and partnerships with business and industry, some faculty and administrators alike are wondering how this new scenario will affect the relationship between faculty and administration, the impact this new model will have on tenure, and just how this shift in expectations for faculty will play out in terms of academic freedom. The American Association of Academic Health Centers points out in its report that the academic commercialization trend has affected the relationship between faculty and administrators (Association of Academic Health Centers, 2005). AHC is calling for a new study to take a closer

look at the entire academic technology transfer model to help ensure that the best model, leadership, and expectations can be implemented.

At the same time, many educational researchers are studying and searching for new approaches to leadership in higher education. For many, the power struggle between administration and faculty, called shared governance, tops the list of leadership models that needs further study and possible revision. Even though most educational scholars agree that universities need both academic and administrative leaders to be effective, they also agree that this unique power sharing causes tensions on both sides. The new commercialization model in higher education is one such example of the growing tensions between faculty and administrators (Gumport, 2000).

Anna Neumann (1991) points out that the research on collegiate leadership has focused on how leaders act and not on how they think. Yet, other than when faced with fiscal issues, the research shows little understanding of how college leaders organize themselves in their roles as heads of institutions or large components of these universities.

Shared governance is unique to colleges and universities, but evolved over time within the academic environment. The idea is based on the concept that institutions of higher education need both administrative and scholarly expertise to function well (Morphew, 1999). Historically, even though universities required both scholarly and managerial expertise, power was not divided equally. The college president had the exclusive authority to oversee operations of the university, including the disciplining and teaching of students. Such a model was imported from the English collegiate model, where faculty were not trusted by college founders and trustees (Lazerson, 1997).

But collegiate America questioned such unilateral authority. In 1825, the faculty at Harvard protested the developmental authority and oversight of the curriculum and won the right to take internal control away from the president for the content of instruction, as well as of disciplining students (Morphew, 1999). This internal faculty control grew over time into what is known today as academic freedom.

Some argue that the present day interpretation of academic freedom is far different from the seeds established at Harvard more than a century ago. According to Lazerson (1997), one of the negative outcomes of a broadened notion of academic freedom has been that faculty have extreme difficulty working toward common goals. This has influenced the faculty's take on what constitutes their authority under shared governance. Lazerson points out that this notion of faculty being in charge of their own operations had sometimes gotten to the point where some of them saw "the primary purpose of the institution was to serve each individual faculty member. Faculty definitions of shared governance tend to revolve around vetoes and resistance" (Lazerson, p. 15).

Morphew (1999) comments that shared governance, including faculty control over the instruction and evaluation of students, has taken such a hold on American higher education that it is the given model for governing our collegiate institutions. Additionally, in his research, Lazerson (1997) has found that shared governance has other, unintended, often exercised consequences. For example, if faculty or administration wants an easy way to enforce the status quo, either can use the excuse that bureaucracy and the slow process of approval in a complex.

On one side, for example, administrators have declared to faculty that, due to pressures from state legislators and decreases in government support, faculty are being asked to take measures to help increase the economic impact that the university has on the state or local

community. For example, licensing and other aspects of commercialization of university-based technologies, adds approximately $40 billion or more to the U.S. economy annually. Just under one billion ($1 billion) dollars was received by American universities in 2003 from its commercialization of technologies (AUTM, 2006).

Even so, for the time being, the amount of royalty money can be far greater than anyone has imagined. For example, the faculty member who discovered the Taxol technology at Florida State University received approximately $30 million in royalties for 1999 (Blumenstyk, 2003b). Notice of such salary supplements cannot help but circulate among other academic researchers around the country. Such amounts also do not escape the notice of administrators as well, who hope that their royalty-split will be incentives for faculty to continue to work at academic institutions.

As a result, the dynamics of shared governance have changed in recent years, with new players being added to the mix. As described in Chapter 1, state governments and academic boards have weighed in more strongly, especially with regard to economic development. Another new academic-based group now shares in influencing university governance with regard to commercialization. Slaughter and Rhoades (2004) describe the shifting administrative structure in which technology transfer officers now share some of the administrative oversight and are integral in incorporating the commercialization focus into the overall research agenda.

The most comprehensive curriculum model is being developed by the NIH, and will encompass 60 comprehensive academic bioscience programs when it is completed in the year 2012. Key to the success of this NIH model are two components: 1) the belief that each academic research environment has unique characteristics, including advantages and barriers which, when utilized correctly, will provide for the highest success at that institution; and 2) the

necessity for university-based customized academic programs to educate and train professionals in order for them to possess the skills necessary for key aspects of translational research, including technology commercialization (NIH News, 2006).

The NIH has recognized that such academic site differences are inherent and has built its new CTSA program within a flexible framework, thus allowing for each university to maximize its unique potential. The NIH wisely recognizes that many key factors at each academic center are very unique or not easily changed and, therefore, so integral to the overall institutional structure, that it is imperative to base the CTSA transformation project on both flexibility and adaptability (NIH, 2007).

For more than 40 years, a highly-regarded NIH paradigm has existed in which comprehensive, flexible mechanisms and adaptable strategic planning have been implemented to maximize translational research success. This model is the highly successful National Cancer Institute (NCI) comprehensive cancer center program, which is based on find the best fit for an institution, using flexibility and customization. This NCI program has contributed significantly to the advancements in treating and detecting cancer and in success in the commercialization of cancer-related inventions and discoveries (NCI, 2007). Many of the NCI program's key components are part of the new NIH CTSA initiative.

Similarly, the best biotechnology cluster model, which includes the University of San Diego (UCSD) health sciences center program, is tailored around flexibility in order to maximize the advantages and minimize the disadvantages at that institution and in the San Diego region (Holmes, 2006; Milken, 2006). The UCSD model contains the two major characteristics being compared in this research study: 1) a specialized research and development fund; and 2) a

customized academic curriculum program, both of which focus on commercialization. These two components are part of the five key components necessary for commercialization success.

As the NIH CTSA program indicates, a more broadly-based, comprehensive change in structure and function is needed in order to ensure a long-term and overall momentum shift in focus and outcomes. As recognized by the NIH, a transformative change needs to occur which requires additional research, scrutiny, planning, and testing before a more balanced, long-term level of success for academic biomedical commercialization will emerge (Association of Academic Health Centers, 2005; NIH, 2007; Spack, 2005).

Augmenting this shift is the revamped translational training programs, which are receiving $10 million from the Howard Hughes Medical Institute (HHMI). This HHMI program was implemented after academic biomedical research leaders recognized that new discoveries were not being pursued partly due to the lack of expertise and understanding of just how to proceed. The academic institutions receiving these funds to augment and restructure their programs are the following:

Baylor College of Medicine

Cleveland Clinic Lerner College of Medicine at Case Western Reserve University

Harvard University

Massachusetts Institute of Technology

Rice University

Stanford University

University of Alabama, Birmingham

University of California, Davis

University of California, San Diego

University of North Carolina, Chapel Hill

University of Pennsylvania

University of Washington, and

Yale University.

As discussed above, the University of California at San Diego has been designated the best model for early-stage biotechnology development and the University of North Carolina at Chapel was one of the three academic models analyzed in this research study (Kuehn, 2006).

Unintended Consequences and Resultant Issues

The resulting perceived or real conflicts of interest are just beginning to be addressed by academia and its research sponsors (NIH, 2006; G-2 Compliance Report, 2006). The tension between tenured and other faculty is one of several unintended consequences that stem from universities and faculty doing whatever they can to maximize external funding source (Kirp, 2003). If a model of scholarship more akin to the one Boyer (1990) proposed was the norm, in which scholarships allowed for research-focused faculty to coexist in academe alongside faculty with teaching-oriented duties, some of the present-day tensions might have been reduced or eliminated.

Yet, even in Boyer's (1990) model, if the research-oriented or discovery-focused faculty were treated as superstars and the applied or teaching faculty were not allotted the same or equivalent status, the rise of the union would probably have still happened. Boyer's model seems a better fit for research universities as long as faculty-controlled outside research funding is not a factor. Boyer's model does not seem to provide a solution for how to control for the inequities in faculty status when star researchers or PIs bring large research and contract revenues with them, which also include substantial overhead dollars for the institution (Bok, 2003; Kirp, 2003).

Another unanticipated result of encouraging scientific research faculty to seek outside income was the rise in financial conflicts of interest. As researchers' relationships with industry grew, so did the perceived, as well as the actual, possibility that the conduct of their research, as well as the results, could be influenced by the sponsor (Bok, 2003; Kerr, 2001; Kirp, 2003). The most controversial situation to date involved a $25 million research deal between the University of California at Berkeley and Pharmaceuticals (Blumenstyk, 2003a; Nature, 2001). Berkeley entered into a five-year contract with the pharmaceutical company in which Novartis agreed to pay $5 million per year to researchers from the Department of Plant and Microbial Biology for independent, non-programmatic research projects, which included already-ongoing research projects not funded by Novartis in addition to those the company funded and also controlled what technologies would be patented (Nadis, 2000).

As the research project progressed, the level of industry control grew as well. Even doctoral dissertation topics and findings by Ph.D. students were subject to Novartis scrutiny. To complicate matters, Novartis sold its plant research division to another company, Syngenta, which took over the Berkeley research contract. In December of 2002, Syngenta announced it was shutting down its California research center and ending its collaboration with Berkeley. The industry-sponsored research relationship was the subject of so much scrutiny that the Berkeley administration hired an outside group of consultants to assess whether the research that faculty had conducted was influenced by Novartis or Syngenta. Several faculty are under scrutiny at this time to determine the quality and independence of their Novartis and Syngenta research (Blumenstyk, 2003a). When the Berkeley administration initially announced the Novartis research project, they spoke of it as the beginning of a positive, new era in academic-industry collaboration (Nadis, 2000).

According to Slaughter and Rhoades (2004), conflicts of interest are the most serious issues facing faculty in terms of professional choices and career development.

"The greatest points of conflict for professors were issues that pushed them to make choices between public service and an academic capitalist knowledge regime. These issues were publishing versus patenting, access versus secrecy, and contested ownership of a wide variety of intellectual property" (p.113).

In response to these issues, Nature (2001) published a list of policies aimed at managing the conflicts of interest that may arise when universities enter into research and development relationships with industry. These recommendations for universities, industry, and the federal government included the following:

1) vigilance and ability to speak out regarding perceived or real conflicts
2) transparency regarding such conflicts of interest or commitment
3) debate at the national level regarding these potential conflicts; and
4) cooperation by industry to sustain the public trust.

All of the above examples demonstrate new problems that have surfaced as a result of the push by research universities toward increased external funding and more competitive recruiting of science faculty superstars that were not anticipated by those institutions or faculty when they set out to improve their academic status and rankings. But, the unintended consequences that have resulted from such actions have created additional issues and problems for both faculty and universities that require new involvement and actions in order to manage and resolve or they will remain as unresolved issues.

This research study was based around the five criteria outlined in Chapter 1. These criteria have been designated as essential in the successful establishment of the best early-stage

biotechnology funding model (University of San Diego Health Sciences Center). This study explored three existing models of early-stage academic commercialization and analyzed how these models were designed and operated (Holmes, 2006, Kuehn, 2006; NIH, 2007). The goal of this study was to analyze three distinct mechanisms for early-stage academic biomedical commercialization and determine what components of each might be applied to a broader range of public institutions. In order to conduct the study, the following questions were answered:

1) What is the individual process by which:
   a. the GRA model works?
   b. the PBRC model works?
   c. the UNC model works?
2) How do the five key components play out in each setting (GRA, UNC, and PBRC) in terms of organization, implementation, and in relation to commercialization?
3) What are the similarities and differences among the three models and how do they compare to the UCSD model?
4) Are there additional key components considered essential for commercialization success?
5) How do the three models address the issues related to unintended consequences, such as conflicts of interest, faculty roles, and the overall mission of the university? and
6) Which findings can be applied to other public research universities?

CHAPTER 3.

RESEARCH DESIGN AND METHODOLOGY

Design of the Study

This research study was designed as an exploratory study which focused on analyzing the following: 1) the mechanisms for commercializing early-stage biotechnology inventions and discoveries, and 2) the processes that could be implemented to minimize or remove unintended consequences resulting from such commercialization activities. The goal of the study was to be able to present possible models, mechanisms, and best practices that other public universities can use to successfully commercialize their early-stage biotechnologies while preserving the overall mission of the university and minimizing or eliminating related unintended consequences.

This study looked at different biotechnology commercialization mechanisms used at different public research universities with substantial research dollars which rank them among the top funded U.S. institutions for biomedical research with the majority of funding originating from the National Institutes of Health (NIH). The University of North Carolina, Chapel Hill, is ranked fourth among all public research universities in the U.S. in total research dollars and ninth in biomedical-related research among public institutions while the Louisiana State University System, including the Pennington Biomedical Research Center (PBRC), ranks 44th overall. The University of California San Diego (UCSD) ranks fifth among all public universities in biomedical research funding (Lombardi, Capaldi, Mirka, & Abbey, 2005). The Georgia Research Alliance model was studied with a focus on how the GRA model played out at the University of Georgia. GRA is a statewide biomedical research and commercialization program for the top six research universities in the state (GRA, 2007).

This study analyzed these three different models for commercializing early-stage academic inventions and discoveries. The PBRC mechanism is based on the creation and implementation of an early-stage research and development investment platform. This program also includes other academic components, a research foundation, and an early-stage investment fund, among others. The goals of the program include commercialization of early-stage inventions and discoveries and the elimination or management of related conflicts of interest and other unintended consequences, while preserving the mission of the university (PBRC, 2007).

The UNC MBA biotechnology entrepreneurship model is a program that reinforces the academic core missions of education and training and also increases the chance of commercialization success for academic biotechnologies. This model also helps to grow the number of local biotechnology industry experts in finance, management, and regulatory areas (Kouri, 2006; UNC MBA, 2007).

The GRA model is focused around four programs which have been designed to maximize the research and development advantages that are in existence in the state of Georgia. The GRA is a collaboration of six universities, the state of Georgia, and private investors (GRA, 2007). The GRA model has been created as a catalyst for biomedical commercialization at these top research universities in the state. The program has been in existence for over 16 years and has contributed to the development of 18 centers of biomedical excellence in the state, the creation of more than 125 new companies, and the infusion of $2 billion of biotechnology research and development in the state (GRA, 2007).

The three models were compared to each other and then to the University of California at San Diego (UCSD) biotechnology economic development program, which is considered the best model for academic biotechnology commercialization based on the creation of biotechnology

commercialization start-up companies (Milken 2004; Milken, 2006). The Milken Institute has recently issued a comprehensive report on the U.S. biotechnology and life science clusters. One of the key areas this report analyzed surrounded start up companies based on university inventions and discoveries. The UCSD School of Medicine has created more than 65 start up companies based on its biotechnologies (Milken, 2006).

Edward Holmes, MD, former Dean of the UCSD School of Medicine and Vice Chancellor for Health Sciences, attributed much of this success on several factors, and they have been combined with the Milken components as follows:

1) the small size of the School of Medicine and the Health Sciences Center;
2) the high ratio of research dollars per faculty member;
3) a very entrepreneurial community;
4) the UCSD College of Integrated Life Sciences (COILS); and
5) the School of Medicine CONNECT program, a specialized biotechnology commercialization program which includes a structured mechanism for taking university biotechnologies, providing them with early-stage funding, expertise in developing their commercial concepts, and a springboard for creating new business partnerships (Milken, 2004; Holmes, 2006; Milken, 2006) .

The Milken Report (2004) points out that few U.S. geographic areas have an entrepreneurial culture along with a critical mass of academic biotechnologies. The UCSD model is located in a geographic region which has demonstrated the existence of a well-developed, long-term entrepreneurial cluster with biotechnologies ready for commercialization. The existence of both characteristics seldom exists in a single geographic location. For example, in many regions where academic biotechnology opportunities are prevalent, a correspondingly

high level of entrepreneurial spirit does not typically exist. If these geographic locations are entrepreneurial, they typically do not contain a critical mass of biotechnologies (Milken, 2004; 2006).

Two of the commercialization mechanisms, UNC and PBRC, were chosen for this study because each approach to commercialization was very different from the other and each contained only a subset of the five UCSD key characteristics described above. Since each of these two cases studied contained a different subset of the key characteristics, each was characterized as an extreme or deviant case. The third model, the GRA program, has been regarded by many as a highly successful biotechnology commercialization program which could be adapted for use by a myriad of other universities, and therefore, it was considered a critical case in this study (BOR, 2007; GRA, 2007; Patton, 2002).

These models were explored in depth, and the research has produced thick descriptions and key data which were used in illuminating the research questions and comparing the five essential commercialization characteristics (Tashakkouri & Teddlie, 1998) which are presented in Table 1.

The curriculum model at the University of North Carolina (UNC) Chapel Hill sits in what is known as the Research Triangle, and has been ranked third by the Milken Report (2006) in terms of biotechnology start-up success. The UNC Chapel Hill campus has also experienced a significant funding gap for early-stage biotechnology inventions and discoveries.

In order to combat this funding gap at UNC Chapel Hill, a curriculum-based program in the business school has been developed as part of the masters degree curriculum in business administration (MBA). This MBA program has been designed to provide education and hands-on practice for faculty inventors and MBA students alike. The program targets academic-based

technologies which emanate from UNC faculty and other researchers, evaluates and analyzes them in terms of commercialization potential, and then proceeds to further develop a select number of these technologies. The process includes creating a comprehensive business plan, setting up a new company, hiring appropriate business development and management personnel, raising necessary funding, and further developing the technologies with commercialization as a goal (Kouri, 2006).

A newly-formed research investment platform has been established to benefit the Pennington Biomedical Research Center (PBRC), a research campus of the Louisiana State University System. The purpose of this investment platform is to provide financial support and business expertise to develop business plans, form new startup companies, and move academic technologies generated out of PBRC further along the commercialization continuum. Despite the existence of the fund, many PBRC early-stage technologies are not being commercialized at the rate it was hoped due to the early-stage status of the technologies (PBRC internal documents, 2007).

The GRA is a highly successful biotechnology commercialization program which has played a key role in generating more than $2 billion in new federal funding and investment capital for research conducted within the state of Georgia. The University of Georgia is one of the six research universities participating in the program. GRA has developed more than 125 new startup companies and created more than 5,000 new jobs (GRA, 2007).

All three models were analyzed on a holistic basis as well as by looking at embedded units (Yin, 2003). Holistic analysis (Denzin, 1989; Moustakas, 1994; Stake, 1995; Yin, 2003) was of great importance in this study because the basic structures of these three mechanisms are very different. Very few defined parameters existed in the formation of these models and, as of

yet, no single technology commercialization model has been proposed as working for all academic institutions. The GRA model has been studied by many states, including Louisiana, but not adopted intact elsewhere, although the comparisons to GRA continue while universities and states search for a better way to commercialize their technologies (BOR, 2007).

The current environment has allowed each of the three research institutions studied here to design and develop a commercialization strategy based on its own institutional and environmental strengths and weaknesses. The three models studied have been designed to augment technology transfer while managing or alleviating the hurdles surrounding academic biomedical research commercialization. Yet, the models are at different stages of development and success.

In this study, the models were looked at in terms of what processes and mechanisms were used to create their programs and what new ideas are being considered for the future to help them in their quest to accomplish the following:

1) bridge the funding gap;
2) support developmental research;
3) minimize conflicts of interest and other unintended consequences; and
4) further the preservation of academic research by finding a balance between:
    a) traditional and new missions of academic biomedical research; and
    b) parameters and limitations imposed by organizational, governmental, legal, ethical, and other entities.

Sampling Procedures

This study was based on the following sampling procedures:

1) purposive sampling: two examples of commercialization strategies (PBRC and UNC) were based on extreme/deviant cases each exhibiting some but not all of the five characteristics considered critical in the UCSD best model design (Tashakkori & Teddlie, 1998);

2) critical case sampling: the GRA model was defined as a critical case due to the assessment that this program is one that could, at least theoretically, be adapted to work in most university settings (Patton, 2002); and

3) convenience sampling: access to the key individuals and organizations involved with these three commercialization strategies were ones that were readily available (Patton, 2002).

More than 20 key individuals were interviewed for this study (see Appendix A), which included one on one interviews, focus group sessions, and other meetings and discussions. The GRC, UNC, and PBRC strategies were assessed in relation to the five key areas described in Table 1 and then compared in relation to the UCSD best practices model as part of the interview sessions.

Data Collection Procedures

Data were collected using a variety of methods and procedures. A significant portion of the study was based on interviews, focus groups, and other meetings. Current and significant historical documents were collected, reviewed, and analyzed, and whenever possible, records of how each strategy had been developed were gathered (Patton, 2002). In addition, emerging

documents and other developing data were collected. Multiple occasions for observation became part of the research process.

By implementing various data collection procedures, the accuracy and trustworthiness of the data were increased through triangulation of data sources (Tashakkori & Teddlie, 1998, 2003). Also, using such diversified data sources increased the construct validity of the study (Yin, 2003).

The main research collection methods included the following:

1) focus group sessions and individual interviews;
2) observations (including participant observer opportunities); and
3) document review.

1) Focus Group Sessions and Individual Interviews:

Interviews with the key informants for PBRC, the GRA program, and the UNC model included those who were central in the development and implementation of their programs. The methods of interviewing all key informants were varied and adapted according to the format used. Some of the interviews of key informants were one on one, some were in small groups, and some were during focus group meetings (See Appendix B).

Focus group sessions included semi-structured interviews and included exploratory and explanatory questions beginning with broad-based low risk inquiries and grand tour or mini tour questions (Spradley, 1979; 1980) followed by more focused questions. Follow-up questions used as probes specifically asked about the five key components outlined in Table 1. At the end of the focus group sessions, the participants were asked about any other issues that had not been discussed.

Focus group sessions have strengths and weaknesses. On the plus side, focus group sessions may include more topics, more extensive discussions, and aspects of a topic that an individual being interviewed might not discuss. At the same time, there are some downsides to this research method. Because of the confidential nature of some technologies and activities which are inherently part of intellectual property commercialization, some issues and discussion topics could not be discussed by researchers or others in group sessions. In addition, there is a possibility that a type of group think or thematic bias can occur in a focus group session. To help with trustworthiness and to be able to gather information not conducive to focus group sessions, individual interviews were also conducted (Patton, 2002).

Semi-structured individual interviews involved the key persons described in Appendix A. The interviews often began with specific issues and worked toward more general inquiries. The individuals might be the ones initiating the meeting with the researcher about some aspect of technology transfer at which time the researcher asked probing, more specific questions about the topic being discussed. The researcher also asked these key individuals about the five key components outlined in Table 1 wherever this fit into the interview process.

2) Observations:

Due to the position of the researcher as the Director of Technology Transfer at the Pennington Biomedical Research Center and one of the key individuals involved in the creation of the PBRC research investment platform, the researcher became a participant observer for the Pennington-related mechanism being analyzed in this study and continues to be an insider viewing the ongoing development of this particular model (Patton, 2002; Spradley, 1980; Stake, 1995).

Ongoing, extensive observations were conducted in many instances and these observations were described using thick descriptions obtained from extensive written field notes (Lincoln & Guba, 1985; Patton, 2002; Tashakkori & Teddlie, 1998, 2003). At times the researcher was a participant/observer in the situation. In such cases, the researcher was able to observe others while also actively participating in the process by entering in the dialogue and asking questions.

On several occasions involving the Louisiana Board of Regents/Louisiana Recovery Authority (BOR) project led by Regional Technologies Strategies, Inc. (RTS), the researcher was a participant/observer. These occasions included a session where the researcher was interviewed by RTS, one town hall meeting which conducted in part like a focus group session, and then a subsequent reporting session in which the researcher and other key participants also asked questions of RTS. This BOR project also provided extensive information, meeting summaries, background research reports, and proposed project information to the participants which the researcher used as background and supportive documentation for this study.

3) Document Review:

Many internal documents were studied and reviewed in the process of gathering in-depth data. Extensive field notes were taken and a reflexive journal was kept. These data were augmented by public documents and external websites to corroborate information from interviews, observations, and document gathering. These research sources were also used to assist in the interview guide and the formation of specific interview questions. All of these methods of gathering research data were used to increase the credibility and trustworthiness of the data gathered and the observations involved in this study.

Mechanisms such as informal conversations, the interview guide model, and open- and closed-end interview sessions (Patton, 2002), employing unstructured interviews anticipated in the process of ethnographic observation (Spradley 1979), grand tour questions triggered by ethnographic observations and participant observations (Spradley 1979; 1980); and more structured sessions were employed to gain specific information. Specific questions and interview guide documents are available in Appendix B. The key informants provided both historical information and valuable insight into the current status and anticipated future activities of all three models.

Data Analysis

Case-specific data were captured and reported in field notes, reinforced by documentation in a reflexive journal, and discovered in historical and other documents as well as through thick descriptions and through individual and focus group interviews. In this study, these data were then analyzed using several methods. Overall data analysis included constant comparative analysis (Lincoln & Guba, 1985) based on unitizing the data into information units and then categorizing these units into thematic categories. Units were further examined in order to discover any emerging patterns and themes not previously described, which led to several new components being identified (Stake, 1995; Yin, 2003). These categories included the five key commercialization components (Table 1) as well as emerging trends not included in these five defined categories.

As described above, none of the three programs studied were build around an already-established model. All three models were interventions with no pre-set solutions prescribed for them, except that the common goal was to increase the success of biomedical research

commercialization (Stake, 1995). Content analysis (Patton, 2002) was used to identify underlying themes, assumptions, and beliefs related to the academic commercialization process.

In addition to analyzing the three cases in terms of categorical analysis and comparisons of detailed information based on the five key components described above and emerging data and themes, the data from all three strategies were reviewed and analyzed holistically (Denzin, 1989; Moustakas, 1994: Stake; Yin, 2003). The resulting new key components and other findings were added to the comparison chart in Table 5 while other new results were discussed in the findings section.

The second part of the study explored how the GRA, UNC, and PBRC commercialization mechanisms address the related unintended consequences, including those surrounding the overall mission of the university, faculty roles, and conflicts of interest. The data collected were also analyzed using constant comparative analysis (Lincoln & Guba, 1985) and content analysis (Patton, 2002). The results included new suggestions for minimizing unintended consequences and supporting the overall mission of the public research university, both of which are discussed in depth in Chapters 4 and 5.

The goal of the study was to be able to present options for other public universities to adopt so that they could accomplish the goals related to commercializing early-stage biomedical inventions and discoveries while managing or eliminating unintended consequences such as conflicts of interest, competing faculty roles, and preserving the overall mission of the university.

CHAPTER 4.

RESULTS AND ANALYSIS

This was an exploratory study which focused on analyzing the following: 1) specific mechanisms for commercializing early-stage academic biotechnology inventions and discoveries, 2) the processes implemented to minimize or remove unintended consequences resulting from such commercialization activities, and 3) how such mechanisms and processes fit into the mission of the public research university. The goal of the study was to present possible best practices that other public universities might use for successful commercialization of biotechnologies while preserving the overall mission of the university and minimizing or eliminating related unintended consequences.

Initially, this study intended to analyze two different mechanisms to develop early-stage, academic biomedical inventions and discoveries at two different public universities. One model, that of the Pennington Biomedical Research Center (PBRC) as part of the Louisiana State University System, is based on an early-stage research and development investment platform, while the second, an MBA entrepreneurial program at the University of North Carolina at Chapel Hill, is focused around a curriculum specialization core in the graduate school MBA program. However, during the initial research phase, an opportunity to study a third model became possible though a hired consultant with extensive experience with the Georgia Research Alliance (GRA). Since the GRA model is seen as one which could be adapted successfully in a wide array of research universities, its inclusion as a critical case, was deemed important. As a result, this study was expanded to include an analysis of the Georgia Research Alliance (GRA), as a third commercialization model. With the addition of the GRA mechanism, the comparison chart below (Table 1) has been revised to reflect the inclusion of this third model.

Table 1
Comparison Chart for Academic Biotechnology Commercialization – 5 Key Components

KEY COMPONENTS	UCSD Best Practice	UNC Model	PBRC Model	GRA Model
Small Size of Institution	Y	N	Y	N
Higher than Norm for Research Money per Biosciences Faculty	Y	N	Y	Y
Extremely Entrepreneurial Community	Y	Y	N	Y
Integrated Life Sciences Curriculum Program	Y School of Medicine and Graduate School Program (COILS)	N	N	N
Integrated Commercialization Track				
➢ Funding	Y	N	Y	Y
➢ R & D Expertise	Y	Y	N	Y
➢ Springboard for New Companies	Y	Y	TBD	Y

Y = yes
N = no
TBD = To Be Determined
UCSD = University of California - San Diego
UNC = University of North Carolina at Chapel Hill
PBRC = Pennington Biomedical Research Center
GRA = Georgia Research Alliance

Since this study involved many tiers of research, observation, and analysis, this chapter is divided into six major sections as follows: 1) background description and performance of each studied model (each individual process), 2) how the five key components play out in each model, 3) the similarities and differences among the three models and compared to the UCSD best practice model, 4) identification of any additional key components considered essential for commercialization success, 5) conflicts of interest, unintended consequences, the overall mission of the research university contained within the models, and solutions to problems related to these issues, and 6) which findings might be applied to other public research universities.

Part 1

Background Description of Each Studied Model, including Each Individual Process

GEORGIA RESEARCH ALLIANCE

What began as a failure to keep Atlanta-based Microelectronics and Computer Technology Corporation (MCC) from relocating to Austin, Texas, in 1984, turned into one of the biggest success stories for the state of Georgia six years later. In response to its inability to keep MCC in Georgia, the state had an outside assessment conducted. McKinsey & Company issued a report to the Georgia Governor in 1985, outlining what measures needed to be taken to prevent other companies with highly-skilled employees from leaving the state (Consultant, 2007; GRA, 2007). After several years involving studies and planning, the Georgia Research Alliance (GRA) was founded in 1990. Representing a partnership of the state's six research universities, the business community, and state government, GRA's mission was and is to foster economic development within the state to develop scientific and technology-based industry, commerce, and business (GRA, 2007).

The overall GRA plan was focused on attracting pre-eminent scientists to Georgia's research universities and providing them with an environment in which they could pursue programs of research and development in promising areas of bioscience. The goal was to create and enhance partnerships with industry to commercialize technologies developed in the research laboratories of these scientists. According to the GRA, such targeted recruiting and research would produce new high-skilled jobs for the state and expand related economic opportunities for the Georgia population (Consultant, 2007; GRA, 2007).

The state of Georgia has been very successful in developing the GRA as a partnership between the six research universities in the state (Clark Atlanta University, Emory University,

Georgia Institute of Technology, Georgia State University, Medical College of Georgia, and The University of Georgia) and private partners. Since its inception, the GRA has played a key role in the generation of more than $2 billion in new federal funding and investment capital for research conducted within the state. Furthermore, GRA has contributed directly by investing $400 million dollars on behalf of the state during the past 16 years (GRA Report, 2006; GRA, 2007).

Leveraging the research capabilities of the universities within the state of Georgia remains a key function of the GRA. The GRA has seen positive results in promoting and expanding university-based research and development to create a robust, skilled, high technology economy. The six GRA research universities have increased their research collaborations with industry 800 percent (800%) since the inception of the GRA. Overall bioscience venture capital investments for the state of Georgia from 1995 to 2000 grew from $200 million to $1 billion dollars (GRA Report, 2006). The State of Georgia has prioritized its state funding to include substantial financial support for this program as a cornerstone of its economic development strategy. As a statewide initiative, the GRA focuses on maximizing its collective academic research expertise and coupling it with research grants and private sponsorship and investments. The GRA realizes a return of $5 for every $1 invested (GRA, 2007).

Part of the success of the Georgia model has been its focus on a narrow set of goals and the implementation of only a few programs. Key among these programs are the Eminent Scholar Challenge Grants, the GRA Innovation Fund, and VentureLab. Each of these programs has had a history of success for Georgia academic institutions and researchers. In addition to the impact for research and scholars, the GRA has launched more than 125 start-up companies since its

inception, created more than 5,000 high-value, high-skilled jobs, and generated more than $600 million in private investment start-ups (GRA, 2007).

Eminent Scholars Program

To attract and retain research scholars of excellence, the GRA created the Eminent Scholar Program, which has been awarded to more than 50 recipients. These permanent endowments of $1.5 million each are a 50%-50% match between GRA and private funds for the purpose of recruiting exceptional research scientists to Georgia and providing funds for their research laboratories (GRA. 2007). Although the Eminent Scholar awards sit outside the individual universities, each scholar has an academic appointment at one of the six research universities. The GRA philosophy for the Eminent Scholars is to focus money on the top people in the top universities by attracting the best and brightest while combining public and private funds to strengthen this research and development structure (GRA Report, 2006).

There is a challenge grants program designed specifically for the Eminent Scholars. Annual awards of up to $50,000 are given to a team of at least two Eminent Scholars to promote scientific collaboration. The scope of work is judged on technical merit and the potential for future commercial success as well as on other funds the scholars have in place to support the project for which Challenge Grant funding is sought (GRA Report, 2006).

For example, Eminent Scholar Challenge Awards are made to support research development in the scientists' areas of expertise, with one criterion for eligibility being the amount of related sponsored research held by the applicant. GRA also funds 18 national Centers of Research Excellence and has seen more than $1 billion in new grants awarded around GRA activities (GRA, 2007).

GRA Innovation Fund

As part of its goal to grow the economic development of the state, the GRA Innovation Fund makes competitive research awards to faculty already working in collaboration with a Georgia company. The Fund is to be used to further the development of already-existing technologies or to begin creating new ones. All awards are made directly to researchers with the goal that the work will lead to Georgia economic development (GRA, 2007).

The fund distributes awards in three different areas of research, 1) bioscience, 2) nanoscience, and 3) advanced materials. The innovation grant can be awarded for a maximum of $100,000, and requires a one-to-one match from a Georgia industry partner. Although preference is to fund new projects or new partnerships, past recipients are also eligible for follow-up funding if their previously awarded project has been successful (GRA, 2007). The philosophy behind this program is that promoting scientific collaboration could result in an increase of new inventions and discoveries not otherwise generated (GRA, 2007).

VentureLab

Support for the VentureLab program includes $2,000,000 in annual funding which is divided among awardees in a peer-reviewed, competitive process from a pool of eligible applicants from the six Georgia academic research institutions. VentureLab's goal is to provide support for early-stage technologies so that they can gain venture funding and entrance into an incubator program as start-up companies. VentureLab was designed to provide funding and expertise to bridge the funding gap for early-stage inventions and discoveries. Each of the six participating research universities has the ability to tailor the VentureLab program to meet the needs of that particular institution. VentureLab addresses many of the valley of death issues pointed out by Friedl (2006), Kouri (2006), and Nowak (2006). The program provides a way of

negotiating the difficulties associated with biotechnology management and market analysis. Entrepreneurial coaches are partnered with inventors to provide guidance for finding the best avenues to commercialize their technologies (Consultant, 2007; GRA VentureLab, 2007).

To initiate the VentureLab process, each university receives seed grant funding for its own VentureLab program after submitting a detailed application of how the funds will be spent at its institution and what outcomes will be measured. This document then serves as the benchmark for evaluating that particular university's VentureLab program. The individual universities are required to provide the following as a match in order to receive the funds:

1) office space and infrastructure for its university-based VentureLab program;
2) access to that particular university's Eminent Scholars, other research faculty, and other activities and researchers dealing with intellectual property where appropriate; and
3) salaries for key personnel, including:
    a. fellows – professional managers with expertise in new business formation who can serve as chief executives for new companies; and
    b. commercialization catalysts – individuals who serve in the capacity of mentors or coaches and are able to function as liaisons between faculty and industry (GRA VentureLab, 2007).

Fellows and commercialization catalysts are required to be university employees in order to allow any related intellectual property to remain connected to that associated research university. The commercialization grant program is divided into the three phases described below:

1) Phase I – Awards are made to the researcher in two equal traunches of $25,000 each with each traunch available for validating the market value of a chosen technology which can be pursued by hiring experts in the research and commercialization area and in beginning the development of a business plan, also assisted by hiring outside experts.
2) Phase II – Awards are made to the researcher in two equal traunches of $50,000 with each traunch available for the further development of the business plan and in beginning the pre-incorporation activities and negotiations with the universities; and
3) Phase III – An award is given as a convertible loan directly to the new company, with the amount of the award determined on a case-by-case basis in this phase (Consultant, 2007; GRA VentureLab, 2007).

University of Georgia and Research Foundation

A further analysis involved studying the GRA was applied at a single university, the University of Georgia and the University of Georgia Research Foundation, Incorporated (UGRF). UGRF functions as the recipient entity for all University of Georgia sponsored research and licensing funds. Having the grants and licenses rest in the UGRF has allowed it to grow two revenue categories, 1) unrestricted licensing royalties and other milestone payments, and 2) restricted grant funds. These revenue streams have been instrumental in allowing the UGRF to create seed funds which are not limited by state constraints, many of which are related to GRA activities, and also develop an internal grants program which is very important in supporting the humanities and the liberal arts (Consultant, 2007; UGRF, 2007).

All intellectual property (IP) created and developed by University of Georgia faculty and staff are assigned to the UGRF, which takes responsibility for all commercialization of the University's IP. UGRF has the ability to take equity ownership in start-up companies and is

directly involved in other aspects of commercialization (UGRF, 2007). UGRF works in conjunction with the GRA in funding university researchers and commercializing inventions and discoveries.

Georgia Venture Partners

The structure described above has worked well overall for the UGRF and the GRA, but, even with such continued success, there remained a two-fold problem regarding the biotechnology investments in Georgia, namely, 1) a lack of biotechnology early-stage capital, and 2) limited access to seasoned biotechnology management. Instead of waiting for the State of Georgia to intercede, three of the six GRA's research universities decided to create a small seed fund on their own in 2004 (GVP, 2007).

Emory University, Georgia Institute of Technology, and the University of Georgia Research Foundation, Inc. developed a $5 million seed fund called Georgia Venture Partners (GVP) by combining $1 million from each of the academic institutions with $2 million from private investors. The GVP is a professionally managed fund at arms-length from the universities and the GRA. The fund has two principle functions, 1) to generate substantial investment returns focused on capital gains, by investing in new companies, and 2) to increase the economic development of life sciences in Georgia through seed or early-stage investments in start-up companies generated from academic inventions and discoveries and in other life sciences companies. Initial investments range from $100,000 to $200,000, with a cap on total investments in a single company of $1 million dollars (Consultant, 2007; GVP, 2007).

Although there are other components in the Georgia Research Alliance model, they are not directly related to the commercialization activities being assessed in this study. The initial discussions and information regarding the GRA program were conducted with the PBRC

consultant. The information obtained from the consultant was further corroborated and augmented with information obtained directly from formal GRA and other related sources.

PENNINGTON BIOMEDICAL RESEARCH CENTER

The Pennington Biomedical Research Center (PBRC, Center) is one of the 11 institutions which comprise the Louisiana State University (LSU) System, a public university organized under the laws of the state of Louisiana (LSU System, 2007). PBRC is a research campus where the Executive Director holds the equivalent status of a campus Chancellor and reports directly to the LSU System President, who reports to the LSU Board of Supervisors. PBRC is a biomedical research campus, with a focus on nutrition, obesity, diabetes, chronic diseases such as cardiovascular disease and cancer, and their prevention. As an academic research campus, the majority of the research funding at PBRC is generated from the NIH, other federal agencies, and the pharmaceutical and food industries (PBRC, 2007).

Although the research revenues are very strong for PBRC, the majority of the Center's inventions and discoveries are very early-stage and often require further development prior to outside investment interest (PBRC internal documents, 2007). Recognizing that a gap existed between initial invention or discovery and the potential for investment, PBRC key individuals began to address possible solutions for this problem. The initial step taken was to create an early-stage seed fund to provide necessary capital to further develop the Center's nascent technologies. A $12 million dollar fund, Themelios Venture Partners (TVP), an arms-length venture fund, was formed to support PBRC inventions and discoveries. A small percentage of inventions and discoveries from outside companies can be partnered with PBRC IP as part of TVP (TVP, 2007; PBRC internal documents, 2007).

Even though TVP has already invested in several PBRC technologies, it has turned down the majority of the technologies it has reviewed, claiming that the discoveries are too early for it to consider for investment. As a result, PBRC has found itself facing the same funding gap described by Friedl (2006), Kouri (2006), and Nowak (2006), even after the formation of TVP (PBRC internal documents, 2007).

Because of this situation, the administration of PBRC realized that a mechanism was needed to successfully bridge this biotechnology funding gap. The process for finding an appropriate solution has evolved and expanded over a period of approximately two years. As the project moved forward, the key individuals at PBRC combined efforts with that of the Pennington Biomedical Research Foundation (PBRF, Foundation), realizing that a more complex solution was necessary to further develop PBRC technologies and increase the probability of attracting venture funding. Through collaborative efforts, the Center and Foundation have been working to expand the opportunities to create the most appropriate commercialization mechanism for Pennington-based technologies (PBRC internal documents, 2007; PBRF internal documents, 2007).

Pennington Biomedical Research Foundation

C.B. "Doc" Pennington and his wife, Irene, donated $125 million to the Louisiana State University System in 1980, which established the Pennington Medical Foundation, a charitable trust, and in 1988, created the Pennington Biomedical Research Foundation. This Foundation, a not-for-profit 501(c)3 entity, was created with the goal of supporting the mission of PBRC. The Foundation recognizes that its mission includes expanding the capabilities related to technology commercialization (PBRF, 2007).

Within the Foundation rests a wholly-owned for-profit subsidiary, Pennington Discoveries, Inc. (PDI), which was developed several years ago with the intent to serve as a vehicle for commercialization opportunities (PDI internal documents, 2007). Up to this point in time, PDI has concentrated its efforts on two primary ventures, a line of spices geared to augment healthy eating, and a minority ownership in a specialized clinical trials company, Pennington Management of Clinical Trials, L.L.C. (PMCT). The Foundation has invested in both of these endeavors in the past, and is now committed to expanding its support of PBRC commercialization activities. The Foundation is in the process of determining how it can best support the enhancement and further development of the PBRC technology transfer program, which includes participating in the creation of a customized commercialization mechanism for PBRC technologies (PBRC internal documents, 2007; PBRF internal documents, 2007).

Outside Consultants

As part of its direct involvement, the Foundation has hired an outside consultant who has expertise regarding the Georgia Research Alliance (GRA). The consultancy is focused on assisting PBRC and the Foundation in creating their own specialized commercialization mechanism aimed specifically at early-stage bioscience inventions and discoveries. In the past, the consultant was one of several directly involved with the LSU System in its formation of the LSU System Research and Technology Foundation (LSUR&TF), and in the creation of Louisiana Fund 1, a State/private venture fund partnership (Louisiana Fund 1, 2007; LSUR&TF, 2007; PBRF internal documents, 2007; PBRC internal documents, 2007). Because of the consultant's past involvement with the LSU System, which also included the PBRC campus, the consultant is familiar with the structure and function of the LSU System and its research campuses, including PBRC. PBRC and the Foundation believe the consultant will be able to

provide customized expertise related to developing a best model for commercializing the early-stage inventions and discoveries which make up the majority of PBRC's intellectual property technologies.

Several programs within the GRA have been reviewed and discussed and the consultant has made recommendations on specific components which might be adapted by PBRC and the Foundation in their quest to create a customized commercialization mechanism. The three specific programs that were studied in-depth and are included for further study and possible development in the PBRC plan are 1) the VentureLab Concept, 2) the GRA Innovation Fund, and 3) Georgia Venture Partners (GVP), all of which were described previously in the GRA section of this chapter (PBRF internal documents, 2007).

Other key entities and situations, described below, affect the operations and performance of the PBRC commercialization mechanism, whether directly or indirectly.

Louisiana Board of Regents/Louisiana Recovery Authority

The Louisiana Board of Regents (BOR) and the Louisiana Recovery Authority (LRA) began a study aimed at strengthening the research infrastructure in the state of Louisiana in the months following Hurricanes Katrina and Rita. The first phase of this study was focused on assessing the research needs of Louisiana academic institutions, businesses, and industry impacted directly by the hurricanes (BOR, 2007).

The second phase, which is currently underway, is to develop a plan to strengthen Louisiana research capabilities throughout the entire state. The BOR and the LRA hired an outside consulting group, Regional Technologies Strategies, Inc. (RTS). A series of six BOR focus group meetings were held in April, 2007, in the three major cities in the state, with two meetings each being held in New Orleans, Baton Rouge, and Shreveport. On August 22, 2007, a

follow-up meeting was held in Baton Rouge in which the interim results were discussed. A fellow meeting was held on October 9, 2007 (BOR, 2007). The final report by RTS to the BOR is due in late fall, 2007.

In addition to these focus group meetings, smaller meetings, with key individuals who were already involved in Louisiana research commercialization, were also held in April, 2007. The key technology transfer individuals from several LSU System campuses, included PBRC. The interim findings of the report acknowledged that the research infrastructure in the state was fragmented even prior to the hurricanes, which further weakened the state's research capabilities and bases.

Life sciences R&D within the state are not exceptionally strong, but some strengths exist in specialized areas (BOR, 2007). The following items were recognized as areas needing to be addressed in order to develop more successful research capabilities in Louisiana:

1) disconnect between academic activities and what businesses need;
2) conflict in faculty roles related to commercialization and faculty promotion and tenure;
3) lack of an experienced workforce to manage and develop start-up biotechnology companies;
4) weakness in statewide entrepreneurial culture regarding research and development of biotechnologies; and,
5) lack of significant accessible investment capital for the biotechnology industry (BOR, 2007).

Baton Rouge Area Foundation

Many states are hoping to capitalize on the GRA model approach, including Louisiana. The Georgia model for commercialization is seen as one that can be adapted to other environments and states with an expectation of success. John Spain of the Baton Rouge Area Foundation (BRAF), adds in the BOR April memo,

> We have been following the tremendous success of the Georgia Research Alliance for several years and are excited about the possibility of creating a similar program in Louisiana. We look forward to being a part of a public-private partnership that brings world class scientists and research to our state (BOR, 2007).

Support of BRAF is especially important to PBRC and the Pennington Foundation because BRAF is one of the key investors in the PBRC-based venture fund, TVP, which has been established to commercialize its early-stage inventions and discoveries (PBRC internal documents, 2007). Spain, BRAF and the BOR/RFA have been studying the GRA model and working with local and state-affiliated entities to determine what type of mechanism to recommend as described in the February, 2007, Phase One report in the BOR documents (BOR, 2007).

> This is not only essential work for Louisiana, but can also provide useful strategic and tactical information for states elsewhere. Every state wants to become more of a player in the knowledge economy; every state examines from time to time the challenge of re-engineering its system of higher education. (BOR, 2007, p. 28).

The key individuals at PBRC and PBRF are moving forward with their plans of developing their own commercialization model. Meanwhile, review and study continues to assess the needs for a better research and development infrastructure and increased opportunities for the entire state.

UNIVERSITY OF NORTH CAROLINA MBA CURRICULUM PROGRAM

Many academic research institutions have encouraged faculty and other employees to commercialize their inventions and discoveries, and have set up offices of technology transfer to oversee these activities. Often, this initiative is still not enough to ensure success in the marketplace for university-based technologies.

One way to increase the rate of success associated with academic biotechnology transfer is to provide a mechanism to bridge the gap between early-stage inventions and early-stage investments. The development of an integrated, interdisciplinary curriculum-based biotechnology commercialization program is one example of such a mechanism.

Unlike the approaches taken by the Georgia Research Alliance and the Pennington Biomedical Research Center, the University of North Carolina (UNC) at Chapel Hill has implemented a curriculum-based approach to help resolve its biotechnology funding gap issue. This program received $3.5 million from the Kauffman Foundation Entrepreneurship Grants program and is matched by UNC on a two-to-one basis, with in-kind and actual funds totaling $7 million, resulting in a $10.5 million program (Kouri, 2006; UNC MBA, 2007).

Out of this grant award, UNC created the Carolina Entrepreneurial Initiative (CEI) which includes the Carolina Challenge and an MBA curriculum-based program for students and inventors. The CEI is comprised of several classes in the MBA program as part of the entrepreneurial track. Students wishing to create an area of focus in entrepreneurism participate in specific classes and in the Carolina Challenge (UNC MBA, 2007).

The MBA program covers an academic year, beginning with the fall semester feasibility phase and a spring semester launch phase. During the first phase, students have the opportunity to initiate their own ideas for a start-up company or chose to develop a business

conceptualization plan for a university-based invention or discovery that is available to the students through the UNC technology transfer office. Requirements for the Carolina Challenge include the development of a business plan, analysis of the potential market and competition, and launch of the plan (Kouri, 2006).

Like other academic research institutions, UNC had experienced the same biotechnology funding gap, where its early-stage inventions and discoveries were not being commercialized. As part of the Carolina Challenge and the MBA program, several medical equipment, device and treatment technologies which were chosen for development, have resulted in the formation of start-up companies, further development of the technologies, and outside investment funding. If a university-based technology is chosen for development as part of the MBA project, the inventor is required to participate in the two-semester program and the Carolina Challenge alongside the MBA students if he or she wishes to remain actively involved in the start-up process (Kouri, 2006).

Even with its success, the researcher who was instrumental in developing the program, Richard Kouri, Ph.D., discussed at the AUTM Annual Meeting in 2006, that the model seemed limited to biotechnologies which do not require the longer, more complex, highly regulatory drug development route. For example, the program has produced business plans, additional funding, and company start-ups with technologies that fall into the categories of medical device, testing kits, diagnostics, and other related areas. No similar successes have been documented for more complex biotechnologies (Kouri, 2006).

On a related topic, the former UNC Entrepreneur-in-Residence, Dr. Kouri, who was instrumental in using the MBA model as a way to bridge the biotechnology funding gap, recently left UNC for North Carolina State (NC State), to head up the NC State College of Management's

BioPharma Management Initiative. The MBA program at NC State which has been designed for students with a background in life sciences, provides them with a comprehensive platform of knowledge about the biotechnology and pharmaceutical industries and related legal and regulatory issues. The new program, headed up by Kouri, is focused on developing skilled professionals who will be able to lead and manage companies from small start-ups to the largest in the biotechnology industry (NCSU, 2007).

As discussed in this study, finding the best candidates to develop a highly-skilled workforce in the biotechnology industry is one of the major concerns even the most successful biotechnology clusters have acknowledged, such as San Diego and Boston. Individuals at the mid-level and support levels are finding it difficult to remain in these areas due to the high cost of living (Coombs, 2007).

Part 2

How The Five Key Components Play Out in Each Model

GEORGIA RESEARCH ALLIANCE

Component 1: Organizational Efficiency Based on a Flat Hierarchy and the Relative Small Size of the Institution:

The Georgia Research Alliance has characteristics of both a statewide super-structure and a very small organization. On one hand, it has a very large sweep, reaching all six major research universities within the state, and providing more than $2 billion in research-related funding since its inception in 1990. It has created and controls the parameters surrounding recruiting and retaining the state's more than 50 Eminent Scholars, and provides the millions of dollars in funding to steer their research toward commercialization (GRA, 2007).

On the other hand, the GRA is a separate entity from any of Georgia's six research universities, directly employing very few individuals. Another reason for the success of the Georgia model has been its focus on a narrow set of goals and the implementation of only a few programs. Key among these programs are the Eminent Scholar Challenge Grants, the GRA Innovation Fund, and VentureLab (GRA, 2007).

It appears that the GRA model contains a hybrid organizational structure, combining characteristics of both a small and a very large organization. This hybrid structure has benefited the GRA program. Since GRA projects and operations sit outside of academic and state institutions, there is little bureaucracy and a flat GRA organizational hierarchy. This type of structure can lead to operational efficiency and effectiveness. Since GRA funds remain external, the goals and focus of the Georgia Research Alliance are not subject to other internal operations needs of the research universities or the state government (GRA, 2007).

Component 2: Higher than Norm for Research Money per Bioscience Faculty:

Since the faculty being studied are limited to the 50-plus Eminent Scholars who are funded by the GRA, the research money per GRA bioscience faculty member is higher than the norm, regardless of which of the six research institutions employs the Eminent Scholar. The unique characteristic of the GRA model is that this research money ratio is based on a pool of expert researchers only. The resultant higher than normal ratio is due to the fact that these faculty members are experts in their field and have been recruited based on their external funding and interest in commercialization. These characteristics translate into a very high ratio of research money per faculty member.

Component 3: Extremely Entrepreneurial Community:

By promoting a statewide initiative in 1990 which led to the creation of the Georgia Research Alliance, the entrepreneurial message from the academic, government, and private partners was clearly sent. The ongoing support, development, expansion, and successes of the GRA and other related initiatives and activities reinforce the commitment to fueling the entrepreneurial spirit within the state of Georgia. As stated in the Georgia Research Alliance Annual Report of 2006,

> The Georgia Research Alliance *creates opportunities* to grow Georgia's economy through scientific discovery. We help recruit enterprising scientists to Georgia…fuel the launch of companies that create high-value jobs…and broker working partnerships between businesses and universities. The impact of GRA's opportunity creation is both deep and far-reaching. Communities all over Georgia reap the rewards of Georgia's investment in GRA. They are home to laboratories, established corporations and start-up companies, all with a connection to our state's research universities – and all helping to grow the Georgia economy (GRA Report, 2006, p. 12).

In addition to GRA's entrepreneurial culture, the state, the industry partners, and the universities which participate in the GRA program are supportive of this statewide commercialization initiative for biosciences (GRA, 2007).

Component 4: Integrated Life Sciences Curriculum Program:

This component does not directly apply to the GRA model. However, if one pulls back to analyze the GRA model as containing an integrated life sciences research scholars program, which substitutes faculty for students and research programs for curriculum, then the GRA can be viewed as a version of an integrated life sciences program focused not on students, but instead, on faculty.

Component 5: Integrated Commercialization Track:

a) Funding:

Since its inception in 1990, the GRA has played a key role in the generation of more than $2 billion in new federal funding and investment capital for the state, with more than $600 million in private investments for new start-up companies. The GRA contains its own funding programs, including the Eminent Scholars and VentureLab programs and the GRA Innovation Fund. The Eminent Scholar awards are permanent endowments of $1.5 million each, with an equal amount being matched by the GRA and private investors. Eminent Scholar Grants consist of up to $50,000 in annual funding given to a team of two Eminent Scholars to promote scientific collaboration. VentureLab awards total $2,000,000 annual funding, and the GRA Innovation Fund requires a one-to-one match with a Georgia industry partner for a total of $100,000 (GRA, 2007; GRA VentureLab, 2007).

Despite such ongoing funding and resultant success, GRA was still suffering from the funding gap described by Friedl (2006), Kouri (2006), and Nowak (2006). Emory University, the Georgia Institute of Technology, and the University of Georgia have teamed up with private investors to create the $5 million Georgia Venture Partners Fund for early-stage biotechnology

investments generated from these three universities. GVP initially invests between $100,000 and $200,000 in each new technology, with a maximum investment of $1 million (GVP, 2007).

b) R&D Expertise:

At the beginning of the GRA, the state did not have a critical mass of biotechnology experts, which was anticipated in the structure of the GRA. To deal with this deficit, funding to hire consultants with specified expertise has been included as part of the VentureFund program.

The first step of the VentureLab program is crucial to its success. In the initial phase, an in-depth technology assessment is conducted. Not only is the technology analyzed for its technical merit, but it is also evaluated in terms of how timely the invention is, and whether or not it will interface successfully into the current marketplace (GRA VentureLab, 2007).

This step is often conducted in a less than optimal manner in academic technology transfer offices due to the lack of expertise and resources. Being able to thoroughly assess early-stage technologies is often difficult due to the nature and stage of the technologies. Traditional sources for due diligence often are not adequate when trying to assess an early-stage technology. The GRA VentureLab service is a very important first step which should be considered by any entity wishing to establish a comprehensive early-stage commercialization program (GRA, 2007; GRA VentureLab, 2007).

Over the years as the available Eminent Scholars, R&D, and bio-business experts have increased due to the success of the GRA, Georgia began to grow its own R&D expertise, yet the ability to use funding to hire outside experts remains a key component of the VentureLab program (GRA, 2007; GRA VentureLab, 2007).

c) Springboard for New Companies:

Several opportunities exist as a springboard for new company start-ups in the state of Georgia. The GRA has the ability to loan funds to start-up companies as part of its Phase 3 VentureLab program. As pointed out, there have been many successful start-ups, with more than 125 new companies formed and more than 5,000 new jobs created. In addition, GRA provides the infrastructure to promote the creation of new companies through the Eminent Scholar Challenge grants, the GRA Innovation Fund, and additional funding for research centers of excellence and research laboratories and equipment (GRA, 2007).

Yet, even with its well-planned, comprehensive GRA program, early-stage inventions and technologies still suffered from the biotechnology funding gap. As a result, Emory University, the Georgia Institute of Technology, and the University of Georgia partnered with private industry to form the $5 million Georgia Venture Partners Fund, which invests between $50,000 and $250,000 in new start-up companies. GVP has recently begun to invest in early-stage biotechnologies (GVP, 2007).

PENNINGTON BIOMEDICAL RESEARCH CENTER

As described previously, five key components have been identified which are considered important to the overall commercialization of early-stage academic biotechnologies (Holmes, 2006; Milken, 2004; 2006). Only a subset of these five key components were present at PBRC prior to the decision to implement a comprehensive commercialization program. PBRC possessed, at least in part, some of the following key components deemed necessary for biotechnology commercialization success.

Component 1: Organizational Efficiency Based on a Flat Hierarchy and the Relative Small Size of the Institution:

PBRC's organizational structure is very similar to that of an organized research unit (ORU), which was discussed in Chapter 2. Unlike traditional ORUs, in which internal divisions such as departments and research units vie for faculty revenue, areas of specialty, and time related to teaching and research; PBRC faculty are not subject to these competing demands in the Center's organizational structure. The Center is based on a flat hierarchy which employees approximately 650 employees, including 85 faculty, with few levels of management bureaucracy (PBRC internal documents, 2007).

A small-sized institution is considered one of the five key components defined as necessary to ensure academic biotechnology commercialization success (Holmes, 2006; Milken, 2004; 2006), without reference to the type of research at the small institution. Unlike larger institutions and typical academic research universities, where the technology disclosures span a very wide range of disciplines and areas of expertise, the PBRC faculty work in a much more narrow area of research. Since the majority of research funding for the faculty for basic science research comes from the NIH, the majority of PBRC's technology disclosures are for very nascent discoveries which are based on discoveries such as gene targets, proof of concept ideas, and other promising technologies (PBRC internal documents, 2007). Therefore, not only does PBRC fit the description of a small institution, PBRC also conducts research in a narrow area of basic science.

The PBRC technology transfer office (TTO) is part of the flat hierarchy and became a separate office in 2002 (See Figure 3). The overall activity in the office has increased in the past several years and the number of technology disclosures has increased greatly since 2000. The

office is currently expanding its staff and operations and further development is being planned for the office. TTO personnel are accessible to faculty and other PBRC employees, and the office operates under the philosophy that each technology is unique and should be evaluated on a case-by-case basis in order to maximize the commercialization opportunities for that particular technology (PBRC internal documents, 2007).

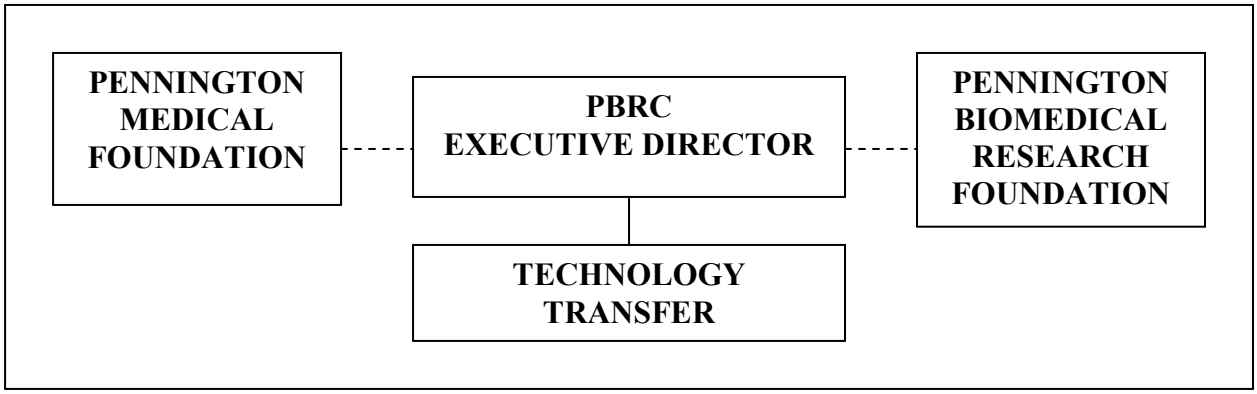


Figure 3. Pennington Biomedical Research Center Organization Chart for Technology Transfer

Close interaction exists between the TTO and the researchers in order to minimize artificial hurdles or barriers to successful commercialization. Because of the close physical proximity of the technology transfer office to the researchers, no part of the campus is more distant from the TTO office than five to ten minutes away on foot. This allows the parties to interact easily in person and increases the level of familiarity and the frequency of interactions. The small campus size also reduces the time and effort needed to meet in person, since no one needs to drive or walk long distances for such interactions (PBRC internal documents, 2007).

In most day-to-day operations, the Center does not suffer from the problems associated with a large bureaucracy, but, as described earlier in the chapter, there are some restrictions facing the commercialization process because PBRC sits within a much larger academic organization, the LSU System. The overall commercialization culture at various LSU campuses and at the LSU System level has been inconsistent, but new programs and directions undertaken

within the past few years are changing the situation, as discussed earlier in this chapter (PBRC internal documents, 2007).

Despite these issues, PBRC is partnering with the Pennington Foundation to move forward in developing a integrated, multi-function commercialization mechanism. The key players recognize there is a balance to be maintained between the Center's obligations to the LSU System and the need for flexibility, some of which is obtained by shifting some of the commercialization activities to the Foundation. With PBRC's characteristics of a flat hierarchy, minimum bureaucracy, and physical proximity to its researchers, the groundwork is in place which allows for efficient and effective operations. Since the Foundation is a separate entity not subject to university or government restrictions, it can provide additional flexibility in operations.

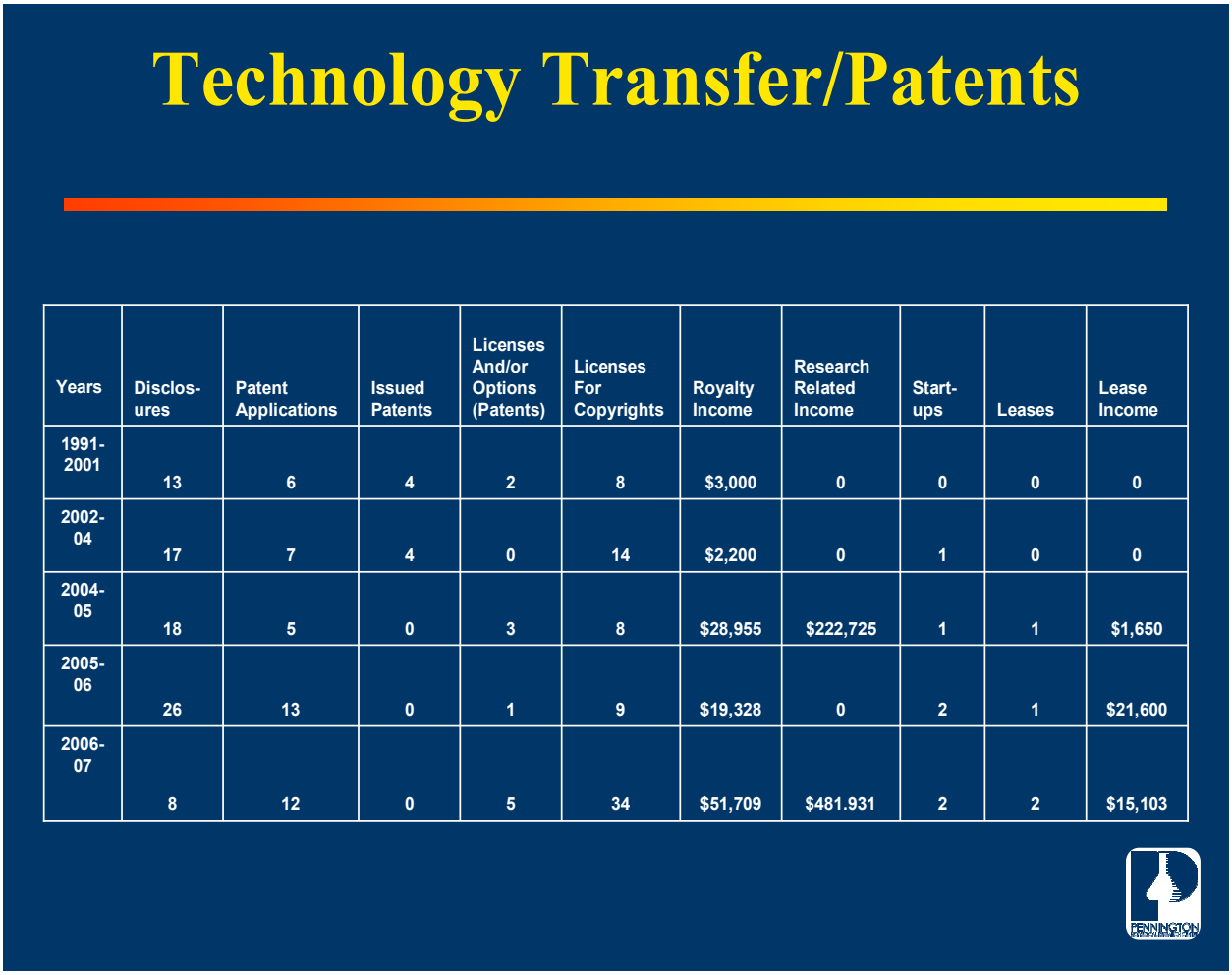
Component 2: Higher than Norm for Research Money per Bioscience Faculty:

With PBRC being a research campus with no teaching duties, faculty promotion and tenure is based on research performance, which includes securing self-generated sponsored research funds that satisfy the overall mission of the Center. Approximately 40% of the faculty are on a five-year rolling tenure track. The remaining faculty members are hired on a more limited basis, with much of their performance assessment related to their research success, such as securing NIH and other grant awards, research-driven pharmaceutical clinical trials, and research-focused industry contracts. The faculty has grown to approximately 85 individuals, but even though PBRC has expanded the overall number of faculty, support researchers, laboratories, and clinical units during the past ten years, several faculty researchers are let go each year due to non-performance and lack of funding (PBRC, 2007; PBRC internal documents, 2007).

The AUTM Survey (2006) cites the strong relationship between NIH funding and the number of invention disclosures, patent applications, and licenses. Technology transfer experts find a high correlation between the research success of faculty by comparing sponsored research grant award funds to subsequent inventions disclosures (AUTM, 2006). The PBRC faculty perform at a much higher ratio of research dollars per faculty member than the average for academic research institutions (PBRC internal documents, 2007).

The overall rate of technology disclosures per faculty member at PBRC is also higher than the norm for research universities, although the status of those technologies is typically very early-stage (Table 2). Due to the early stage status of the technology disclosures, PBRC has a lower rate of licensing per disclosure than the average research university PBRC internal documents, 2006). The PBRC administration believes this lower ratio is an example of the commercialization gap described by Friedl (2006), Kouri (2006) and Nowak (2006).

Table 2. Pennington Biomedical Research Center Technology Transfer Activities 1991-2007



Years	Disclos-ures	Patent Applications	Issued Patents	Licenses And/or Options (Patents)	Licenses For Copyrights	Royalty Income	Research Related Income	Start-ups	Leases	Lease Income
1991-2001	13	6	4	2	8	$3,000	0	0	0	0
2002-04	17	7	4	0	14	$2,200	0	1	0	0
2004-05	18	5	0	3	8	$28,955	$222,725	1	1	$1,650
2005-06	26	13	0	1	9	$19,328	0	2	1	$21,600
2006-07	8	12	0	5	34	$51,709	$481.931	2	2	$15,103

Component 3: Extremely Entrepreneurial Community:

Pennington Biomedical Research Center

PBRC's highly-competitive research culture has, by its very nature, faculty members who, typically, possess a higher level of comfort with risk-taking and identify themselves as self-starters who gain satisfaction from forging new research paths. This results in a high ratio of faculty to research dollars which is considered one of the key components necessary for biotechnology commercialization success, according to Edward Holmes (2006), former Vice President for Health Sciences at UCSD.

In addition, PBRC faculty are expected to generate their own funding after a negotiated initial period of institutional support. This funding requirement tends to weed out faculty who are more risk-averse and less entrepreneurial. As a result, the faculty who do remain part of PBRC typically possess qualities and interests which put them in line with the culture and characteristics more closely associated with commercialization success (PBRC internal documents, 2007).

Much emphasis at PBRC has been placed on commercialization of technologies and on the importance of PBRC in contributing to the overall economic development of the region and the state. On average, for every dollar given PBRC, the Center generates three to four times that amount in economic impact, but these numbers are based primarily on research dollars generated and not on technology commercialization revenues (PBRC, 2007), unlike the Georgia Research Alliance's five-fold return on commercialization investment (GRA, 2007).

Louisiana State University System

Historically, the technology transfer administrative culture in place at the LSU System level and on some of the other LSU System campuses has not been as entrepreneurial as at PBRC. For several years, like the situation at many research universities, the technology transfer initiative was not given high priority and was often plagued with roadblocks or barriers to commercialization. Recently, some shifts have occurred at various levels within the LSU System to promote technology transfer and economic development (LSU System, 2007).

Such changes include 1) the formation of the Louisiana State University Research and Technology Foundation (LSUR&TF, 2007); 2) the opening of the LSU Emerging Technology Center (2007), a partnership between the Louisiana Department of Economic Development (LED) and the University, which includes office space as well as wet labs and core research

facilities for start-up companies; 3) LED matching funds used to form several venture funds set up to focus on commercializing academic-based technologies (Louisiana Fund 1, 2007); and 4) an increase in budget and personnel for technology transfer activities at several individual campuses and at the LSU System level (LSU System, 2007). Although it is recognized that the outcomes of such changes will take time to disseminate into the larger technology transfer community, these shifts have been very well-received at PBRC and have resulted in a more entrepreneurial academic culture.

The Greater Baton Rouge Region and the State

According to Richard Florida (2002) in his studies of the creative class in the United States, the Baton Rouge community ranks as one of the more creative areas in the U.S. for medium-sized regions with populations between 500,000 and one million residents, while Houma, Louisiana, ranks near the bottom of the list, even though it is less than 100 miles away from Baton Rouge. In Florida's more recent study, published in 2005, the New Orleans area is ranked as one of slow creative growth and a higher than average divide among socio-economic classes, a characteristic his studies have shown to be counterproductive to entrepreneurial development. Florida's assessments can be helpful in trying to understand the overall entrepreneurial culture differences within the State of Louisiana.

At the local level, another positive outcome is that, for the past several years, the Greater Baton Rouge Area Chamber of Commerce has been promoting the Pennington Biomedical Research Center and its value as an economic development asset in the community. PBRC is one of the five key areas the Chamber of Commerce is focused on promoting and developing as central drivers of the local economy. With its membership of local leaders in business and

industry, the Chamber's constant support of and dissemination of information about PBRC continues to be pivotal (Baton Rouge Area Chamber, 2007).

At the state level, the Louisiana Department of Economic Development (LED) has funded the construction of three state-of-the-art biotechnology incubators (one of which sits on the LSU A&M Campus in Baton Rouge), provided matching dollars for three venture capital investment funds geared toward academic technology transfer, and is working on new legislative initiatives to attract the biotech industry into the state. Several start-up companies are residing in these new business incubators (BOR, 2007; Emerging Technology Center, 2007).

A critical mass is building regarding the necessity for the Baton Rouge area and the state to plan a course of action that can create a twenty-first century model of biotechnology commercialization success. This shift in awareness was demonstrated at the Louisiana Board of Regents and Louisiana Recovery Authority meeting, August 22, 2007, (BOR, 2007) where the following interim recommendations were made.

1. Enhance research in focused areas
2. Attract top faculty to the state
3. Grow technology companies through student internship clinics
4. Increase university-industry technology training workforce development, and
5. Find or train technology managers due to shortage.

The following overall observations were made

1. Culture building is extraordinarily important
    a. "Tipping" can occur with right leadership promoting entrepreneurship
    b. Business schools as cultural leaders
2. Training of support staff at the community college level

3. Flexibility in organizations
4. Emphasize few programs, and
5. GRA promotes cross-collaboration (BOR, 2007).

As a result, although the PBRC community is entrepreneurial, the overall culture of the region and state is mixed in terms of being risk-averse and encouraging the development of the creative class. The proactive changes made to move the LSU System and other campuses, Baton Rouge, and the State of Louisiana toward being more entrepreneurial, are very important and timely, but it will be some time before these initiatives have a lasting effect on the overall entrepreneurial status of the community and the state.

In the interim, PBRC finds itself still needing to expand its own entrepreneurial culture in order to increase biotechnology commercialization success. The question remains as to whether or not having a very entrepreneurial culture (PBRC and PBRF) which sits within a larger, mixed-risk culture at the LSU System, regional, and state levels, is enough to cultivate overall commercialization success. As pointed out above, the need for an entrepreneurial culture is one of the five key components recognized as being necessary for academic biotechnology commercialization success (BOR, 2007; Holmes, 2006; Milken, 2004; 2006). Currently, PBRC finds itself in a culture which is only partially entrepreneurial.

Component 4: An Integrated Academic Life Sciences Curriculum Program:

The Pennington Biomedical Research Center is a research campus which does not offer a life sciences curriculum. This key component does not exist at the Center.

Component 5: A Specialized Biotechnology Commercialization Program:

a) Funding:

As described in Part 1, in late 2005, an early-stage venture fund was created to help bridge the commercialization funding gap for inventions and discoveries emanating from the Pennington Biomedical Research Center (TVP, 2007). The PBRC administration realized that the Center was experiencing difficulties with commercialization of its inventions and technologies very similar to that described by others such as Friedl (2006), Khouri (2006), and Nowak (2006). The following chart (Figure 4) was produced by PBRC in order to convey the funding gap problem as it specifically pertained to PBRC (PBRC internal documents, 2007).

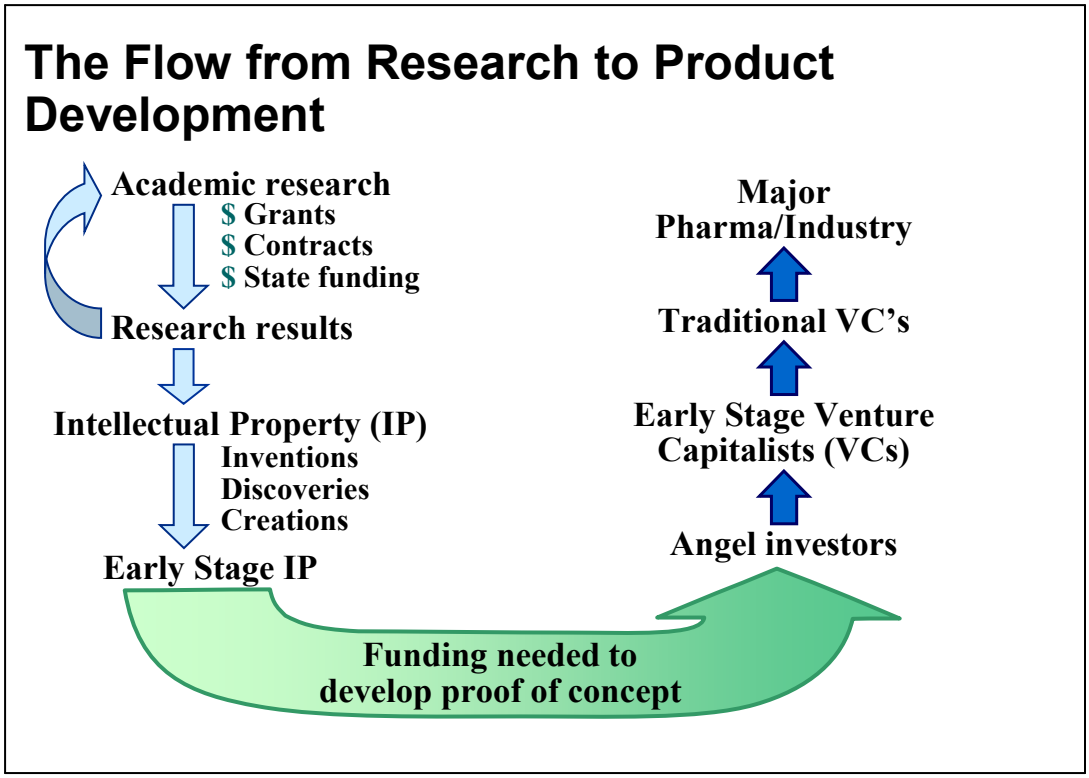


Figure 4. Commercialization Flow from Academic Research to Product Development

Themelios Venture Partners, LLC (TVP), the venture fund that was created, allows for flexibility in the type of technologies which are commercialized. Sixty to seventy percent (60%

to 70%) of the technologies must be generated from within the PBRC, with the remaining thirty to forty percent (30% to 40%) of the technologies originating from outside PBRC which can be combined with PBRC expertise and technologies as part of the commercialization platform (PBRC internal documents, 2007; TVP, 2007).

This venture fund, which currently has a value of $12 million, has already invested in two PBRC-based technologies and is reviewing several others. After two issued patents and a decade of laboratory results, the first investment for TVP is a cancer technology start-up company, Esperance Pharmaceuticals, Inc. Even TVP and its investment partners, including Louisiana Fund 1, determined that more research was needed on the technology, after agreeing to invest. The second technology the fund has decided to invest in includes an interactive software and behavioral psychology assessment tool that can be used by a wide range of behavioral therapists (PBRC internal documents, 2007).

Even with TVP's investment, the majority of the remaining technologies, approximately four out of five, are still caught in the valley of death funding gap. The venture funds which have reviewed these technologies are all early-stage investors and have all determined that the inventions are still too early for them to invest in at this time. The PBRC inventors realize they cannot receive additional traditional funding to further this research, as described by Karl Friedl (2006) in Chapter 1, and they do not have the internal financial resources nor the developmental expertise to know how to move along their own technologies. At the same time, the technology itself is often too embryonic to consider application for NIH small business grant awards (NIH, 2007).

This situation has led to the realization at PBRC that even with its new venture, the majority of PBRC technologies are still caught in a commercialization standstill. As a result,

PBRC, in conjunction with PBRF are analyzing mechanisms to expand the commercialization activities in order to bridge this gap.

b) R&D Expertise:

PBRC key individuals recognize that there is a lack of R&D expertise in the Baton Rouge area and the state. A critical mass is building regarding the necessity for the Baton Rouge area and the state to plan a course of action that can create a twenty-first century model of biotechnology commercialization success. This shift in awareness was demonstrated at the Louisiana Board of Regents August 22, 2007, meeting, where discussions surrounded how to implement a customized plan to bring research and development expertise to the state (BOR, 2007).

c) Springboard for New Companies:

As discussed previously, several mechanisms have been developed to help with the creation of new companies. TVP has been established as a PBRC-focused early stage venture fund, Louisiana Fund 1 has been created by LED and the LSU System. Louisiana Fund 1 has a mission of commercializing inventions and discoveries by Louisiana's universities. Louisiana Fund 1 has invested in the new cancer start-up company, Esperance Pharmaceuticals, Inc., and is negotiating investments in several other PBRC-related technologies. Despite this activity, Louisiana Fund 1, like TVP, has turned down the majority of the PBRC technologies it has reviewed (PBRC internal documents, 2007).

Other Discussions and Analyses

Although the interactions with the faculty play a very central role in how PBRC will develop its new commercialization model, there are additional players and issues which are integral to this process. The relationship between the Center and the Foundation in terms of the

best placement of specific commercialization programs and activities is a crucial one. The Foundation is also determining which of the activities it decides to oversee should be housed within a non-profit organization and which would better fit in a for-profit entity. One advantage to creating an integrated, multi-tiered R&D commercialization mechanism at this time is that there are some outside examples already in place which can be reviewed and adapted in order to create the most appropriate application in a new setting. At the same time, the examples from the outside can also provide so much information that choosing a path becomes a fragmented process which could weaken the overall efficiency and effectiveness of the newly created mechanism. The PBRC and PBRF key individuals are aware of the need to find the right balance between assessing other models and creating a sound, achievable commercialization mechanism for their specific needs. The process is still ongoing.

UNIVERSITY OF NORTH CAROLINA MBA CURRICULUM PROGRAM

Component 1: Small Size of the Institution:

Although the University of North Carolina is one of the largest public research universities in the state, the MBA entrepreneurial curriculum program at UNC Chapel Hill is a highly-focused graduate program available to a limited number of students and university inventors (Kouri, 2006; UNC MBA, 2007). The result is that the small scale of the MBA program mimics a small-sized institution even though it sits within a very large organization. Some of the same benefits that a small academic setting can offer, such as a flat hierarchy, minimal roadblocks and bureaucracy, and links to essential personnel and key organizational components. This small-scale program is in place within a much larger academic setting comprised of 16 campuses located throughout the state (UNC, 2007).

Component 2: Higher than Norm for Research Money per Bioscience Faculty:

Since this MBA curriculum program does not focus directly on research activities from the bioscience faculty, this key element does not apply directly to the UNC model.

Component 3: Extremely Entrepreneurial Community:

The Research Triangle region of North Carolina is a highly entrepreneurial area, with its main focus on the biosciences. Like the Georgia model, the North Carolina Research Triangle initiative was a planned, collaborative partnership among the three research universities in the region, the state of North Carolina, and private industry (Milken, 2004; 2006; Washburn, 2005). With a 20-year history of pharmaceutical industry and related businesses operating in the area, the Research Triangle is home to numerous experts in various areas of bioscience research and development who are willing to participate in the MBA program as mentors and advisors to the participants. Some experts have even played an integral role in securing venture funding for the biotechnologies being developed as part of the Carolina Challenge (Kouri, 2006; UNC, 2007).

Even with an inherently entrepreneurial community and easy access to a large number of local experts, the UNC MBA model has only been able to successfully commercialize biotechnologies in the areas of medical devices, diagnostics, and testing and not in the drug development area. It remains to be seen if the launch of the $1.5 billion North Carolina Research Campus will have a positive impact on early stage biotechnology commercialization culture at UNC and the other major research universities in the state. In the North Carolina Research Campus project the state has committed nearly $30 million annually, focused on hiring academic researchers. The participating universities are preparing to hire for new faculty members, UNC is looking to fill 18 faculty positions while NC State is slated to hire 13 faculty (Fischer, 2007).

Component 4: Integrated Life Sciences Curriculum Program:

Since no direct link exists between any life science curriculum programs and the MBA-based program, this component does not apply. Instead, the UNC MBA program is a business curriculum based program, with commercialization of technologies as one of the outcomes to this MBA program.

Component 5: Integrated Commercialization Track:

a) Funding:

Other than the Kauffman Foundation and matching UNC funding which comprise the bases for the Carolina Entrepreneurial Initiative, there is no specifically designated university-based fund to springboard early-stage academic technologies for commercialization as a direct part of the MBA entrepreneurial program (Kouri, 2006). If a technology wins the Carolina Challenge, the winners receive a $25,000 prize to further develop the technology (UNC MBA, 2007). Some statewide funding is available through other organizations, and the Carolina Challenge participants might be eligible for the following related funding sources:

1) Eno River Capital

A specialized biotechnology revenue source, the Eno River Capital fund, was created in 1998 to commercialize life science technologies developed in North Carolina's public academic universities through the formation and development of locally-based start-up companies. In addition, the fund was charged with creating new, high-paying, high-skill jobs and attracting new capital from later stage investment firms. The core expertise of Eno River Capital is in technology commercialization, with a major focus on transforming discoveries into products or services and turning a profit. Areas of expertise are described as deal-structuring and intellectual

property licensing along with operational experience in the areas of information technology and the life sciences. Consulting services are also provided (Eno River Capital, 2007).

As part of its responsibilities, Eno River Capital manages the $26 million North Carolina Bioscience Investment Fund (NCBIF), which is a seed-stage venture capital fund for life science inventions and discoveries. NCBIF's activities center on the research universities and other research institutions in North Carolina (NCBIF, 2007).

2) North Carolina Bioscience Investment Fund

In June, 2007, it was reported that NCBIF's $10 million dollar investment in the Eno River Fund had a net worth of approximately $1.3 million. Of the 10 companies the Eno fund has invested in, eight have been sold or are out of business. Norris Tolson, newly elected Director of NCBIF, who has recently resigned from his position as the state of North Carolina Secretary of Revenue, to take the NCBIF appointment, admitted that the Eno River Fund has not performed well, although he cited other investments in new companies that did result in new jobs. The report indicates that NCBIF received approximately $12 million in annual funding from the state of Georgia (Weisbecker & John, 2007, 2007). At the present time, funding for further development of early-stage biotechnologies is in transition.

3) North Carolina Research Campus

Seven universities in North Carolina are partnering with Dole Foods owner, David H. Murdock, to build a $1.5 billion biotechnology research complex 30 miles northeast of Charlotte (Fischer, 2007). Although specific R&D funds have not yet been defined, it is anticipated that commercialization will play a key role.

b) R&D Expertise:

A significant number of highly-skilled biotechnology experts live in the Research Triangle area and are available to help develop new biotechnologies in the region. Such a concentration of experts can prove to be highly valuable to biotechnology start-ups and inventors in the area. Since the biotechnology field is such a highly specialized one, experts are difficult to find in most geographic areas. Having such a high concentration of biotechnology experts, including senior management, developmental scientists, bio-business experts, highly-skilled research technicians, and others, is unusual and very valuable to the UNC MBA program and the participants in the Carolina Challenge. Several of these experts participate in the Carolina Challenge to assist inventors and the MBA teams with their business plans and with other issues necessary to ensure successful commercialization. The collaboration is typically done on a voluntary, informal basis (Kouri, 2006; UNC MBA, 2007).

The creation of the North Carolina Research Campus will provide a new infusion of R&D experts. In the North Carolina Research Campus project, the state has committed nearly $30 million annually, focused on hiring academic researchers. The participating universities are preparing to hire new faculty members. UNC is looking to fill 18 faculty positions while North Carolina State is slated to hire 13 new faculty (Fischer, 2007).

Unlike the other models, the larger North Carolina biotechnology commercialization program does contain a workforce development component which has been implemented at the North Carolina community college level to educate and train this very important component of skilled biotechnology workers (NCBIF, 2007).

The state of North Carolina has implemented a program through its community colleges to train these individuals for workforce deployment. Expanding this community college program

is a major area of focus in the North Carolina Research Campus. Rowan-Cabarrus Community College has initiated a specialized biotechnology program to train students to become laboratory technicians, and biomanufacturing workers (Fischer, 2007). This focus, in conjunction with the UNC MBA entrepreneurial program, may provide a significant cadre of regionally grown biotechnology employees necessary for growing this specific biotechnology component for economic development in the state.

c) Springboard for New Companies:

It appears that the UNC Chapel Hill MBA curriculum program and the state of North Carolina have had mixed results in creating success as a springboard for new companies. The UNC MBA entrepreneurship curriculum program and the Carolina Challenge have produced some biotechnology successes. Yet, these new companies are limited to those in the medical device, diagnostics, and testing areas (UNC MBA, 2007).

As discussed in this study, the UNC model has not worked for the more complex, highly expensive process of taking a biological compound through the numerous hurdles and significant expenses, often lasting more than 10 years and costing upwards of $800 million dollars (Feldman, et al., 2002). Supporting the existence of this inherent difficulty surrounding the commercialization of pharmaceutical drugs, the Alfred E. Mann Institute for Biomedical Engineering at the University of Southern California acknowledges that its extensive commercialization program has only been put in place at this time to commercialize medical devices. The Fund acknowledges that immense time and funding surrounds more complex biotechnologies and is too expensive for implementation at this time (Robbins-Roth, 2007).

Another option for Carolina Challenge participants is to look to the NCBIF for possible development funding. Although NCBIF has established several years ago, its main funding

remains state dollars and start-up success has been inconsistent, even though some new high-skilled, high-paying jobs have been created since the inception of NCBIF. Yet, as recently as late June, 2007, the NCBIF is undergoing restructuring efforts and the ties between NCBIF and the Eno River Capital fund appear to be under review (Weisbecker & John, 2007, 2007).

As described above in the funding section, NCBIF has been established to promote and commercialize North Carolina bioscience inventions and discoveries, primarily generated from the state's academic research universities. The Eno River Capital fund investments have not been as successful as hoped, but newly-elected NCBIF Director Norris Tolson declared that the NCBIF's other investments have created new jobs and produced returns on investments (Weisbecker & John, 2007, 2007). The state of North Carolina invests approximately $12 million dollars annually into the NCBIF (NCBIF, 2007).

A future catalyst for starting up new companies could be part of the North Carolina Research Campus project (Fischer, 2007). Specifics regarding early-stage biotechnology commercialization programs in relation to the program have not yet been described. Projected funds for the program are currently estimated at $1.5 billion (Fischer, 2007).

Part 3

Similarities and Differences among the Three Models and in Relation to the UCSD Best Practice Model

This section will compare the three models with each other and with the UCSD best practices model. The five components analyzed throughout this study will be revisited by comparing all models in terms of each component. The following chart (Table 3) outlines the five key components present in the UCSD best practices model and the three models analyzed in this study.

Table 3.
Comparison Chart for Academic Biotechnology Commercialization – 5 Key Components

KEY COMPONENTS	UCSD Best Practice	UNC Model	PBRC Model	GRA Model
Small Size of Institution	Y	N	Y	N
Higher than Norm for Research Money per Biosciences Faculty	Y	N	Y	Y
Extremely Entrepreneurial Community	Y	Y	N	Y
Integrated Life Sciences Curriculum Program	Y School of Medicine and Graduate School Program (COILS)	N	N	N
Integrated Commercialization Track				
➢ Funding	Y	N	Y	Y
➢ R & D Expertise	Y	Y	N	Y
➢ Springboard for New Companies	Y	Y	TBD	Y

Y = yes
N = no
TBD = To Be Determined
UCSD = University of California - San Diego
UNC = University of North Carolina at Chapel Hill
PBRC = Pennington Biomedical Research Center
GRA = Georgia Research Alliance

By comparing the UCSD best practice model with the three models analyzed in this study, it is possible that the results will show that not all five components are necessarily the best fit for other institutions.

> Perhaps the best example of this is the often-believed misconception that "if you could only create an organization like San Diego's Connect, we could transform this state into the next biotech capital of the world!" Consequently, my caveat to this chapter is that, just because the programs described here are producing results at UCLA, they may not work well at your university (Neighbour, 2006, p. 13).

Component 1: Small Size of the Institution:

None of the three models studied fit the traditional definition of a small institution, yet each contains some of the characteristics of a small-sized institution deemed important in the UCSD model. For example, the UNC MBA model can be described as a small organization when looking only at the MBA curriculum program. This program is well-defined and focused, based on a flat hierarchy, and subject to little bureaucracy. In addition, the majority of the funds for the program are generated from sources outside of the university. The fact that the University of North Carolina at Chapel Hill is one of the largest single campuses in the state, does not seem to have a negative impact on the efficiency or effectiveness of the MBA curriculum program (UNC MBA, 2007).

Similarly, the GRA model is also based on a small organization which directly employees very few individuals. The GRA is comprised of a focused program, flat hierarchy, and little bureaucracy. In the GRA model, the mission is to serve the biotechnology commercialization needs for Georgia's top six research universities, but GRA functions as its own separate entity. The difficulties often encountered in large organizations, such as bureaucratic gridlock, fragmentation, and multiple layers within a multi-tiered hierarchy, do not penetrate the GRA,

even though the state government and six major universities are collaborative partners in this alliance along with business and industry (GRA, 2007).

With both the UNC and GRA models, it appears that when a specific program is contained within a small organization, it can work well, even if that small organization sits within or adjacent to a very large organization. This success depends on whether or not the mechanism is directly dependent on a larger organization for its operations, direct funding, and survival, no matter whether or not the mechanism sits within or in parallel to that large organization.

A somewhat different situation exists at the Pennington Biomedical Research Center, which is one of 11 institutions in the Louisiana State University System. PBRC employs more than 650 individuals, but has a narrow research focus and no teaching component. PBRC is modeled on the organized research unit (ORU) structure with the advantage that the funding sources and faculty duties are not bifurcated. The culture of the Center is to be efficient and effective and the administrative organization is very lean and flat (PBRC internal documents, 2007).

In most day-to-day operations, the Center does not suffer from the problems associated with a large bureaucracy, but, as described earlier in the chapter, there are some restrictions facing the commercialization process because PBRC sits within a much larger academic organization, the LSU System. The overall commercialization culture at various LSU campuses and at the LSU System level has been inconsistent, but new programs and directions undertaken within the past few years are changing the situation, as discussed earlier in this chapter (PBRC internal documents, 2007).

Despite these issues, PBRC is partnering with the Pennington Foundation to move forward in developing a integrated, multi-function commercialization mechanism. The key players recognize there is a balance to be maintained between the Center's obligations to the LSU System and the need for flexibility, some of which is obtained by shifting some of the commercialization activities to the Foundation. With PBRC's characteristics of a flat hierarchy, minimum bureaucracy, and physical proximity to its researchers, the groundwork which allows for efficient and effective operations. Since the Foundation is a separate entity not subject to university or government restrictions, it can provide additional flexibility in operations.

In the end, none of the three commercialization models fits the definition of a traditional small institution, and none has the structure that is in place at UCSD, yet there have been significant successes generated out of the three models. In addition to being a small-sized organization, the following characteristics of an organization also appear to be important for commercialization success:

1) efficient and effective operations whether the overall organization is small or large;
2) separate funding sources which are not part of traditional university coffers, and if possible, rest outside of the overall university umbrella;
3) well-focused, small scope, targeted commercialization program; and
4) a flexible approach in order to implement non-traditional activities such as industry partnerships, research development funding for faculty, patent activities, and R&D expertise in a fluid commercialization marketplace.

These four characteristics appear to play an important role, at least to some degree, in how efficiently the organization runs.

Component 2: Higher than Norm for Research Money per Biosciences Faculty:

In the traditional definition of the ratio of research money per bioscience faculty, the Pennington Biomedical Research Center is the only one of the three models that contains this component. Yet, PBRC finds itself faced with a serious early-stage technology funding gap, with a small number of invention disclosures translating into viable venture startups or licensed technologies. Therefore, the ratio of research money per faculty does not equate with successful commercialization at PBRC, even though this component was deemed essential in the UCSD model.

The UNC MBA program is different from the other two models analyzed because it involves a small number of technologies and therefore, a small number of faculty. Mostly near-commercialization possibilities such as medical devices and testing and diagnostics products become part of the Carolina Challenge (Kouri, 2006). The small number of participating faculty and their technologies do not capture the collective research funding of the UNC bioscience faculty. Therefore, it is not feasible to apply this funding ratio to the small group of biotechnology researchers participating in the UNC MBA entrepreneurial program.

The Georgia model does meet the criterion of higher than norm research money per bioscience faculty member if its GRA Eminent Scholars are the only researchers in the pool. The GRA model is an example of a very successful commercialization program that does not depend on an overall high ratio of funding for all bioscience faculty. Instead, this model leverages and maximizes traditional biosciences research funding only for Eminent Scholars by combining it with GRA's funding sources and collaborative programs. This results in higher than normal research dollars and fuels even more funding for the select Eminent Scholars (GRA,

2007). The high ratios of combined research dollars per Eminent Scholar have translated into exceptional commercialization success over the past 16 years.

Keep in mind that GRA's success is for a mix of public and private universities with different inherent levels of bioscience research funding and bioscience faculty strengths, and the program works well in all of the six universities. Targeting a much smaller group of faculty is a GRA formula that works for both public and private research universities and reinforces the belief that a version of the Eminent Scholar program could be adapted for use by a range of research universities.

Ironically, the only model which meets the traditional definition of this higher than norm research ratio is PBRC, which finds itself needing to implement a more comprehensive commercialization program in order to be consistently successful. As mentioned above, the UNC model is very limited in the number of faculty participating and the scope of technologies it can commercialize, so it is not feasible to calculate the ratio of research funding per faculty involved in the Carolina Challenge.

For this component, it appears that the most successful model is the GRA program, one which contains some basic characteristics which are different from the UCSD model. The GRA model only applies the funding ratio to the targeted group of Eminent Scholars. Small, focused, similar programs applied to select faculty might be easily adapted by other universities. In actuality, it might not matter if there is an overall high ratio of research dollars per bioscience faculty members as long as there is a high ratio for those targeted faculty researchers who actually participate in the commercialization mechanism.

Component 3: Extremely Entrepreneurial Community:

The ongoing support, development, expansion, and successes of the Georgia Research Alliance and its related initiatives and activities such as the Georgia Venture Partners Fund, reinforce the state of Georgia's commitment to fueling the entrepreneurial spirit. As described by the GRA itself, its mission is to create the opportunities to grow the economy of the state through scientific discovery and related commercialization activities (GRA, 2007; GVP, 2007).

Unlike San Diego or the North Carolina Research Triangle, historically the state of Georgia had not been culturally entrepreneurial regarding bioscience development prior to the creation of the Georgia Research Alliance in 1990. Yet, the GRA is an example of a statewide initiative that includes partnerships of academic, government, and private organizations that have proven very successful in meeting its mission (GRA, 2007). Nevertheless, even with all of the success and the highly entrepreneurial culture in Georgia, there is a commercialization gap for early-stage academic biotechnologies, which led to the formation of the Georgia Venture Partners Fund in 2004 (GVP, 2007).

Although inherently entrepreneurial, PBRC finds itself needing to expand its broader entrepreneurial culture in order to move ahead with successful biotechnology commercialization. The question remains as to whether or not having a very entrepreneurial internal culture at PBRC is enough to cultivate a successful, broader-based mechanism for commercialization success. PBRC sits within a larger, mixed-risk culture in place at the LSU System, the greater Baton Rouge area, regionally, and around the state. There is some movement toward the development of a more creative class within the overall traditional, conservative, risk-averse setting, but it remains to be seen if this movement is enough to be a catalyst for PBRC's economic activities.

Like UCSD and Georgia, the Research Triangle region of North Carolina also has been a highly entrepreneurial area for several decades, with its main focus on biosciences R&D. The Research Triangle has been home to Glaxo Smith Kline, a pharmaceutical company for several years and has, within its region, a large number of experts in the biotechnology field. Like the Georgia model, the North Carolina Research Triangle initiative was a planned, collaborative partnership among the three research universities in the region, the state of North Carolina, and private industry. But upon closer inspection, the Research Triangle appears to more closely resemble the overall entrepreneurial culture of the San Diego area than it does that of Georgia.

Despite its long-term culture of entrepreneurship, UNC also found itself faced with the same biotechnology valley of death that has been described in detail throughout this study (Friedl, 2006; Kouri, 2006; Nowak, 2006). In such an entrepreneurial climate, UNC still could not successfully commercialize its early-stage biotechnology inventions and discoveries. The overall culture of entrepreneurship was not enough to guarantee biotechnology success at UNC, as witnessed by the need for the MBA entrepreneurial program and the Carolina Challenge (Kouri, 2006; UNC MBA, 2007).

On the state level, the North Carolina government has more recently declared the need to overhaul the North Carolina Bioscience Investment Fund which was created to commercialize inventions and discoveries generated in the state. The state government also made the admission that its past mechanisms for commercializing biotechnologies have had mixed results (NCBIF, 2007).

It appears that an entrepreneurial culture or community is important to successful commercialization, but this entrepreneurism can be deliberately created, as was the case in Georgia, and still result in a positive economic impact. Conversely, the presence of a highly

entrepreneurial community does not guarantee, in and of itself, a corresponding success rate for commercializing early–stage biotechnologies, as witnessed in North Carolina. The emergence of the new North Carolina Research Campus may provide North Carolina with a more entrepreneurial culture. As part of the new movement, UNC System President Erskine Bowles has declared that economic development is part of the university's mission (Fischer, 2007).

Component 4: Integrated Life Sciences Curriculum Program:

This component is not directly related to any of the three commercialization models studied, yet its importance may be undervalued in this study by virtue of the characteristics of the particular models being analyzed. One reason that the importance of an integrated life sciences curriculum program might have a much larger overall impact on an academic institution than is present in the three models, is based on a new NIH program.

The NIH has realized that it has been largely unsuccessful in its ability to translate its federal clinical research funding into an adequate number of positive outcomes related to patient care and new bioscience discoveries to improve the overall health of the population. As a result, the NIH has launched a new initiative called the Clinical Translational Science Awards (NIH, 2007).

Both the UCSD model and the NIH Clinical Translational Science Awards emphasize a new approach to training bioscience researchers at least partly through an integrated curriculum. This new NIH program is geared toward breaking down the barriers or silos of research so that cross-collaboration and a broader spectrum of possibilities becomes the norm for the individuals being trained. The belief is that, by cross-training clinical researchers, an increase in broader-based translational research activities will occur, as will an increase in treatment initiatives (Holmes, 2006; NIH, 2007).

In its own way, the GRA has accomplished some of these same outcomes in terms of developing cross-trained translational researchers by its requirements and criteria for its Eminent Scholars Program and Eminent Scholars Innovation Fund. Unlike the UCSD model or the NIH CTSA program, the Georgia Eminent Scholars are senior, expert bioscientists, not students, who are awarded funding based on cross-collaboration and commercializable areas of research. In the GRA model, the requirements for the Eminent Scholar programs are substituted for the curriculum requirements of the life sciences students.

It might be possible in certain circumstances, for example, at the Pennington Biomedical Research Center, to implement a version of the Eminent Scholars model as an alternative to the UCSD model because PBRC has no students and does not confer degrees, yet needs to improve its ability to generate biotechnology commercialization opportunities for its research faculty. In the focus group discussions and in individual meetings with PBRC faculty, they welcomed an opportunity to vie for membership in a program similar to the GRA Eminent Scholars program.

Overall, a more comprehensive model might include a combination of the UCSD integrated life sciences curriculum program, the NIH CTSA program and the GRA Eminent Scholars program. A parallel program involving both senior researchers and life sciences students, including graduate, medical, doctoral, and postdoctoral students, could produce a more immediate impact from the researcher level and a longer-term sustainable impact from the education and training levels. The combination of these programs might even result in synergistic overall commercialization successes beyond what has been observed in any one model alone, including that at UCSD.

Component 5: Integrated Commercialization Track:

a) Funding:

Despite its very successful, well-planned, statewide, comprehensive program in place, the problem of commercializing early-stage bioscience inventions and discoveries still appeared in Georgia. Since it was recognized as such a critical issue, three of Georgia's research universities decided to create a small seed fund on their own and not wait for the state to intercede. Emory University, Georgia Institute of Technology, and the University of Georgia developed a $5 million fund called Georgia Venture Partners (GVP) by combining $1 million from each of the academic institutions with $2 million from private investors. The GVP is a professionally managed seed fund at arms-length from the universities and the GRA (GVP, 2007).

The fund has two principle functions, 1) to generate substantial investment returns, primarily through capital gains, by investing in a portfolio of companies; and 2) to increase the economic development of life sciences in Georgia through seed or early-stage investments in life sciences start-up companies based around academic inventions and discoveries. GVP initially invests between $100,000 and $200,000 in a single company, with a maximum investment capped at $1 million dollars for that company. The fund just recently began investing in new technologies (GVP, 2007).

A different scenario was in place at PBRC. The majority of PBRC's inventions and discoveries are very early-stage and often require further development prior to outside investment interest. The initial step taken to correct this problem at PBRC was to create an early-stage seed fund to provide the necessary capital for inventors to further develop their nascent technologies. A $12 million dollar seed fund, Themelios Venture Partners (TVP), an arms-length venture fund, was formed to support in PBRC inventions and discoveries and also

allow a small percentage of investments in outside companies which would partner with PBRC on specific commercialization projects (PBRC internal documents, 2007; TVP, 2007).

The overall structure of TVP is similar to that of the Georgia Venture Partners. In PBRC's case, the seed fund was created first and the commercialization platform is being developed after TVP, while, in Georgia, the commercialization platform was created first, followed by the seed fund. Even though TVP has already invested in several PBRC technologies, it has turned down the majority of the technologies it has reviewed, claiming that the discoveries are too early for it to consider. As a result, PBRC has found itself facing the same funding gap described by Friedl (2006), Kouri (2006), and Nowak (2006), even after the formation of TVP. PBRC and PBRF are now exploring additional funding mechanisms such as some adaptation of GRA's VentureLab fund and a corporate sponsorship to help with further development of its nascent technologies.

A third situation exists in North Carolina. Other than the Kauffman Foundation and matching UNC funding which comprise the bases for the Carolina Entrepreneurial Initiative, there is no specifically designated university-based fund to springboard early-stage academic technologies for commercialization as a direct part of the UNC MBA entrepreneurial program. If a technology wins the Carolina Challenge, the winners receive a $25,000 prize to further develop the technology. Some statewide funding is available through other organizations, but there has been a reassessment of those sources recently (Kouri, 2006; NCBIF, 2007).

The first fund discussed was the Eno River Capital and the second was the North Carolina Bioscience Investment Fund (NCBIF). The Eno River Capital fund, which was created in 1998 to commercialize life science technologies developed in North Carolina's public academic universities through the formation and development of locally-based start-up

companies, has been under close review recently. The fund was initially charged with creating new, high-paying, high-skill jobs and attracting new capital from later stage investment firms. The core expertise of Eno River Capital is in technology commercialization, with a major focus on transforming discoveries into products or services and turning a profit. Areas of expertise are described as deal-structuring and intellectual property licensing along with operational experience in the areas of information technology and the life sciences. Consulting services are also provided (Eno River Capital, 2007).

Until recently, Eno River Capital has managed the $26 million North Carolina Bioscience Investment Fund (NCBIF), which is a seed-stage venture capital fund for life science inventions and discoveries. In June, 2007, it was reported that NCBIF's $10 million dollar investment in the Eno River Fund had a net worth of approximately $1.3 million. Of the 10 companies the Eno fund has invested in, eight have been sold or are out of business. NCBIF's new director admitted that the Eno River Fund has not performed well, although he points out other investments in new companies that did result in new jobs (NCBIF, 2007). At the present time, NCBIF receives approximately $12 million in annual funding from the state of North Carolina (Weisbecker & John, 2007 , 2007).

The $1.5 billion NCR campus, a collaboration of seven universities, the State of North Carolina and Dole Foods owner, David H. Murdock, is just beginning its development (Fischer, 2007). Such an enormous statewide research and development initiative could have a major impact on economic development for the entire state of North Carolina.

The three models are not alone in facing investment difficulties. Even with its overall success, the UCSD model also recognizes some challenges to its commercialization pathway. Edward Holmes (2006) points out that there are at least two gaps in the road to clinical

translation, 1) between discovery and development (Post-NIH and pre-commercialization) and 2) between R&D and clinical evaluation (FDA Phase 1-2 and Phase 3). Holmes acknowledges that funding for the gap between discovery and development or the valley of death as described by Friedl (2006), Kouri (2006) and Nowak (2006), is typically not available in the UCSD university setting.

All three models studied as well as and the UCSD model, appear to indicate that a funding source is crucial, but not enough by itself, to ensure commercialization success. This component appears to be closely linked with the need for available R&D expertise. The PBRC situation clearly reflects this need, while the GRA model indicates that the R&D expertise without the funding is also not enough for commercialization success.

b) R&D Expertise:

Different situations in terms of R&D expertise exist at each of the three models studied. In Georgia, the state was not flush with R&D experts when the GRA program was introduced in 1990, and acknowledging that lack, GRA integrated a planned mechanism for access to R&D experts as part of its VentureLab program. In addition, the GRA program recruits expert researchers who are R&D experts for its Eminent Scholars program. As a result, the GRA has proven to be a successful combination of outside expertise and internally-grown R&D experts (GRA, 2007).

The GRA VentureLab program contains fellows and commercialization catalysts which have much in common with the local R&D experts in the Research Triangle area of North Carolina, with one major difference. The GRA VentureLab program requires that the fellows and commercialization catalysts be employed by the specific research university where they are

working. The UNC MBA entrepreneurial program's affiliation with its local experts is informal and voluntary (GRA VentureLab, 2007; UNC MBA, 2007).

The model with the highest number of inherent R&D experts is the UNC MBA curriculum program which resides within the North Carolina Research Triangle. A significant number of highly-skilled biotechnology experts are available locally to help develop new biotechnologies. Since this part of North Carolina has been home to a major pharmaceutical company (Glaxo Smith Kline) in addition to being the center of bioscience activity for several decades, there are signification numbers of local R&D experts who are willing and able to participate in biotechnology commercialization activities (Kouri, 2006; Milken, 2004; 2006).

Such a concentration of experts can prove to be highly valuable to biotechnology start-ups and inventors in the region. Since the biotechnology field is such a highly specialized one, experts are difficult to find in many geographic areas. Having such a high concentration of local experts in many areas of biotechnology, including senior management, developmental science, bio-business, and others, is unusual and very valuable to the UNC MBA program and the participants in the Carolina Challenge.

Despite this atypical collection of R&D experts, there is a limited amount of success in terms of commercialization of early-stage technologies at UNC and overall in the state of North Carolina. This limited success might indicate that there is a need for a combination of components in order to ensure commercialization success, as pointed out by Dr. Kouri in his AUTM presentation (2006). The new $1.5 billion North Carolina Research Campus initiative which involves seven North Carolina research universities could be the catalyst for commercialization success (Fischer, 2007).

In a related R&D issue, the San Diego area was identified as an area that is finding it difficult to retain some of its specialty-trained biotechnology workforce (Milken, 2004; 2006). In particular, those individuals at the mid-level and support levels of the workforce are finding it difficult to remain in the area due to the extraordinary high cost of living in the region and also in the Boston area (Coombs, 2007). Although this is a newly recognized issue, the need for such a skilled workforce is important to the overall success of a biotechnology economy.

The state of North Carolina has implemented a program through its community colleges to train these individuals for workforce deployment. Expanding this community college program is a major area of focus in the North Carolina Research Campus. Rowan-Cabarrus Community College has initiated a specialized biotechnology program to train students to become laboratory technicians, and biomanufacturing workers (Fischer, 2007). This focus, in conjunction with the UNC MBA entrepreneurial program, may provide a significant cadre of regionally grown biotechnology employees necessary for growing this specific biotechnology component for economic development in the state.

The need for a support biotechnology type of workforce was also recognized at the Louisiana BOR focus group meeting in April, 2007 (BOR, 2007). Recognizing the lack of R&D experts to assist in the further development of early-stage technologies, PBRC and PBRF key individuals along with PBRC faculty, expressed the need to be able to access such outside expertise. Faculty suggested some form of mentoring or coaching as a possible solution to help develop early-stage technologies. The GRA VentureLab model was suggested as one which could be implemented.

PBRC faculty and key individuals also recognized the importance of recruiting senior scientific experts to PBRC who have expertise in or who want to focus on commercialization.

The key individuals are exploring using some form of the Eminent Scholars program as a model. The Louisiana Board of Regents, the Louisiana Recovery Authority, and the Baton Rouge Area Foundation also found many aspects of the GRA model, including the Eminent Scholars program, as a model that might be adapted for the state of Louisiana (BOR, 2007). In that case, PBRC could benefit from such a statewide academic recruiting initiative.

c) Springboard for New Companies:

Of the three models studied, the most comprehensive and overall successful springboard for new companies is the GRA model, which has launched more than 125 new companies since its inception in 1990. More than 5,000 new jobs have been created as a result, and more than $600 million in private investments in these new companies has occurred. The program has also fueled partnerships with more than 100 Georgia companies. The combination of a narrow focus along with well-developed, strategically integrated phases of commercialization funding and R&D expertise all play into a successful springboard for new companies (GRA, 2007).

The successful VentureLab program contains specific requirements which are paramount to R&D activities. These requirements include the further development of the technology, design and implementation of a business plan and coordination of the Eminent Scholars' funding sources, which led to the formation of solid new start-up companies. This series of phases provides progressive steps in an overall process geared toward commercialization success (GRA VentureLab, 2007).

Once again, this is not the entire story, because an early-stage funding gap still emerged in Georgia, despite the success of the GRA VentureLab program and other economic plans for new company development. As a result, three of the six GRA research universities combined with private partners to create a special early-stage biotechnology funding source called the

Georgia Venture Partners Fund (GVP). The GVP has helped to bridge the gap between nascent biotechnologies and the next stage of commercialization (GVP, 2007).

In contrast, PBRC has had mixed results related to creating a springboard for new companies. On one hand, the TVP venture fund has been very supportive in the formation of new companies for the few technologies it has invested in, but TVP has declined to invest in the majority of PBRC technologies it has reviewed. TVP cites the early-stage nature of the inventions as its reason to decline investment. Currently, PBRC and PBRF are analyzing what multi-tiered commercialization programs it might adapt to further develop PBRC discoveries. Focus is on developing local R&D expertise, creating a VentureLab-type program, and recruiting expert faculty who commercialize.

It appears that the state of North Carolina also has had mixed results in providing a springboard for new companies. Even with its cache of locally highly-skilled R&D experts, the success of new company start-ups in North Carolina has been inconsistent. Although the state established the North Carolina Bioscience Investment Fund (NCBIF) several years ago, its main funding source remains the state, although some new high-skilled, high-paying jobs have been created since its inception. As recently as late June, 2007, the NCBIF was undergoing restructuring efforts while the ties between NCBIF and the Eno River Capital fund were under review (NCBIF, 2007).

Yet the North Carolina climate may change very soon with the $1.5 billion bioscience research and development program involving major research universities, the State, and Dole Foods owner David Murdock (Fischer, 2007).

The UCSD model is ranked number one by the Milken Report (2004, 2006) in terms of new start-up companies created and still in existence. Even so, there is a growing concern over

the high cost of living in the San Diego area, which is of concern when new start-up companies are trying to recruit new Ph.D.'s, support scientists, and management teams (Coombs, 2007; Milken, 2004).

This section has shown that the three models are often different from each other as well as from the UCSD model. As a result, a revised version of the comparison chart is presented below (Table 4). In almost every category, there are some changes in the assessments as to whether or not a component is present or absent. As described in this chapter, a simple yes or no answer often is not an accurate reflection of the presence or absence of specific components. Sometimes, pieces of a component exist, or a hybrid situation occurs. This broader interpretation of the five essential components could assist academic research institutions in determining what is necessary for commercialization success at their particular institution.

Table 4. Post Study Comparison Chart for Academic Biotechnology Commercialization – 5 Key Components

KEY COMPONENTS	**UCSD Best Practice**	**UNC Model**	**PBRC Model**	**GRA Model**
Small Size of Institution	Y	H	Y	H
Higher than Norm for Research Money per Biosciences Faculty	Y	NA	Y	Y/N
Extremely Entrepreneurial Community	Y	Y	H	Y
Integrated Life Sciences Curriculum Program	Y School of Medicine and Graduate School Program (COILS)	N	N	H
Integrated Commercialization Track				
➢ Funding	Y	N	Y	Y
➢ R & D Expertise	Y	Y	N	Y
➢ Springboard for New Companies	Y	P	TBD	Y

Y = yes
N = no
NA = not applicable
TBD = to be determined
H = Hybrid
P = Partial
UCSD = University of California - San Diego
UNC = University of North Carolina at Chapel Hill
PBRC = Pennington Biomedical Research Center
GRA = Georgia Research Alliance

Part 4

Additional Key Components Considered Essential for Commercialization Success

The commercialization models analyzed in this study exist in various geographic locations, have organizational structures different from each other, include only some of the key components of the USCD model, and often exhibit those key components in new, partial or hybrid ways. In addition, the models studied contain additional significant characteristics that appear to be very important in terms of commercialization success. Extensive interviews with PBRC faculty were conducted and the issues discussed were germane to this study. Significant parts of these discussions have become part of the additional key components. Due to the significance of these interviews, the eight topics that were discussed are contained below.

FACULTY ROLES AND EXPERIENCES

In individual and group meetings with PBRC researchers, these inventors voiced their frustrations with the difficulties for moving their technologies forward along the commercialization continuum. Of the nine researchers taking part in individual and focus group meetings, the majority of them have had experience with venture capitalists, start-up companies, and the biotechnology industry in the past. Several of them have issued patents and all of them have been listed as inventors on patent applications. Some are or have been equity owners in biotechnology start-up companies, and all have been hired at various times as consultants to the biotechnology industry (PBRC internal documents, 2007).

Even with their familiarity with biotechnology investment funds, start-up companies, and the overall industry, all of the faculty interviewed recognize they are not expert investors and do not wish to take on that role themselves. But, because the majority of them have had some experience with the commercialization end of the biotech industry and three of them have held

positions for extended periods of time within the industry, their observations and analyses are based on actual experience. At the present time, their chosen areas of interest and expertise lie within the realms of academic biomedical research, but they include commercialization as part of their interests. In this sense, these researchers are similar to GRA Eminent Scholars.

At this time, all of these researchers believe that a better way can be developed in which their technologies can move forward more successfully. They have been encouraged to relay their concerns and thoughts on how to improve the PBRC commercialization process. As a result, several one-on-one meetings and discussions and focus group meetings have been conducted over several months. The PBRC administration and key individuals in the Foundation believe that the faculty, especially those researchers who are inventors, can contribute significantly to the entire process of developing a better model of commercialization at PBRC (PBRC internal documents, 2007; PBRF internal documents, 2007).

In the course of the interviews and focus group meetings, the PBRC researchers revealed the following concerns and provided suggestions they thought might be implemented in order to overcome the commercialization obstacles they have experienced. Here are the following eight suggestions and concerns that the researchers discussed with PBRC and PBRF administrators:

1) More feedback from venture capitalists (VCs) on the status of technologies after they have been reviewed by the venture capitalists;
2) R&D mentor/coaches to help guide further development of technologies;
3) Seed funds for continued early stage development of technologies;
4) Later-stage funds for further R&D work, pre-clinical studies, and federal regulatory requirements;
5) Wider selection of patent counsel with expertise in specialized/niche areas;

6) Increased freedom for faculty to operate in start-up activities and the ongoing commercialization process;
7) Business development/interface to promote networking between scientific endeavors and commercialization; and
8) Establishment of special high dollar research commercialization faculty chairs.

Each of the eight items above will be discussed below in terms of how the researchers perceive them as well as how they might be addressed in a new PBRC commercialization model.

1) Feedback from Venture Capitalists:

The majority of the faculty members interviewed had been told, at one time or another, by the various Louisiana-based venture funds (TVP, Louisiana Fund 1 and others), that their technologies needed further developmental work before they would be ready for those investment funds to consider. Even so, the inventors had not received feedback from the VCs regarding why their technologies were not funded nor what specific steps they should take in order to be reconsidered for future funding. Even after the inventors asked for feedback on several occasions from the VCs and the VCs agreed to do so, the VCs did not provide any written or oral feedback to the inventors.

Although this lack of feedback appears to be the norm for venture capitalists, it is a new type of interaction for researchers. Academic researchers who compete for grant funding are accustomed to receiving detailed written feedback from their unfunded grant applications. Often, these critiques, written by experts in the same specific scientific field of the application, are the cornerstone by which the researchers are able to adjust their scope of work, rewrite their research studies, resubmit their applications and often, successfully gain funding.

As discussed in Chapter 1, resubmission of grant applications is a common occurrence, and researchers acknowledge this as a part of the funding process (Couzin & Miller, 2007). Given the extremely high success rate PBRC scientists achieve through resubmission, these researchers quite possibly would be able to produce an equivalent high rate of success in commercialization given feedback. PBRC researchers have an exceptionally high re-submission success rate at NIH, approximately 80% (PBRC internal documents, 2007).

In addition, researchers also receive written comments for peer-reviewed manuscript submissions, and as part of the process, address these comments by writing additional sections or adjusting the focus of their submissions in order to gain approval for publication. These processes are standard in grant and manuscript review in biomedical research areas (NIH, 2007; PBRC internal documents, 2007).

Therefore, academic inventors not only respond to feedback, they expect it in order to make adjustments to the scope of work they have proposed or the manuscripts they prepare to publish. Every one of the PBRC inventors discussed the interactions they had experienced with the VCs. They had expected and welcomed some type of feedback from the investors and the opportunity to adjust their work, perform additional studies or other research, and then be able to meet with the investors at a subsequent time, with technologies which were further developed.

As the researchers discussed this issue in the focus group meetings, they all felt confident that, if they had received feedback from the VCs, they would have been able to address the concerns, do additional work in order to move their technologies along, and increase the probability that their technologies could be funded. This belief was held by all of the inventors regardless of which venture fund investors they had met with in the past. It is important to note again that several of the researchers being interviewed had past experience with VCs, both in

academia and also in industry. So, the group as a whole had been involved, at least at some level, with some of them having had a very intimate and long-term involvement with VCs and others in the biotechnology industry.

2) R&D Mentor/Coaches to Help Guide Further Development of Technologies:

During the focus group meetings and also in individual interviews, faculty suggested that they could benefit from having a mentor or coach, or some other form of customized guidance in place to aid the process of technology commercialization. Even though the valley of death or funding gap has been previously described (Friedl, 2006; Kouri, 2006; Nowak, 2006). It is important to note here that this gap encompasses a range of activities necessary to technology transfer, and the steps and time needed to further develop the invention or discovery will vary from technology to technology.

Very often, the next steps needed in the development process are most appropriately conducted by the inventor with some guidance or advice from an individual or team of individuals who can be described as research and development experts. These scientists typically have backgrounds in industry in addition to working as bench scientists or clinicians. Often, these positions are not part of academic research institutions, and so inventors from universities have little or no contact with this type of scientist in an academic setting. The PBRC researchers find themselves in a similar position. Both of the other models studied (GRA and UNC) have such experts available. For example, to aid in overcoming this roadblock, the GRA has established the VentureLab program and UNC has included access to this type of regionally-based biotechnology R&D experts in its Carolina Challenge program (GRA VentureLab, 2007; Kouri, 2006; UNC MBA, 2007).

A suggestion was made that there could be a team of two or three research and development experts who would review a specific technology, make written suggestions to the inventors, and act as guides or mentors to the inventors as they carried out the suggested next steps in research development. This suggestion was received positively by the faculty in the focus groups as well as in individual meetings with researchers. The faculty felt quite confident that, within such a model, they would be able to further their technologies, and add value, resulting in a product, method, or treatment which would have a higher chance of being funded by early-stage VCs.

Another suggestion was made by a faculty member that a consultant could also serve as a mediator between the researchers and the venture capitalists while aiding in the scientific review process. This idea led to the realization that knowing the right path to take in terms of research and development was only one step that was needed, but the inventors would also need to secure seed funding to be able to carry out the R&D suggestions made by the commercialization review team. The PBRF consultant pointed out that the GRA VentureLab program contains a component that employs individuals called fellows and commercialization catalysts who have been strategically put in place to act in these capacities to mentor and coach and advise on commercialization.

3) Seed Funds for Continued Development of Technologies:

As suggested by the faculty and reinforced by the PBRF consultant, seed funding to further the research and development of their technologies was a vital next step in order to increase the chances that, eventually, the early-stage VCs would invest in the technologies that had been presented to them by faculty inventors. The consultant used the example of the Georgia Research Alliance, which provided these types of seed funding to academic researchers

with early-stage technologies. The GRA offers a seed or grant fund stage, followed by a three-phase innovation fund with funds of up to $50,000 in the first phase, $100,000 in the second phase, and a negotiable convertible loan to the start-up company in the final phase. The consultant also described the GVP fund, which makes awards of up to $250,000 for research and development of promising technologies (GRA, 2007; GRA VentureLab, 2007).

The faculty were encouraged that such a fund, coupled with written feedback and guidance from an R&D team, would go a long way in allowing continued research which would advance technologies along the commercialization continuum. The researchers also felt confident that such activities would fit into their faculty roles quite appropriately at PBRC and would not fragment their research activities nor require them to out-license their inventions at a discount and surrender control to an outside party at such an early stage of development. The faculty were encouraged by the plausibility of success for them to continue moving their technologies forward through this approach of coupling a team advisory group with seed funding.

4) Later-Stage Funds for Further R&D Work, Pre-Clinical Studies, and Federal Regulatory Requirements:

The researchers thought the seed fund described above would help when their research was very early in its development. The faculty also asked if there could be a second-stage type of fund available as well, which would be used as a later-stage, after the initial R&D work was completed. Once again, the PBRF consultant described the Georgia Research Alliance VentureLab program, which has the ability to fund both early and more advanced technologies (GRA VentureLab, 2007).

The group of faculty discussed the amount of money which might be appropriate for this type of fund, suggesting that a one-time amount between $50,000 and $100,000 would fit with

the scope of work anticipated at this stage of research development. This amount mirrors the GRA VentureLab Phase II funding range (GRA VentureLab, 2007).

The consultant had mentioned that there are specialty funds set up at a few academic institutions that offer special, fee-based memberships to leading corporations and other entities in industry in related scientific fields as a way to create opportunities for developing collaborative research and commercialization. The consultant suggested that development of a similar fund be considered by PBRC and PBRF.

5) Wider Selection of Patent Counsel with Expertise in Specialized/Niche Areas:

Several of the faculty members indicated that additional issues existed which impeded the technology transfer process. One such issue is related to the restrictions on what patent counsel could be hired by PBRC as part of the LSU System. Because of state restrictions, the LSU System only permits Louisiana law firms to represent its campuses for patent activities, and the list of approved law firms is very limited. Patent counsel can be very good, but the areas of expertise any one individual can have are limited. Therefore, even the most capable patent lawyer cannot be an expert in every area of bioscience (LSU System, 2007).

Since the focus of many biotechnology patent applications are very specialized, it is important that expert patent counsel be able to write the patent application since the claims in the application form the foundation of protection and define the commercialization monopoly. Some of the scientific areas of expertise for the PBRC scientists are very specialized and, at times, only select law firms in the entire country, specialize in that specific area of patent work.

Numerous researchers, especially those who had experience with more specialized outside patent counsel in the past, commented that not being able to contract with the most knowledgeable patent counsel might limit the range of patent protection which then could limit

the potential for commercialization markets. A related factor is that the LSU System will only allow approved outside patent counsel if a licensee or potential licensee will pay for the legal work. The faculty and administrators indicated that this factor could compromise negotiations for licensing the technologies and could lead to licensing at a discount just to secure out-of-state expert patent counsel. A proposed solution was to engage the Pennington Biomedical Research Foundation in the process of securing outside expert patent counsel, since it is not under the same constraints as PBRC.

Contracting with expert patent counsel is supported by several venture capitalists. Eric Nicolaides, a venture partner with Wildcat Venture Management, explains.

> A firm commitment – especially to patents from university administrators is a key element of wooing venture capital. Nicolaides says, "we understand patents are expensive, but [we] will walk away from a project that's revolutionary yet does not have exclusive IP…" Some schools, he adds, basically patent everything within reason, while others take a more limited approach. The latter will often say up front that if there's a patent renewal or patent filing coming up, they'll have to let it go because they don't have the money. That puts VCs in an understandably precarious position (Technology Transfer Tactics, p. 43).

6) <u>Increased Freedom for Faculty to Operate in Start-Up Activities and the Ongoing Commercialization Process:</u>

Several of the faculty members discussed whether or not universities should really have the responsibility of technology transfer, mentioning that some European universities give their faculty control over their inventions and discoveries. This IP transfer gives university researchers the individual freedom to operate in relation to their own technologies. In addition to the high costs for patent and other legal fees, it was acknowledged that many examples exist of researchers not being able to create and oversee a start-up company due to their lack of this specialized business expertise.

In response, the PBRF consultant described GRA's Georgia's Advanced Technology Development Center and the Eminent Scholars Program as possibilities for developing long-term returns on investment by maximizing inherent advantages, creating innovative partnerships, and recruiting new scholars who know how to or want to commercialize intellectual property (GRA, 2007). In such a structure, the faculty have more opportunities to participate in commercialization as part of their faculty roles.

Other suggestions made by the consultant described a cross-degree program between Emory University and the Georgia Institute of Technology as a way to facilitate collaborations and expand areas of scientific interest (GRA, 2007). The Georgia Research Revolving Fund was suggested as an example of a funding opportunity to assist with faculty recruiting. This loan program has been created by the state of Georgia in conjunction with federal programs and other organizations. One of the areas of focus is its small business resources, which includes financial opportunities and other support activities (Georgia Small Business Resources, 2007).

7) Business/Development Interface to Promote Networking between Scientific Endeavors and Commercialization:

A suggestion was made to set up a symposium and invite key business and industry leaders and promote available PBRC technologies. The consultant discussed that the Georgia Center for Entrepreneurial Development (2007) acts as a business interface between researchers and business and industry concerns in the state of Georgia. A similar program might be appropriate for the PBRC model. The particulars of the Georgia model were not discussed, but it was acknowledged that there would need to be adaptations to reflect both the different composition of industry within the state of Louisiana as well as reflect the scope of the biotechnology activities within PBRC and the state.

Importantly, the BOR/LRA study concludes that, unlike the state of Georgia, Louisiana is not home to Fortune 500 companies which can help to finance such an industry partnership program (BOR, 2007). Therefore, PBRC and PBRF will need to create a different model to implement locally.

Given the early-stage of the PBRC inventions and discoveries, the focus of a business development interface should be broader than just commercialization because very few PBRC technologies currently sit in a place ready to commercialize. Instead, the interface should be geared toward PBRC's overall expertise in scientific areas of interest to business and industry. In such a way, the value from interacting with PBRC researchers would span a wider range from scientific expert to technology inventor (PBRF internal documents, 2007).

The Foundation is considering the development of a consortium of business and industrial partners with participation based on an annual fee which would provide unique access to PBRC's scientific faculty and their areas of expertise, including ideas emanating from the researchers while providing the opportunity to consider development of collaborative research initiatives or the possibility to review existing technologies (PBRF internal documents, 2007).

8) Establishment of High Dollar Research Development Faculty Chairs:

Recruiting and retaining high-quality faculty was acknowledged as an ongoing issue. In addition, several faculty discussed the importance of recruiting researchers who are committed to and capable of creating technologies for biotechnology commercialization. As an example, the Georgia Research Alliance Eminent Scholars Program was discussed as a model where faculty are recruited based on their success or interest in commercialization. In addition, GRA grants are based on this commercialization focus and on cross-collaboration with other Eminent Scholars (GRA, 2007).

The PBRC faculty agreed that some version of the GRA Eminent Scholars Program might be appropriate for PBRC. As mentioned previously, this idea is also supported by the Baton Rouge Area Foundation and the Louisiana BOR and LRA. Of all the programs reviewed and discussed by the BOR, LRA and BRAF, the Eminent Scholars program is one that all parties believe could be adapted most easily for the researches in the state of Louisiana (BOR 2007).

ADDITIONAL COMPONENTS

Since these additional components have been instrumental in the success of the commercialization processes for the three particular models studied, they are included here as possible new key components to consider when another university is looking to develop a plan for commercialization success.

1) Create a Structured, Highly Focused Funding Gap Program which Includes Outcomes Measures and a Formal Evaluation Process:

In addition to the GRA program focusing on a limited number of goals and a small pool of researchers, the GRA VentureLab program has other specific requirements in place which have augmented its success. In order for each of the six GRA research universities to receive seed grant funding for their specific VentureLab programs, the universities must submit a detailed application of how the funds will be spend and what outcomes will be measured as benchmarks for success (GRA VentureLab, 2007). These documents serve as a baseline for annual evaluation of the project in terms of progress. Tying goals to measured outcomes is one way to ensure that the program remains focused and the goals met. Since the biotechnology field is so fluid and the needs of new companies change along with the marketplace, it is important to develop a tie-in between the funding of technology development and the ongoing evaluation of the project.

The GRA has shown that by narrowly focusing the commercialization components in its model, a strong core program can be developed. In the case of the GRA, this focus is based on recruiting the best in biosciences through its Eminent Scholars and their related innovations and discoveries, not on transforming the broader business culture of each university. Given that there has been such a high rate of success in the GRA program, this limited focus has proven to be of importance. There seems to be a synergistic effect between the success of each individual scholar and the GRA program as a whole, much of which is attributed to the narrow focus of the program itself and its outcome-directed financial incentives (GRA Report, 2006). This Georgia strategic investment is focused around four programs at the six leading research universities in the state: eminent scholars, research laboratories and equipment, national centers for research and innovation, and the overall technology transfer process.

In North Carolina, the state is reevaluating the role of the North Carolina Bioscience Investment Fund. By its own admission, the fund has not remained focused on its original economic development goals (Weisbecker & John, 2007, 2007).

2) Building a Critical Mass of Bioscience Researchers Focused on Commercialization:

Building a critical mass of translational researchers with a commitment to biotechnology commercialization is a key component in the Georgia model. The Georgia Research Alliance program has been very successful with its Eminent Scholars Program, which is a highly focused, specialized recruiting and funding program aimed entirely at bringing the best bioscience researchers to Georgia specifically for discovery and commercialization activities. Since its inception in 1990, the GRA program has recruited and funded more than 50 Eminent Scholars, been integral in securing more than $2 billion dollars in new federal research funding and private

investments and creating more than 125 new companies and more than 5,000 new high-skill, high-paying jobs within the state of Georgia (GRA, 2007; GRA Report, 2006).

The GRA awards its Eminent Scholars with Innovation Funds to pursue bioscience projects geared toward commercialization if these scholars collaborate with already-existing Georgia companies. The GRA also offers Challenge Grants if the Eminent Scholars work in collaboration with at least one other Eminent Scholar, and VentureLab funds for commercialization activities geared to further develop early-seed inventions and discoveries. All of these funds are important in and of themselves, but the GRA has gone a step further by focusing the awards to a very small pool of Eminent Scholars, with results (GRA, 2007).

Many recognize that Georgia's bioscience recruiting and funding approach is one they would like to adapt for their own institutions or states. The Pennington Biomedical Research Center administrators, the inventor faculty, and the Pennington Foundation key individuals suggested that such a program be initiated at PBRC, while the Louisiana Board of Regents, the Louisiana Recover Authority, and the Baton Rouge Area Foundation have also voiced interest in the GRA model and the Eminent Scholars Program in particular, to boost the research capabilities for the academic bioscience researchers in the state of Louisiana (BOR, 2007).

The UNC MBA curriculum program has taken a different path which has some of the same characteristics of the GRA model. At UNC, there is a requirement for faculty inventors who wish to remain involved in the management of their technology to attend the MBA entrepreneurship classes and participate in the Carolina Challenge program. The philosophy behind this approach is that science, especially academic-based science, is very different from biotechnology commercialization, and the faculty do not have expertise in nor knowledge of these areas. By requiring participation in aspects of the MBA entrepreneurship program and the

Carolina Challenge, the role of faculty is automatically focused on to the basic components needed for development of the technology and creation of a new start-up company (Kouri, 2006; UNC MBA, 2007).

No matter how it is accomplished, developing a critical mass of bioscience researchers focused on commercialization appears to be important for commercialization success.

3) Creating Specialized Workforce Development Programs:

The UCSD model contains an integrated life sciences curriculum program to train doctors and scientists in translational research (Holmes, 2006). Such programs have become a very high priority at the NIH, with its new, 60 site, $700 million dollar program called the Clinical Translational Science Awards program (CTSAs). The CTSA program includes funding for educating and training translational researchers in the country's academic medical centers, both public and private. One of the goals of the CTSA project is to increase the successful commercialization of academic-generated inventions, technologies, and treatments more rapidly, comprehensively, and efficiently into the patient population (NIH, 2007).

But training physicians and scientists is not enough to build a successful biotechnology environment. Other highly-skilled workers are also needed as part of the overall economic development plan. The University of North Carolina at Chapel Hill MBA Entrepreneurial program is geared toward educating and training graduate business school students in the specifics of technology commercialization professions such as finance, accounting, business law, economics, and management (Kouri, 2006; UNC MBA, 2007). Some technologies that become part of the MBA students' Carolina Challenge projects are biotechnology-based, thus providing the students with experience in the biotechnology commercialization industry.

One of the ongoing and growing difficulties noted in the Milken Reports (2004; 2006), is that ancillary biotechnology professionals are difficult to find, require specialized training, and find it challenging to afford being gainfully employed in a high cost-of-living geographic area, such as San Diego or Boston (Coombs, 2007).

To address this difficulty, the state of North Carolina has initiated a biotechnology curriculum program which functions as part of its community college system. This program has been developed specifically to train individuals who are needed in support staff roles in biotechnology, including those who receive certificate and associate degrees. Certain specific training areas are targeted, such as those for expanding and new industries, with programs of study running in parallel to the technology support needs of the state (North Carolina Community College System, 2007).

It has been discussed earlier in this study that there is a push for many research institutions, regardless of their geographic location, increase their ability to commercialize academic-based biotechnology inventions and discoveries, create new jobs and new companies, and contribute more directly to their region and state in terms of economic impact. If these commercialization programs are located at research universities in various geographic areas, they will need to have some mechanism to train and employ these specialized high-skilled workers locally, both at the professional and graduate school level and at the undergraduate and associate degree level. Such a program could diminish the impact many sates and regions are suffering related to the out-migration of their most highly-trained young professionals. The new $1 billion North Carolina project is just such an example. Located 30 miles northeast of Charlotte, in Kannapolis, this new large-scale economic development project is poised to replace a closed

textile manufacturing plant (Fischer, 2007). Part of this initiative includes a community college education program to train individuals for jobs in the biotechnology field.

The state of North Carolina has implemented a program through its community colleges to train these individuals for workforce deployment. Expanding this community college program is a major area of focus in the North Carolina Research Campus. Rowan-Cabarrus Community College has initiated a specialized biotechnology program to train students to become laboratory technicians, and biomanufacturing workers (Fischer, 2007). This focus, in conjunction with the UNC MBA entrepreneurial program, may provide a significant cadre of regionally grown biotechnology employees necessary for growing this specific biotechnology component for economic development in the state.

There may be an advantage to training and retaining these workers in geographic areas where the cost-of-living is more moderate. Since the number of such highly-skilled workers available locally or regionally is small, implementing locally-based education and training programs could be very beneficial. If these programs are located in the same higher education institutions or at collaborating institutions in the area, this could also reduce the problem of brain drain, where the best and the brightest highly-skilled graduates from an institution leave the area or the state. Such education and training programs could be an important component to the success of a region's or state's academic-based biotechnology industry while keeping its highly-skilled workforce in the area (BOR, 2007).

4) Creating Cross-Collaborations to Promote New Areas of Discovery:

The GRA program's focus on expanding bioscience research through cross-collaboration among its Eminent Scholars has yielded successful new ventures which would not have been developed otherwise (GRA, 2007). The GRA Eminent Scholar Challenge Grants have been

created to promote cross-collaboration. This challenge grant program is designed specifically for the Eminent Scholars. Annual awards of up to $50,000 are given to a team of at least two Eminent Scholars to promote scientific collaboration. The scope of work is judged on technical merit and the potential for future commercial success as well as on other funds the scholars have in place to support the project for which Challenge Grant funding is sought (GRA, 2007).

Researchers are trained to focus on a narrow research area or research silo, which the NIH has acknowledged (NIH, 2007). But such a narrow approach has resulted in very few successful outcomes related to translational research. The need to remedy the situation has led the NIH to initiate a new $700 million Clinical Translational Science Award program (NIH, 2007).

The need to correct this problem has also been recognized at UCSD, which has established an integrated life science curriculum program, which focuses on developing and training life science students in a multidisciplinary fashion. Yet, the time line to create a new generation of translational researchers is long. On the other hand, a program that redirects the focus of already-established scientists could have more immediate impact. For example, the GRA Eminent Scholars program provides research funds to its scholars who collaborate with another eminent scholar, a program which has been very successful. Combining a student curriculum with a research collaboration mechanism could promote near-term (research level) and long-term translational science and discoveries.

5) Developing Faculty Incentives and Rewards for Commercialization:

Faculty rewards and incentives can play an integral role in promoting cross collaboration, increasing translational activities, fueling new inventions and discoveries, and providing the foundation for new start-up companies.

Traditional promotion and tenure criteria do not include these activities, but a shift in direction is beginning. Texas A&M announced in 2006 that it would include commercialization activities in its consideration for faculty promotion and tenure (Lipka, 2007). The GRA program provides specific research funding for projects focused on commercialization and its Eminent Scholars program recruits bioscience experts for faculty positions whose research programs focus on commercialization (GRA, 2007). The President of the UNC System, Erskine Bowles, recently has announced that economic transformation will now be part of the mission of the university, which further strengthens the support for commercialization as an integral part of university activities (Fischer, 2007). The ten component comparison chart (Table 5) reflects the original five components and the five new components considered important to commercialize early-stage inventions and discoveries.

Table 5.
New Comparison Chart for Academic Biotechnology Commercialization – 10 Key Components

KEY COMPONENTS	**UCSD Best Practice**	**UNC Model**	**PBRC Model**	**GRA Model**
Small Size of Institution	Y	N	Y	N
Higher than Norm for Research Money per Biosciences Faculty	Y	N	Y	Y
Extremely Entrepreneurial Community	Y	Y	N	Y
Integrated Life Sciences Curriculum Program	Y School of Medicine and Graduate School Program (COILS)	N	N	N
Integrated Commercialization Track ➢ Funding ➢ R & D Expertise ➢ Springboard for New Companies	 Y Y Y	 N Y Y	 Y N TBD	 Y Y Y
Structured, highly focused commercialization program with measured outcomes		N	P	Y
Critical mass of bioscience researchers Focused on commercialization		N	P	Y
Work force development program		Y	N	N
Cross-collaboration programs		TBD	N	Y
Faculty incentives and rewards for commercialization		TBD	N	Y

Y = yes
N = no
TBD = to be determined
P = partial
UCSD = University of California - San Diego
UNC = University of North Carolina at Chapel Hill
PBRC = Pennington Biomedical Research Center
GRA = Georgia Research Alliance

Part 5

Unintended Consequences within the Commercialization Mechanisms and Solutions to These Problems

Much discussion has revolved around whether or not biotechnology commercialization should be pursued by higher education, and whether or not it fits into the mission of the academic research institution. Proponents on both sides believe that their stance is correct, yet commercialization activities still continue whether there is new momentum to increase this economic development. At the federal level, there is the commercialization mandate created by the Bayh-Dole Act (Washburn, 2005) and related federal technology transfer regulations, the SBIR/STTR technology transfer grant program, (NIH, 2007) and much more recently, the NIH CTSA initiative (NIH, 2007). At the state and local levels, incentives and encouragement also point to the fact that there is governmental belief that such economic development activities should not only continue, but also increase.

Over the years, academic research institutions have increased their commitment to commercialization with the development of technology transfer/licensing offices, participation in research parks and technology incubators, and partnerships with various entities and organizations to increase commercialization activities surrounding the biotechnology enterprise (AUTM, 2006). Public universities are taking equity ownership in start-up companies and ensuring their state legislatures that they can contribute to the ongoing successful economic impact of their regions and states (Fischer, 2006; 2007).

All these activities are occurring in parallel with other commitments and obligations. Public institutions, including public universities, have duties to provide for the public good, create social benefits, and, in the case of academic health centers, to improve the public health. At the same time, public research universities also have as their core missions the duty to teach

and also participate in community involvement. All of these activities and expectations already exist at public research universities, and therefore, the most plausible next step is to create ways to balance between these competing initiatives and responsibilities.

One of the main goals of this study was to explore the possibility of finding a hybrid solution for the myriad of unintended consequences related to academic biotechnology commercialization. Such a solution would allow for the commercialization of academic-based biotechnologies to stand alongside the traditional roles played by public research universities. Yet, it was acknowledged that there have been concerns over some of the commercialization relationships and activities entered into by public universities in recent years. Some believe that industry and business-driven activities should remain in the marketplace, not at the doorstep of academia.

Concerns were raised and discussed in Chapters 1 and 2 regarding the idea that some technologies are not ready or may never be appropriate for commercialization. If some technologies are not appropriate to commercialize, universities need better mechanisms to determine this. One solution is to implement a type of GRA VentureLab program which contains a technology assessment component (GRA VentureLab, 2007). With a better initial analysis process, non-rival goods or technologies could be appropriately disseminated for the greater good instead of being held indefinitely without being commercialized or released. Other concerns regarding unintended consequences are often focused around faculty roles and university involvement in start-up companies, which are discussed in more detail below.

FACULTY ROLES

Since the majority of academic-based inventions and discoveries are created by faculty, the concern over issues related to faculty roles is very important to biotechnology

commercialization. Chief among the issues surrounding faculty roles are the following: 1) faculty activities that raise conflicts of interest, and 2) time off from other faculty duties to pursue commercialization activities.

1) faculty activities that raise conflicts of interest

Some argue that allowing faculty equity ownership in new start-up companies can be a perceived or real financial conflict of interest in regard to the research that is being commercialized. Historically there has been support for this point of view due in part to the situation that the University of California had with regard to its plant biology program in conjunction with Novartis Pharmaceuticals (Blumenstyk, 2003a; Nadis, 2000; Nature, 2001), the relationship of the University of Toronto with a biotechnology company regarding clinical research data (Olivieri, 2003), and other similar situations described in Chapters 1 and 2 of this study.

As a result, some public universities have already developed mechanisms to address the perceived or real conflicts of interest that can arise with faculty equity ownership. The LSU System has enacted a reporting mechanism that involves the documentation and reporting of faculty or university employee ownership in a company doing business with the University. In addition to these disclosures, there is a requirement for removing that individual from the negotiating process with the company and, more restrictive, in relation to research, there are mechanisms to limit or remove that individual from the overall research process for any university activities conducted with that company (LSU System, 2007).

Some other public universities, such as the University of Texas, have developed an internal process to address perceived and real conflicts of interest as part of its larger compliance

and oversight requirements (University of Texas, 2007). Many academic institutions offer release time to their faculty to pursue technology development.

A different approach has been taken by the Georgia Research Alliance, which has developed its Eminent Scholars Program around the requirements of biotechnology commercialization activities with the goal of generating new start-up companies and allowing these Eminent Scholars to participate in the scientific and managerial oversight in a very direct fashion. These Eminent Scholar faculty have been recruited specifically with the intentions of having them lead the state in research and development in the biosciences. The overall mission of the GRA is to grow biotechnology research and commercialization activities and create new start-up companies for its six top research universities and the state of Georgia.

Since this is the mission of the GRA and not directly that of the six participating research universities, there is an arms-length relationship already in place between the parties. This arms-length structure may be one way of ensuring that both commercialization and traditional academic missions can coexist while decreasing the perceived or real conflicts of interest. Also, the GRA focuses only on the top six research universities in the state, not on every higher education institution. By doing so, it is only providing its comprehensive program to those higher education institutions which have already been classified as research universities.

2) time off from other faculty duties to pursue commercialization activities

The federal government has also contributed to the expectation that there should be the ability for faculty to participate directly in a significant way in the development of new or small biotechnology companies. The United States Small Business Administration's SBIR and STTR technology transfer grant awards for commercialization have been in existence for several years in more than 10 different federal agencies including the NIH (NIH, 2007). In these programs,

not only are faculty allowed to become directly involved in a new company or in small business R&D programs, in the STTR program, there is a direct mechanism for faculty to do so while remaining employed as faculty at their research universities. The federal sponsors have encouraged this program as an incentive for start-up companies and as a way to promote the proliferation of small business growth in the United States (NIH, 2007). The federal government expects that the players will manage the inherent conflicts of interest related to the roles faculty play as both university and company employees.

At the same time, there are already-existing mechanisms to help manage some of these inherent conflicts of interest. The United States Department of Health and Human Services Office of Research Integrity oversees the Federal-Wide Assurance (FWA) program, which requires all research entities receiving federal human subject research funding to protect these human research subjects no matter the source of funds for such research (DHHS, 2007). This protection includes strict guidelines regarding conflicts of interest involving the study Principal Investigator (PI) or any other key individual involved in the human research study. Research universities accepting federal research money for human subjects studies have signed the FWA agreement and thus, are already required to limit direct research activities of any key individuals with financial or other significant interests in human research studies conducted at their institutions, regardless of the source of funds (DHHS, 2007).

The key to managing such conflicts is in keeping the relationships transparent, by documenting relationships and activities, and in implementing specific plans to keep the affected parties at arms-length. Some of the examples reiterate that activities involving faculty and outside entities are sometimes and regulated by government. In any event, this reality of public private partnerships involving direct faculty roles is not a new one. If anything, new partnership

programs, such as the $1.5 billion North Carolina Research Campus will only increase dual faculty roles (Fischer, 2007).

TRADITIONAL MISSION OF THE PUBLIC UNIVERSITY

One way to help ensure the integrity of the traditional mission of the public research university in terms of its teaching obligations is to provide funding for such activities. The Georgia Venture Partners Fund (GVP) has included as one of its missions, to provide financial support for the humanities and arts at its research universities out of the income that the GVP generates. This fund is an example of how the promotion of increased commercialization can directly benefit the traditional mission of the public research university (GVP, 2007).

Another way to keep within the mission is to include economic development and commercialization in the mission of the university, which has been done at the UNC System. UNC System President, Erskine Bowles, has announced that economic transformation is now a component of the University's mission (Fischer, 2007).

The responsibilities for public research universities go beyond traditional teaching, service, and research obligations. As stated above, public research universities have duties to provide for the public good and the public health, and preserve and expand social benefits wherever possible. One way to fulfill this part of the academic mission is to commercialize academic-based bioscience inventions and discoveries which can improve the health of the population and contribute to the public good and the advancement of society.

UNIVERSITY EQUITY OWNERSHIP

Recently, there has been an increase in the number of public universities which have taken equity ownership in new companies developed from academic inventions and discoveries. Arguments against such ownership include the fact that by allowing a university to take direct

ownership, it is exposed to increased liability, and that such equity ownership could compromise the academic freedom of its faculty and the overall independence of research activities of the university (Washburn, 2005).

One mechanism to reduce the direct liability of the university regarding equity ownership is to have that ownership rest within a university-related foundation, not within the university itself, as is the practice at the University of Georgia Research Foundation, Inc. (UGRF, 2007). Research foundation ownership can also provide an arms-length position in terms of the ability of the academic institution to ensure its academic freedom for its faculty and to allow for independent research activities at the university.

The Pennington Biomedical Research Foundation has added another layer of equity possibilities to this mechanism. PBRF's for-profit entity, PDI, Inc., can invest up to twenty percent (20%) of the total investment made by TVP in any new deal. For example, if TVP has invested fifty percent (50%), as a result, the Pennington Foundation's for profit subsidiary, PDI, could invest up to twenty percent (20%) in TVP's 50% investment, or 10% overall (PBRC internal documents, 2007). These examples indicate that these are possible solutions available to overcome the conflicts related to commercialization of academic technologies.

Part 6

Findings Applied to Other Public Research Universities

One of the most significant findings from this study that can be applied to other public research universities is that not all of the five key components for commercialization success studied here need to be present in whole or in part in order for an academic entity to be successful at commercializing its early-stage biotechnology inventions and discoveries. At the same time, the following original key components should be present, at least to some extent, to help ensure success:

1) Small size of the organization,
2) a highly entrepreneurial community,
3) integrated commercialization track
    a) funding,
    b) research and development expertise, and
    c) a springboard for new company development.

In addition to these components, the study has indicated that the small size of the organization might be just one important component related to organizational structure and function. To support this point, organizational size might not be the definitive necessity, but organizational efficiency and effectiveness may be a more accurate description of the important part of this key component. The following characteristics of an organization also appear to be important for commercialization success:

1) efficient and effective operations whether the overall organization is small or large;
2) separate funding sources which are not part of traditional university coffers, and if possible, rest outside of the overall university umbrella;

3) well-focused, small scope, targeted commercialization program; and
4) a flexible approach in order to implement non-traditional activities such as industry partnerships, research development funding for faculty, patent activities, and R&D expertise in a fluid commercialization marketplace.

These four characteristics appear to play an important role, at least to some degree, in how efficiently the organization runs, regardless of the size of the organization.

Two of the original five components warrant further study to determine whether or not they might be advantageous in specific academic settings. Due to the nature of the three models which were analyzed in this study, these components would not be looked at in-depth. The components noted for further study are as follows:

1) the ratio of research money per bioscience faculty; and
2) an integrated life sciences curriculum program.

Regarding the research money ratio, PBRC was the only model in which the ratio of research money per bioscience faculty could be directly calculated. Ironically, PBRC did have a higher ratio than is the norm for research dollars per faculty member, yet the number of licensed technologies generated by PBRC is lower than the norm. In addition, PBRC is working diligently to develop a comprehensive commercialization mechanism because it finds itself suffering from the valley of death or funding gap for its biotechnologies (Friedl, 2006; Kouri, 2006; Nowak, 2006).

The UNC MBA model engages such a small number of biotechnologies, most of which are near-production medical devices or diagnostics, that determining this ratio for all of its bioscience inventors is neither feasible nor meaningful. Even so, some of the biotechnologies which make it into the Carolina Challenge have been successfully commercialized.

The Georgia model does meet the criterion of higher than norm research money per bioscience faculty member if the only researchers contained in the pool are the GRA Eminent Scholars. The GRA model is an example of a very successful commercialization program that does not depend on an overall high ratio of funding for all bioscience faculty. Instead, this model focuses only on the 50 plus Eminent Scholars and leverages traditional biosciences research funding by combining it with GRA's own funding sources which results in higher than normal research dollars for GRA's Eminent Scholars.

In considering the integrated curriculum program, none of the three models which were studied contained a traditional life sciences curriculum. Thus, this study was not able to analyze this component in direct relation to the three commercialization models. Further study of integrated life sciences curriculum programs could offer further insight. What was recognized in this study was that the need for an integrated life sciences program at the faculty and staff level could also be of benefit to commercialization success.

Overall, a more comprehensive model might include a combination of UCSD's integrated life sciences curriculum model for students along with the GRA Eminent Scholars program. A parallel program involving both senior researchers and life sciences students, including graduate, medical, doctoral, and postdoctoral students, could produce a more immediate impact from the researcher level and a longer-term sustainable impact from the education and training levels. The combination of these programs might even result in synergistic overall commercialization successes beyond what has been observed in any one model, including that at UCSD.

In addition to the existence in some form of the five original components listed above, it also appears that the following additional components might be necessary, at least to some extent, in order to produce commercialization success:

1) a structured, highly focused funding gap program which includes outcomes measures and an ongoing evaluation process;
2) a critical mass of bioscience researchers, including translational researchers, focused on commercialization;
3) specialized workforce development programs;
4) cross-collaborations to promote new areas of discovery; and
5) faculty incentives and rewards for commercialization.

A STRUCTURED, HIGHLY FOCUSED FUNDING GAP PROGRAM WHICH INCLUDES OUTCOMES MEASURES AND AN ONGOING EVALUATION PROCESS

With regard to creating a structured funding gap program, the GRA VentureLab model is one that can be used as a best practice example. In order for each of the six GRA research universities to receive seed grant funding for their specific VentureLab programs, the universities must submit a detailed application of how the funds will be spend and what outcomes will be measured as benchmarks for success. These documents serve as a baseline for annual evaluation in terms of progress (GRA VentureLab, 2007). Tying goals to measured outcomes is one way to ensure that the program remains focused and the goals met. Since the biotechnology field is so fluid and the needs of technologies and new companies change along with the marketplace, it is important to develop a tie-in between the funding of technology development and the ongoing evaluation of the progress.

The GRA model has shown that by narrowly focusing the commercialization components, a strong core program can be developed. In the case of the GRA, this focus is based on its Eminent Scholars and their related innovations and discoveries, not on transforming the broader bioscience culture of each university. Given that there has been such a high rate of success in the GRA program, this limited focus has proven to be of importance. There seems to

be a synergistic effect between the success of each individual scholar and the GRA program as a whole, much of which is attributed to the narrow focus and outcome-directed financial incentives (GRA Report, 2006).

As discussed throughout this study, there has been a recent push away from investments in early-stage, nascent technologies by venture capitalists, which has resulted in the biotechnology funding gap or valley of death (Friedl, 2006; Kouri, 2006; Nowak, 2006). Rather than hoping that these investors will reverse their direction and move toward funding such early-stage technologies, it is more realistic to acknowledge that such a gap exists and work from within academia to lessen the gap and build stronger, more narrowly-focused commercialization bridges and mechanisms.

A CRITICAL MASS OF BIOSCIENCE RESEARCHERS, INCLUDING TRANSLATIONAL RESEARCHERS, FOCUSED ON COMMERCIALIZATION

Building a critical mass of translational researchers with a commitment to biotechnology commercialization is a key component in the Georgia model. The Georgia Research Alliance program has been very successful with its Eminent Scholars Program, which is a highly focused, specialized recruiting and funding program aimed at bringing the best bioscience researchers to Georgia specifically for discovery and commercialization activities. Since its inception in 1990, the GRA program has recruited and funded more than 50 Eminent Scholars, been integral in securing more than $2 billion dollars in new federal research funding and private investments, creating more than 125 new companies and more than 5,000 new high-skill, high-paying jobs within the state of Georgia (GRA, 2007). Others recognize that Georgia's recruiting and funding approach is one they would like to adapt for their own institutions or states.

No matter how it is accomplished, developing a critical mass of bioscience researchers focused on commercialization may be a more targeted way to achieve a successful

commercialization program than by trying to attain the same commercialization success by achieving an overall higher than average ratio of research funding per faculty member.

SPECIALIZED WORKFORCE DEVELOPMENT PROGRAMS

One of the ongoing and growing difficulties noted in the Milken Reports (2004, 2006), is that ancillary professionals, such as those trained in the MBA program along with those considered support scientific and technical staff in the biotechnology commercialization industry, are difficult to find, require specialized training, and find it challenging to afford being gainfully employed in a high cost-of-living geographic area, such as San Diego or Boston (Coombs, 2007).

It has been discussed earlier in this study that there is a push for many research institutions, regardless of their geographic location, to be increasing their ability to commercialize academic-based biotechnology inventions and discoveries, create new jobs and new companies, and contribute more directly to their region and state in terms of economic impact. As a result, there will need to be some mechanism to train and employ these specialized high-skilled workers locally, both at the professional and graduate school level and at the undergraduate and associate degree level. Such a program could diminish the impact many sates and regions are suffering related to the out-migration of their most highly-trained young professionals (BOR, 2007).

There may be an advantage to training and retaining these workers in geographic areas where the cost-of-living is more moderate. Since the number of such highly-skilled workers available locally or regionally is small, implementing locally-based education and training programs could be very beneficial. If these programs are located in the same higher education institutions or at collaborating institutions in the area, this could also reduce the problem of brain

drain, where the best and the brightest highly-skilled graduates from an institution leave the area or the state. Such education and training programs could be an important component to the success of a region's or state's academic-based biotechnology industry while keeping its highly-skilled workforce in the state.

The University of North Carolina at Chapel Hill MBA Entrepreneurial program is geared toward educating and training graduate business school students in the specifics of technology commercialization professions such as finance, accounting, business law, economics, and management (Kouri, 2006; UNC MBA, 2007). Some technologies that become part of the MBA students' Carolina Challenge projects are biotechnology-based, thus providing the students with experience in the biotechnology commercialization industry.

One of the ongoing and growing difficulties noted in the Milken Reports (2004; 2006), is that ancillary biotechnology professionals are difficult to find, require specialized training, and find it challenging to afford being gainfully employed in a high cost-of-living geographic area, such as San Diego or Boston (Coombs, 2007).

CROSS-COLLABORATIONS TO PROMOTE NEW AREAS OF DISCOVERY

The GRA Eminent Scholar Challenge Grants have been created to promote cross-collaboration. This challenge grant program is designed specifically for the Eminent Scholars. Annual awards of up to $50,000 are given to a team of at least two Eminent Scholars to promote scientific collaboration. The scope of work is judged on technical merit and the potential for future commercial success as well as on other funds the scholars have in place to support the project for which Challenge Grant funding is sought (GRA Report, 2006).

As proof of this lack of expertise in academic research, the NIH recently recognized that its funding for clinical research and treatment of diseases and conditions was not making the

advances it had hoped (NIH website 2006). NIH determined that it had funded silos of research and excellence in the past, which promoted narrowly-focused scientific endeavors, resulting in the fact that experts in one area did not often communicate with or collaborate with those in other areas.

A byproduct of this type of narrowly-focused research is that there is little or no scientific expertise or experience within academic research centers to know how to bridge R&D, moving early-stage biotechnology inventions or discoveries along the commercialization continuum. As discussed previously, the NIH is now beginning to address this deficit in its sponsored research funding paradigm by launching its 60-site, multi-year, $700 million Clinical Translational Science Award (CTSA) project, but the results from its efforts to boost translational research will not affect academic researchers for some time.

FACULTY INCENTIVES AND REWARDS FOR COMMERCIALIZATION

Faculty rewards and incentives can play an integral role in promoting cross collaboration, increasing translational activities, fueling new inventions and discoveries, and provide the foundation for new start-up companies.

Traditional promotion and tenure criteria do not include these activities, but a shift in direction is beginning. Texas A&M announced in 2006 that it would include commercialization activities in its consideration for faculty promotion and tenure (Lipka, 2006). The GRA program provides specific research funding for projects focused on commercialization and its Eminent Scholars program recruits bioscience experts for faculty positions whose research programs focus on commercialization (GRA, 2007). The President of the UNC System, Erskine Bowles, recently has announced that economic transformation will become part of the mission of the

university, which further strengthens the support for commercialization as an integral part of university activities (Fischer, 2007).

Unintended Consequences

As discussed previously, those in academe have concerns regarding unintended consequences related to the increase in commercialization activities at research universities. Recognizing that perceived or real conflicts of interest may arise, some higher education institutions have put in place some processes to deal with these issues, with the understanding that transparency and arms-length relationships can diminish or even eliminate these conflicts and make them manageable.

Key among such conflicts regarding research commercialization are those affecting faculty roles and university relationships with industry. With regard to faculty roles, examples have been given as to how to manage these conflicts. The Georgia Research Alliance has an arms-length relationship with the six research universities it collaborates with for bioscience economic development, and is able to provide recruiting and ongoing R&D funding for faculty that sits outside the university organizational umbrella (GRA, 2007). Other universities have put in place standard operating procedures to assess perceived and real conflicts of interest on a case-by-case basis, such as the University of Texas, and manage the conflicts with designated organizational and operational requirements for each case (University of Texas, 2007).

The federal government has parameters surrounding its SBIR and STTR grant awards which inherently include faculty roles that can lead to perceived or actual conflicts of interest. Some of these conflicts are managed through the government's structure in its eligibility requirements, and others are documented through related grant documents, such as the Model Use Agreement, to outline activities and intellectual property ownership at the university and

small business levels (NIH, 2007). The remainder of the conflicts generated through the SBIR/STTR grant award process require oversight and management on the part of the higher education institutions and small businesses participating in the awards.

University-industry roles have also been under scrutiny. The concern over outside control of academic research by an industry sponsor has sparked debate and has resulted in termination of such agreements, as in the University of California situation regarding the plant biology Novartis research agreements (Blumenstyk, 2003a; Nadis, 2000; Nature, 2001) and led to legal action as in the University of Toronto situation regarding publishing of faculty research data and a corporate sponsor (Olivieri, 2003).

Continued awareness of such issues is one way to help in managing them. By creating mechanisms for commercialization which reduce or eliminate such conflicts, an ongoing monitoring of sorts can be established. For example, the GRA model has distinct funding and activity phases in its VentureLab program. Awards for business development in Phase 3 go directly to the small business, not to the university or faculty inventor (GRA, 2007).

Other academic institutions have determined that commercialization activity is better coordinated and memorialized through an affiliated research foundation. The University of Georgia Research Foundation, Inc. (UGRF) is an example of a research foundation that engages in the contractual relationships for grants, contracts, and licenses for the University of Georgia, and works in parallel with the Georgia Research Alliance regarding its programs. The UGRF is the entity which will take equity ownership in any new start-up company that is formed around academic technologies (Consultant, 2007; UGRF, 2007).

One of the main goals of this study was to explore the possibility of funding a hybrid solution to the myriad of unintended consequences related to academic biotechnology

commercialization. Concerns were raised regarding the issue that some technologies are not ready to be commercialized or should never be commercialized. To deal with this issue, an institution can implement a version of the GRA VentureLab program that assesses the commercial possibilities for technologies. If it is determined that the technology should not be further developed, even if funds are available, then the technology should be released for the public good. If the technology shows promise but is early-stage, then the organization can create an early-stage R&D program which also includes funding to further develop the technology.

Faculty roles were also discussed. The GRA Eminent Scholars program hires and funds scientists who are expected to commercialize their inventions and discoveries and are encouraged to become part of start-up companies. Rewarding faculty for commercialization activities and including these successes in promotion and tenure decisions reinforce the importance of economic development. Some universities have developed formal processes that document faculty ownership in companies and manage their other conflicts of interest.

There are also ways to preserve the mission of the research university while encouraging commercialization activities. University foundations can play a central role in the licensing and equity activities surrounding invention commercialization. Venture funds can allocate a portion of income back to the university to support academic activities, which is part of the Georgia Venture Fund mission.

Overall, there are ways to manage conflicts of interest and other unintended consequences while still preserving the mission of the public research university. Examples exist where the commercialization process brought revenues back to the academic institution to support other teaching and research programs. In other instances, the public health of the

population benefits from new medical treatments or drugs or society overall benefits from the technology.

Other Findings

In addition to all of these key components and issues, other findings have emerged regarding university commercialization. In all three models studied, it was very important to have the ability to take an in-depth look at what type of organization and culture already existed, and what other initiatives were planned or in place prior to determining how to develop a better program. There have been examples in higher education of the "me, too" syndrome, where universities push quickly to adopt a model from another institution without regard for differences in institutional structure and cultures, without spending adequate time analyzing and assessing the models being considered, and often without the key players weighing in on the factors necessary to make an informed decision.

Chapter 2 discussed how this "me, too" scenario played out at many academic health centers (AHCs) after the introduction of managed care, and described the devastating results due, at least in part, to the lack of analysis and assessment prior to implementation of new AHC models. Loyola University of Chicago and other academic institutions suffered substantial unintended consequences due to the quick adoption of another institution's model as is.

Biotechnology commercialization is a fluid, complex area that requires much study and review by many experts in order to possibly implement the best model for any institution looking to expand, revise, or create a well-designed and effective commercialization mechanism.

To this end, a level of ongoing flexibility in terms of program creation and adaptation was apparent in all three models studied. The Georgia Research Alliance has seen the creation of an ancillary program, the Georgia Venture Fund, which runs in parallel to its own

commercialization program. The Pennington Biomedical Research Center is developing a more comprehensive, multi-tiered approach to early-stage biotechnology development due to the realization that having a venture fund in place was not enough on its own for commercialization success. The state of North Carolina is in the process of restructuring its North Carolina Bioscience Investment Fund (NCBIF), after several years of existence.

Restructuring or reformulating the commercialization model can take place while there are ongoing, working, successful components already in place. In an area such as biotechnology, which is still relatively young but which must respond quickly to numerous marketplace shifts, the mechanisms in use should be adaptable and adjustable.

In addition to flexibility in the commercialization structure, those who are the key individuals involved in these activities need to be comfortable with risk-taking and thinking in non-traditional ways. This is evidenced by the need for a flexible, non-bureaucratic organizational structure, the existence of a highly entrepreneurial culture, and the ability to change and adapt in a high-paced, evolving industry.

CHAPTER 5.

SUMMARY, CONCLUSIONS, AND RECOMMENDATIONS

Study Overview

Three decades have passed since universities have been given the federal mandate to commercialize their inventions and discoveries, and the process still faces some obstacles. A growing issue facing universities is the lack of research and development funding and expertise available for the successful commercialization of early-stage academic biotechnology inventions and discoveries. As a result, some of the most promising technologies might never reach the marketplace. To help address this situation, closer relationships have developed between universities and industry. Unintended consequences, such as concerns over faculty roles, financial conflicts of interest, and the mission of the public university have occurred as a result.

Despite these issues, missing out on the opportunities to develop promising biotechnologies could have significant negative consequences for universities and for the public good. Many communities, regions, and states are increasing their economic development expectations in relation to academe, seeing universities as the key to successfully revitalizing and expanding their underperforming economies.

These expectations have resulted in an escalation in the formation of closer relationships between academia and communities. Some argue that higher education institutions are more important to a community's economic development than tax cuts or other incentives (Fischer, 2006). Washburn (2005) discusses the danger of universities marketing themselves as engines of economic growth, which could create false expectations, especially in the so-called "catch-up" schools. One of the concerns Washburn explores is that if these universities are unable to deliver

on the promises they have made to their legislatures and communities, this failure could jeopardize their requests for future funding.

In support of this point of view, many faculty and others are concerned that the expectations being placed on academia are out of proportion, especially in economically depressed regions. Those who push this economic platform know that academic-based blockbuster biotechnology hits, which have grossed millions of dollars for universities, faculty, related institutions, academic teaching hospitals and other affiliated centers, are central to their success (Fischer, 2006).

Even though the nation's universities are the largest source of such academic capital, transforming this raw resource into successful market bioscience products and treatment is a complex process with a low success rate. Despite more than 25 years of technology transfer activity, this resource is still difficult to harness (Pisano, 2006).

Several experts argue that academia's fascination with the technology industry and the commercialization of its own inventions and discoveries is not based on extensive review of the process and the realistic probably of success, nor on comprehensive strategic planning geared toward maximizing opportunities (Pisano, 2006; Powers, 2006). Those who are skeptical declare that the shift from more traditional revenue sources to this new model, which focuses on commercial returns and economic impact, was implemented hastily This lack of vision, Pisano (2006) points out, has contributed to the lackluster overall performance of the biotechnology industry.

As reinforcement for this argument, Washburn (2005) reports that the biotechnology commercialization problem may go back as far as the late 1970s. At that time, Washburn reports that data presented to Congress in support of the Bayh-Dole Act of 1980 was somewhat

misleading. This watershed piece of federal legislation, which marked a significant change in the federal science and technology policy, became a catalyst for commercialization of academic-based inventions and discoveries. Proponents of the Bayh-Dole Act argued that federally-licensed patents, including those from academia, were sitting dormant and not being commercialized. What was not disclosed in the data presented to Congress, was the fact that the majority of the patents held by the federal government at that time, had been offered to industry but were turned down because they were too early-stage and needed further developmental research funding which those in industry were unwilling to provide (Washburn).

This same problem of how to develop and fund early-stage inventions and discoveries remains a major issue for universities today (Friedl, 2006; Kouri, 2006; Nowak, 2006). Yet, the fact that many academic technologies are too early or even inappropriate to commercialize is often overshadowed by the assumption that success for early-stage technologies is all but assured with just additional time and money. The revelation that most university-generated technologies were not commercialized prior to Bayh-Dole because they were too early-stage or not appropriate to market, begs the question as posed by Washburn (2005), "what share of the university-based inventions generated since 1980 were commercialized *because* of the institutions created under Bayh-Dole, and what share *would have been commercialized anyway*?" (p.143).

Statement of the Problem

Powers (2006) and Pisano (2006) suggest that university leaders need to rethink the technology transfer model in order for these institutions to reach their true commercial potential. One of the most important pieces absent from the current commercialization paradigm is a reliable mechanism for bridging the gap between early-stage academic biomedical inventions

and discoveries and venture fund investment interest. This valley of death, or funding gap, as described by Friedl (2006), Kouri (2006), and Nowak (2006), exists today despite more than twenty years of increasingly sophisticated academic biotechnology transfer activities.

This exploratory study focused on analyzing the following: 1) the mechanisms for commercializing early-stage academic inventions and discoveries, and 2) the resulting unintended consequences and how to minimize or remove them from such commercialization activities. The goal of the study was to be able to present possible mechanisms, models, and best practices that other public universities could use to successfully commercialize their own early-stage biotechnologies while preserving the overall mission of the university and minimizing or eliminating related unintended consequences.

Initially, this study intended to analyze two different mechanisms for early-stage, academic biomedical inventions and discoveries at two different public universities. One model, that of the Pennington Biomedical Research Center (PBRC) as part of the Louisiana State University System, is based on an early-stage research and development investment platform; while the second, an MBA entrepreneurial program at the University of North Carolina at Chapel Hill, is focused around a curriculum specialization in the graduate school MBA program. However, during the initial research phase of the analysis, a decision was made to study a third model. As a result, this study has been expanded to include an analysis of the Georgia Research Alliance (GRA), which is considered a highly successful commercialization mechanism and perceived as being adaptable in many other research university settings. Therefore, this study was expanded to include an analysis of the GRA as a third commercialization mechanism.

Summary

Five key components were identified as being important in order to ensure successful, academic biotechnology commercialization. These components were analyzed individually at each site and then comparatively studied, with a summary of the results described below.

GRA, PBRC, UNC AND UCSD

Component 1: Small Size of the Institution:

None of the three models studied fits the traditional definition of a small institution, yet each contains some of the characteristics of a small-sized institution deemed important in the UCSD model. For example, the UNC MBA model can be described as a small organization when looking only at the MBA curriculum program. This program is well-defined and focused, based on a flat hierarchy, and subject to little bureaucracy. In addition, the majority of the funds for the program are generated from sources outside of the university. The fact that the University of North Carolina at Chapel Hill is one of the largest single campuses in the state, does not seem to have a negative impact on the efficiency or effectiveness of the MBA curriculum program (UNC MBA, 2007).

Similarly, the GRA model is also based on a small organization which directly employees very few individuals. The GRA is comprised of a focused program, flat hierarchy, and little bureaucracy. In the GRA model, the mission is to serve the biotechnology commercialization needs for Georgia's top six research universities, but GRA functions as its own separate entity. The difficulties often encountered in large organizations, such as bureaucratic gridlock, fragmentation, and multiple layers within a multi-tiered hierarchy, are not present in the GRA, even though the state government and six major universities are collaborative partners in this alliance along with business and industry (GRA, 2007). With both the UNC and GRA models, it

appears that when a specific program is contained within a small organization it can work well whether or not the program is part of or runs in parallel to a large organization.

A somewhat different situation exists at the Pennington Biomedical Research Center, which is one of 11 institutions comprising the Louisiana State University System. PBRC employs more than 650 individuals, but has a narrow research focus and no teaching component. PBRC is modeled on the organized research unit (ORU) structure with the advantage that the funding sources and faculty duties are not bifurcated. The culture of the Center is to be efficient and effective and the administrative organization is very lean and flat (PBRC internal documents, 2007).

In most day-to-day operations, the Center does not suffer from the problems associated with a large bureaucracy, but, as described earlier in the chapter, there are some restrictions facing the commercialization process because PBRC sits within a much larger academic organization, the LSU System. The overall commercialization culture at various LSU campuses and at the LSU System level has been inconsistent, with varying performance records, but new programs and directions undertaken within the past few years are changing the situation, as discussed earlier in this chapter (LSU System, 2007; PBRC internal documents, 2007).

Despite this situation, PBRC has been able to partner with its Foundation to move forward in the development of an integrated, multi-function commercialization mechanism. The key players recognize that there is a balance to be maintained between the Center's obligations to the LSU System and the need for flexibility, some of which is obtained by partnering some of PBRC's activities with its Foundation (PBRF internal documents, 2007).

With PBRC's characteristics of a flat hierarchy, minimum bureaucracy, and physical proximity to its researchers, the groundwork is in place to allow for efficient and effective

operations. Since the Foundation is a separate entity not subject to university or government restrictions, it can allow for some additional flexibility, such as hiring out-of-state patent counsel and outside consultants. The Foundation is also able to provide additional types of funding for R&D of early-stage technologies, partner with the biotechnology industry, and play a significant role in new company start-up activities as well as in other related commercialization processes (PBRF internal documents, 2007).

In the end, none of the three commercialization models studied fits the definition of a traditional small institution, and none has the structure that is in place at UCSD, yet there have been some significant start-up company successes generated out of these three models. When analyzing the infrastructure of a complex organization, the following characteristics related to size of the institution and methods of operations appear to be important for commercialization success:

1) efficient and effective operations within the commercialization model whether the overall organization is small or large;
2) separate funding sources for the commercialization program which are not part of traditional university coffers, and if possible, resting outside of the overall university umbrella;
3) well-focused, small scope, targeted commercialization program; and
4) a flexible operations approach in order to implement non-traditional activities such as industry partnerships, research development funding for faculty, patent activities, and R&D expertise in a fluid commercialization marketplace.

Component 2: Higher than Norm for Research Money per Biosciences Faculty:

In the traditional definition of the ratio of research money per bioscience faculty, the Pennington Biomedical Research Center is the only one of the three models analyzed that contains this component. Yet, PBRC faces an early-stage technology funding gap and a small ratio of invention disclosures translating into viable venture startups of licensed technologies (PBRC internal documents, 2007). Therefore, the ratio of research money per faculty does not equate with successful commercialization at PBRC, even though this component was deemed essential in the UCSD model.

The UNC MBA program is different from the other two models analyzed because it looks at such a small number of technologies and therefore, a small number of faculty. Mostly near-commercialization possibilities such as medical devices and testing and diagnostics products become part of the UNC MBA Carolina Challenge (Kouri, 2006). This small number does not capture a true cross-section of the research funding of the UNC bioscience faculty. Therefore, it is not feasible to apply this funding ratio to the small group of biotechnology researchers participating in the UNC MBA entrepreneurial program.

The Georgia model does meet the criterion of higher than norm research money per bioscience faculty member if its GRA Eminent Scholars are the only researchers in the pool. The GRA model is an example of a very successful commercialization program that does not depend on an overall high ratio of funding per bioscience faculty. Instead, this model leverages traditional biosciences research funding for its Eminent Scholars by combining it with GRA's own funding sources. This specifically targeted funding program generates additional research dollars and fuels even more funding for the select Eminent Scholars. The high ratios of combined research dollars per Eminent Scholar have translated into exceptional success with

commercialization results over the past 16 years. Keep in mind that GRA's success is for a mix of public and private universities with different inherent levels of bioscience research funding and bioscience faculty strengths and the program works well in all six universities (GRA, 2007).

As pointed out here, at least for two of the three models researched in this study, the UCSD component of higher than norm research dollars per faculty member does not apply. The fact that by targeting a much smaller group of faculty is a formula that works for both public and private research universities in Georgia reinforces the belief that a targeted Eminent Scholar program could be adapted for use by a range of research universities.

As mentioned above, the UNC model is very limited in the number of faculty participating and the scope of technologies it can commercialize, so it is not feasible to calculate the ratio of research funding per faculty involved in the I\UNC MBA Carolina Challenge.

Ironically, the only model which meets this higher than norm ratio present in the UCSD model is PBRC, which finds itself needing to implement a more comprehensive commercialization program in order to be successful.

In this study, the most successful example of this component is the GRA Eminent Scholar program, which contains some characteristics which are different from the UCSD model. The GRA model only applies the ratio to its targeted group of 50-plus Eminent Scholars. A more focused program, such as the GRA, might easily be adapted by other universities since it is not dependent on an overall higher than normal ratio of research dollars per faculty but can be focused around a much smaller group of targeted bioscience faculty. In actuality, it might not matter if there is a high ratio of research dollars for all bioscience faculty members as long as there is a correspondingly high ratio for those particular faculty researchers who actually participate in the commercialization mechanism.

Component 3: Extremely Entrepreneurial Community:

The ongoing support, development, expansion, and successes of the Georgia Research Alliance and its related initiatives and activities such as the Georgia Venture Partners Fund, reinforce the state of Georgia's commitment to fueling the entrepreneurial spirit. As described by the GRA itself, its mission is to create the opportunities to grow the economy of the state through scientific discovery and related commercialization activities. Unlike San Diego or the North Carolina Research Triangle, which had developed entrepreneurial cultures decades ago, the state of Georgia had not been culturally entrepreneurial regarding bioscience development prior to the creation of the Georgia Research Alliance in 1990. The GRA is an example of a statewide initiative that includes partnerships of academic, government, and private organizations which have proven very successful in meeting its mission (GRA, 2007). Yet, even with all of the success and the highly entrepreneurial culture in Georgia, there is a commercialization gap for early-stage academic biotechnologies, which led to the formation of the Georgia Venture Partners Fund in 2004. GRF has just recently begun to invest in early-stage technologies (GVP, 2007).

Although inherently entrepreneurial in terms of risk-taking to seek outside research funds and agree to faculty positions that only include five-year rolling tenure, PBRC finds itself hoping to work within a broader entrepreneurial culture in order to move ahead with successful biotechnology commercialization. PBRC sits within this larger, mixed-risk culture in place at the LSU System, the greater Baton Rouge area, regionally, and at the state level. There is some movement toward the development of a more creative class within this overall traditional, conservative, risk-averse setting, but it remains to be seen if this fragmented movement is enough to provide a catalyst for PBRC's commercialization initiative.

Like UCSD, the Research Triangle region of North Carolina also has been a highly entrepreneurial area for several decades, with its main focus on biosciences R&D. It has been home to Glaxo SmithKline, a very large pharmaceutical company, for several years and has, within its region, a large number of experts in the biotechnology field. Like the Georgia model, the North Carolina Research Triangle initiative was a planned, collaborative partnership among the three research universities in the region, the state of North Carolina, and private industry (Milken, 2004; Washburn, 2005).

Despite this long-term culture of entrepreneurship, UNC also found itself faced with the same biotechnology valley of death that has been described in detail throughout this study. In such an entrepreneurial climate, UNC still could not successfully commercialize its early-stage biotechnology inventions and discoveries. The overall culture of entrepreneurship was not enough to guarantee biotechnology success at UNC, as witnessed by the need for the Carolina Challenge (Kouri, 2006). On the state level, the government has more recently declared the need to overhaul the North Carolina Bioscience Investment Fund, which was created to commercialize inventions and discoveries generated in North Carolina. The state also made the admission that its past mechanisms for commercializing biotechnologies have had mixed results (Weisbecker & John, 2007, 2007).

The recent creation of the $1.5 billion North Carolina Research Campus, a collaboration which includes seven North Carolina research universities, the state, and David Murdock, owner of Dole Foods, is significant. In addition to this enormous biotechnology initiative, the President of the University of North Carolina System has declared that the University's mission will include economic transformation (Fischer, 2007).

Based on the models studied, it appears that an entrepreneurial culture or community is important to successful commercialization, but this entrepreneurism can be deliberately created, at the same time as a successful program is implemented, as was the case in Georgia. Conversely, the presence of a highly entrepreneurial community does not guarantee, in and of itself, a corresponding success rate for commercializing early–stage biotechnologies, as witnessed in North Carolina. As with the analysis of other components in this study, they appear to be necessary but not singularly sufficient in terms of translating into commercialization success.

Component 4: Integrated Life Sciences Curriculum Program:

This component is not directly related to any of the three commercialization models studied, yet its importance may be undervalued in this study by virtue of the characteristics of the particular models being analyzed. One reason that the importance of an integrated life sciences curriculum program might have a much larger overall impact on an academic institution than is present in the three models, is based on a new NIH program. The NIH has realized that it has been largely unsuccessful in its ability to translate its federal clinical research funding into an adequate number of positive outcomes related to patient care and new bioscience discoveries to improve the overall health of the population (NIH, 2007). As a result, the NIH has launched a new initiative called the Clinical Translational Science Awards (CTSA).

Both the UCSD model and the NIH CTSA emphasize a new approach to training bioscience researchers at least partly through an integrated curriculum. This new NIH program is geared toward breaking down the barriers or silos of research so that cross-collaboration and a broader spectrum of possibilities becomes the norm for the individuals being trained (Milken, 2004; 2006). The belief is that, by cross-training clinical researchers, an increase in broader-

based translational research activities will occur, as will an increase in treatment initiatives (NIH, 2007).

In its own way, the GRA has accomplished some of these same outcomes in terms of developing cross-trained translational researchers by its requirements and criteria for its Eminent Scholars Program and Eminent Scholars Innovation Fund. Unlike the UCSD model or the NIH CTSA program, the Georgia Eminent Scholars are senior, expert bioscientists, not students, who are chosen for further funding based on cross-collaboration and commercializable areas of research. In this model, the requirements for the Eminent Scholar programs are substituted for the curriculum requirements of the life sciences students (GRA, 2007).

It might be possible in certain circumstances, for example, at the Pennington Biomedical Research Center, to implement the Eminent Scholars model as an alternative to the UCSD model because PBRC has no students and does not confer degrees, yet needs to improve its ability to generate biotechnology commercialization opportunities for the research scientists on its faculty. In the focus group discussions and in individual meetings with PBRC faculty, they welcomed an opportunity to vie for membership in a program similar to the GRA Eminent Scholars program (PBRC internal documents, 2007).

Overall, a more comprehensive model might include a combination of the UCSD integrated life sciences curriculum model, the NIH CTSA program, and the GRA Eminent Scholars program. A parallel program involving both senior researchers and life sciences students, including graduate, medical, doctoral, and postdoctoral students, could produce a more immediate impact from the researcher level and a longer-term sustainable impact from the education and training levels. The combination of these programs might even result in

synergistic overall commercialization successes beyond what has been observed in any one model alone, including that at UCSD.

Component 5: Integrated Commercialization Track:

a) Funding:

Despite having a very successful, well-planned, statewide, comprehensive bioscience economic development program in place, the problem of commercializing early-stage bioscience inventions and discoveries still appeared in Georgia. Since it was recognized as such a critical issue, three of Georgia's research universities decided to create a small seed fund on their own and not wait for the state to intercede. Emory University, Georgia Institute of Technology, and the University of Georgia developed a $5 million fund called Georgia Venture Partners (GVP) by combining $1 million from each of the academic institutions with $2 million from private investors. The GVP is a professionally managed seed fund at arms-length from the universities and the GRA (GVP, 2007).

The GVP fund has two principle functions, 1) to generate substantial investment returns, primarily through capital gains, by investing in a portfolio of companies ; and 2) to increase the economic development of life sciences in Georgia through seed or early-stage investments in life sciences start-up companies based around academic inventions and discoveries and other bioindustry companies. GVP initially invests between $100,000 and $200,000 in a single company, with a maximum investment capped at $1 million dollars for that company. GVP has recently begun to invest in early-stage technologies (GVP, 2007).

A different scenario is in place at PBRC. Although PBRC's research revenues are very strong, the majority of PBRC's inventions and discoveries are very early-stage and often require further development prior to outside investment interest. The initial step taken to correct this

problem at PBRC was to create an early-stage seed fund to provide the necessary capital for inventors to further develop their nascent technologies. A $12 million dollar seed fund, Themelios Venture Partners (TVP), an arms-length venture fund, was formed to support in PBRC inventions and discoveries and also allow a small percentage of investments in outside companies which would partner with PBRC on specific commercialization projects (PBRC internal documents, 2007; TVP, 2007).

The overall structure of TVP is similar to that of the Georgia Venture Partners. In PBRC's case, the seed fund was created first and the commercialization platform is being developed after TVP, while, in Georgia, the commercialization platform was created first, followed by the seed fund. Even though TVP has already invested in several PBRC technologies, it has turned down the majority of the technologies it has reviewed, claiming that the discoveries are too early for it to consider. As a result, PBRC has found itself facing the same funding gap described by Friedl (2006), Kouri (2006), and Nowak (2006), even after the formation of TVP. PBRC and PBRF are now exploring additional funding mechanisms such as some adaptation of GRA's VentureLab fund and a corporate sponsorship program to further develop the nascent technologies in-house (PBRC internal documents, 2007).

A third situation exists in North Carolina. Other than the Kauffman Foundation and matching UNC funding which comprise the bases for the Carolina Entrepreneurial Initiative, there is no specifically designated university-based fund to springboard early-stage academic technologies for commercialization as a direct part of the UNC MBA entrepreneurial program. If a technology wins the Carolina Challenge, the winner receives a $25,000 prize to further develop the technology. Some statewide funding is available through other organizations, but there has been a reassessment of those sources recently (Kouri, 2006; UNC MBA, 2007).

The first fund being reevaluated is Eno River Capital and the second is the North Carolina Bioscience Investment Fund (NCBIF). The Eno River Capital fund, which was created in 1998 to commercialize life science technologies developed in North Carolina's public academic universities through the formation and development of locally-based start-up companies, has been under close review recently. The fund was charged with creating new, high-paying, high-skill jobs and attracting new capital from later stage investment firms. The core expertise of Eno River Capital is in technology commercialization, with a major focus on transforming discoveries into products or services and turning a profit. Areas of expertise are described as deal-structuring and intellectual property licensing along with operational experience in the areas of information technology and the life sciences. Consulting services are also provided (Eno River Capital, 2007).

Until recently, Eno River Capital has managed the $26 million North Carolina Bioscience Investment Fund (NCBIF), which is a seed-stage venture capital fund for life science inventions and discoveries (NCBIF, 2007). In June, 2007, it was reported that NCBIF's $10 million dollar investment in the Eno River Fund had a net worth of approximately $1.3 million. Of the 10 companies the Eno fund has invested in, eight have been sold or are out of business. NCBIF's new director admitted that the Eno River Fund has not performed well, although he sites other investments in new companies that did result in new jobs. At the present time, NCBIF receives approximately $12 million in annual funding from the state of North Carolina (Weisbecker & John, 2007, 2007). Ongoing realignment is occurring in the state of North Carolina regarding its funding for early-stage technologies.

Most recently, the $1.5 billion North Carolina Research Campus initiative has begun. Details regarding specific commercialization activities are not yet available, but the UNC System

President has announced that economic transformation is part of the University's mission (Fischer, 2007). With seven research universities participating, a state commitment of $30 million annually, and an overall budget of $150 million per year, this program could provide significant impact in North Carolina regarding an integrated commercialization track.

The three models are not alone in facing investment difficulties. Even with its overall success, the UCSD model also recognizes some challenges to its commercialization pathway. Edward Holmes (2006) points out that there are at least two gaps in the road to clinical translation at UCSD, 1) between discovery and development (Post-NIH and pre-commercialization) and 2) between R&D and clinical evaluation (FDA Phase I-II and Phase III). Holmes acknowledges that funding for the gap between discovery and development, or the valley of death as described by Friedl (2006), Kouri (2006) and Nowak (2006), is often not available in the UCSD university setting.

Analyzing all three models as well as the UCSD model, it appears that a funding source is crucial, but not enough by itself, to ensure commercialization success. This funding component appears to be closely linked with the need for available R&D expertise. The PBRC situation clearly reflects this need, while the GRA model indicates that the R&D expertise without the funding is also not enough to guarantee commercialization success.

b) R&D Expertise:

Different situations in terms of R&D expertise exist at each of the three models studied. In Georgia, the state was not flush with R&D experts when the GRA was introduced in 1990, and acknowledging that lack, GRA integrated a planned mechanism for access to R&D experts as part of its VentureLab program (GRA VentureLab, 2007). In addition, the GRA program specifically recruits researchers who are R&D experts for its Eminent Scholars program. As a

result, the GRA has proven to be a successful combination of outside expertise and internally-grown R&D experts (GRA, 2007).

The GRA VentureLab program contains fellows and commercialization catalysts who have much in common with the local R&D experts in the Research Triangle area of North Carolina, with one major difference. The GRA VentureLab program requires that the fellows and commercialization catalysts be employed by the specific research university where they are working (GRA VentureLab, 2007). The UNC MBA entrepreneurial program's affiliation with its local experts is informal and voluntary (Kouri, 2006).

The model with the highest number of inherent R&D experts is the UNC MBA curriculum program which resides within the North Carolina Research Triangle. A significant number of highly-skilled biotechnology experts are available locally to help develop new biotechnologies. Since this part of North Carolina has been home to a major pharmaceutical company for many years in addition to being the center of bioscience activity for several decades, there are signification numbers of local R&D experts who are willing and able to participate in biotechnology commercialization activities (Kouri, 2006).

Such a concentration of experts can prove to be highly valuable to biotechnology start-ups and inventors in the region. Since the biotechnology field is such a highly specialized one, experts are difficult to find in many geographic areas. Having such a high concentration of experts in many areas of biotechnology, including senior management, developmental science, bio-business, and others, is unusual and very valuable to the UNC MBA program and the participants in the Carolina Challenge (Kouri, 2006; UNC MBA, 2007).

Despite this atypical collection of R&D experts, there is a limited amount of success in terms of commercialization of early-stage technologies at UNC and overall in the state of North

Carolina. This limited success might indicate that there is a need for a combination of components in order to ensure broader commercialization success, as pointed out by Dr. Kouri in his AUTM presentation (2006).

In a related R&D issue, the San Diego area was identified as a region that is finding it difficult to retain some of its specialty-trained biotechnology workforce (Milken, 2004; 2006). In particular, those individuals at the mid-level and support levels of the workforce are finding it difficult to remain in the area due to the extraordinary high cost of living in the San Diego region and also in the Boston area (Coombs, 2007). Although this is a newly recognized issue, the need for such a skilled workforce is important to the overall success of a biotechnology economy.

In contrast, the state of North Carolina has implemented a program through its community colleges to train individuals for workforce deployment. This focus, in conjunction with the UNC MBA entrepreneurial program, may provide a significant cadre of regionally grown biotechnology employees necessary for growing this specific biotechnology component for economic development in the state (NCBIF, 2007). North Carolina's Rowan-Cabarrus Community College has implemented a biotechnology curriculum program to prepare students to become laboratory technicians and biotechnology manufacturing workers (Fischer, 2007).

The need for this type of workforce was also recognized at the research and development focus group meeting in April, 2007, Baton Rouge, Louisiana, sponsored by the Louisiana Board of Regents and the Louisiana Recovery Authority (BOR, 2007). Recognizing the lack of R&D experts to assist in the further development of early-stage technologies, PBRC and PBRF key individuals, along with PBRC faculty, expressed the need to be able to access such outside expertise. Faculty suggested some form of mentoring or coaching for inventors as a possible

solution as a development plan for early-stage technologies, which was reinforced by the consultant, who suggested that the GRA VentureLab model could be implemented. PBRC faculty and key individuals also recognized the importance of recruiting senior scientific experts to PBRC who have expertise in or who want to focus on commercialization, and are exploring using some form of the Eminent Scholars program as a model (PBRC internal documents, 2007).

The Louisiana Board of Regents, the Louisiana Recovery Authority, and the Baton Rouge Area Foundation also found many aspects of the GRA model, including the Eminent Scholars program, as a model that can be adapted for the state of Louisiana (BOR, 2007). In that case, PBRC could benefit from such a statewide academic recruiting initiative.

c) Springboard for New Companies:

Of the three models studied, the one which contains the most comprehensive and overall successful springboard for new companies is the GRA model, which has launched more than 125 new companies since its inception in 1990. More than 5,000 new jobs have been created as a result, and more than $600 million in private investments in these new companies has occurred. The program has also fueled partnerships with more than 100 Georgia companies. The combination of a narrow focus along with well-developed, strategically integrated phases of commercialization funding and R&D expertise all play into a successful springboard for new companies (GRA, 2007).

The GRA VentureLab phases contain specific requirements which are paramount to R&D activities and formation of new companies. These requirements include the further development of the technology, design and implementation of a business plan and coordination of the Eminent Scholars' funding sources, which leads to solid new start-up companies. This

series of phases provides progressive steps in an overall process geared toward commercialization success (GRA VentureLab, 2007).

Even with such a successful program, an early-stage funding gap still emerged, despite the comprehensiveness of the GRA economic plan for new company development. As a result, three of the six GRA research universities combined with private partners to create a special early-stage biotechnology funding source called the Georgia Venture Partners Fund. The GVP has helped to bridge the gap between nascent biotechnologies and the next stage of commercialization. GVP has recently begun to invest in early stage technologies (GRA, 2007; GVP, 2007).

In contrast, PBRC has had mixed results related to a springboard for new companies. On one hand, the TVP venture fund has been very supportive as a springboard for new companies for the few technologies it has invested in, but TVP has declined to invest in the majority of technologies it has reviewed. TVP cites the early-stage nature of the inventions as its reason to decline investment. Currently, PBRC and PBRF are analyzing multi-tiered commercialization programs to further develop these early discoveries. Focus is on R&D expertise and VentureLab-type funding and also on recruiting faculty who have experience in commercializing (PBRC internal documents, 2007).

It appears that the state of North Carolina also has had mixed results as a springboard for new companies. Even with its cache of local highly-skilled R&D experts, the success of new company start-ups in North Carolina has been inconsistent. Although the state established the North Carolina Bioscience Investment Fund (NCBIF) several years ago, its main funding source remains the state, although some new high-skilled, high-paying jobs have been created since its inception. As recently as late June, 2007, the NCBIF was undergoing restructuring efforts while

the ties between NCBIF and the Eno River Capital fund were under review (Weisbecker & John, 2007, 2007).

The UCSD model is ranked number one by the Milken Reports (2004; 2006) in terms of new start-up companies created and still in existence. Even so, there is a growing concern over the high cost of living in the San Diego area, which is crucial when new start-up companies are trying to recruit new Ph.D.'s, support scientists, and management teams (Coombs, 2007).

This research study has shown that, overall, the three models are often different from each other as well as from the UCSD model. As a result, a revised version of the comparison chart is presented below (Table 6). In almost every category, there are some changes in the assessments as to whether or not a component is present, absent, or appears as a hybrid or in partial form. A simple yes or no answer often is not an accurate reflection of the presence or absence of specific components. Sometimes, pieces of a component exist, or a hybrid situation occurs. This broader interpretation of the five essential components could assist academic research universities in determining what is necessary for commercialization success at their particular institutions.

Table 6. New Comparison Chart for Academic Biotechnology Commercialization – 10 Key Components

KEY COMPONENTS	**UCSD Best Practice**	**UNC Model**	**PBRC Model**	**GRA Model**
Small Size of Institution	Y	N	Y	N
Higher than Norm for Research Money per Biosciences Faculty	Y	N	Y	Y
Extremely Entrepreneurial Community	Y	Y	N	Y
Integrated Life Sciences Curriculum Program	Y School of Medicine and Graduate School Program (COILS)	N	N	N
Integrated Commercialization Track ➢ Funding ➢ R & D Expertise ➢ Springboard for New Companies	 Y Y Y	 N Y Y	 Y N TBD	 Y Y Y
Structured, highly focused commercialization program with measured outcomes		N	P	Y
Critical mass of bioscience researchers Focused on commercialization		N	P	Y
Work force development program		Y	N	N
Cross-collaboration programs		TBD	N	Y
Faculty incentives and rewards for commercialization		TBD	N	Y

Y = yes
N = no
TBD = to be determined
P = partial
UCSD = University of California - San Diego
UNC = University of North Carolina at Chapel Hill
PBRC = Pennington Biomedical Research Center
GRA = Georgia Research Alliance

Implementation Model for PBRC

Based on this study, restructuring of the PBRC model in the following manner is recommended:

1) Small size of the institution – Even though PBRC fits the definition of a small-sized organization, this study pointed out that other characteristics related to organizational structure might be as or more important, namely being efficient and effective. Improvements can be made in the overall organizational operations of PBRC by adopting the specific projects and programs outlined in this section, such as a version of GRA's VentureLab, an Eminent Scholar program for those committed to commercialization, and specific funding mechanisms.
2) Higher than normal ration of research dollars per faculty – Since PBRC has met this criterion when assessing the ratio for all of its faculty, the future focus should be on recruiting and retaining researchers with a specific focus on commercialization who possess this higher ratio of research dollars.
3) Extremely entrepreneurial community – PBRC can increase the opportunities for commercialization-focused researchers to become more entrepreneurial using a version of VentureLab. In addition, more programs should be developed to provide entrepreneurial information and R&D education and training for researchers.
4) Integrated life sciences program – Since PBRC does not educate students, a faculty version of this integrated program could be implemented based on funding Eminent Scholars who focus their research on commercialization.
5) a) Funding – PBRC and PBRF should adopt some version of GRA's VentureLab and its Eminent Scholars programs and also develop a corporate sponsorship program.

b) R&D expertise – PBRC and PBRF can develop mechanisms to assist with the R&D expertise needed to move their early-stage biotechnologies along the commercialization continuum by engaging consultants and through the adoption of some form of the VentureLab program.

c) Springboard for new companies – PBRF can provide loans to new companies and develop a mechanism for equity ownership. PBRF should develop programs to assist with new company formation, management initiatives, and other new company activities in some manner.

6) Structured, highly focused commercialization program with measured outcomes – PBRC and PBRF should incorporate these evaluation measures in its Eminent Scholars programs, its new research and development funds, and in its corporate sponsorships program.

7) Provide a critical mass of bioscience researchers focused on commercialization – PBRC and PBRF need to focus on recruiting this nucleus of specialized researchers and provide them with significant research and laboratory funding as a catalyst for increasing inventions and discoveries and developing more mature technologies.

8) Work force development program – PBRC should partner with other higher education institutions which will be educating and training this workforce. PBRC also has an opportunity to provide its own work force development in terms of postdoctoral training that focuses on commercialization. The NIH CTSA grant application is one program for developing this cadre of a more sophisticated biotechnology workforce.

9) Cross-collaboration programs – PBRC should promote new ideas and provide grants for researchers who will collaborate with other researchers focused on commercialization.

10) Faculty incentives and rewards – PBRC promotion and tenure should include recognition for commercialization activities. Faculty release time for working with new company formation and further R&D should also be implemented.

The PBRF also can develop a mechanism that will provide for some direct payback to PBRC, and therefore, the university, with regard to further research funding, as a way to continue the mission of the Center and the LSU System. Although PBRC is mentioned in most of the ten components listed above, the involvement of PBRC and PBRF should be assessed in order to determine which entity would better be able to carry out that particular component.

Recommendations for Other Public Research Universities

Several of the key components analyzed as part of this study were found to be essential for early-stage biotechnology commercialization success, while others were not necessarily essential. One of the most significant findings from this study that can be applied to other public research universities is that it is not necessary for all components for commercialization success to be present in order for an academic entity to be successful at this endeavor. At the same time, it appears that the following original key components should be present, at least to some extent to help ensure success related to the formation of start-up companies. These three components form a confluence of factors considered essential for successfully moving technologies along the commercialization continuum:

1) organizational efficiency,

2) a highly entrepreneurial community, and

3) an integrated commercialization track
    a) funding for new biotechnologies,
    b) research and development expertise, and
    c) a springboard for new company development.

Two components warrant further study to determine whether or not they might be advantageous in specific academic settings. Due to the nature of the three models which were analyzed in this study, these components could not be studied in-depth. The components noted for further study are presented below.

1) the ratio of research money per bioscience faculty; and
2) an integrated life sciences curriculum program.

In addition to the existence in some form of the five original components listed above, it also appears that the following new components are necessary, at least to some extent, in order to produce commercialization success:

1) creating a structured, narrowly focused funding gap program which includes outcomes measures and an ongoing evaluation process;
2) achieving a critical mass of bioscience researchers, including translational researchers, focused on commercialization;
3) creating specialized workforce development programs,
4) creating cross-collaboration to promote new areas of discovery, and
5) creating faculty incentives and rewards for commercialization.

Unintended Consequences

One of the main goals of this study was to explore the possibility of finding a hybrid solution to the myriad of unintended consequences related to academic biotechnology

commercialization. Concerns were raised regarding the issue that some technologies are not ready to be commercialized or should never be commercialized. To deal with this issue, an institution can implement a version of the GRA VentureLab program that assesses the commercial possibilities for technologies. If it is determined that the technology should not be further developed, even if funds are available, then the technology should be released for the public good so that this knowledge can be disseminated to support the overall research initiative. If the technology shows promise but is early-stage, then the organization can create an early-stage R&D program which also includes funding to further develop the technology.

Faculty roles were also discussed. The GRA Eminent Scholars program hires and funds scientists who are expected to commercialize their inventions and discoveries and are encouraged to become part of start-up companies. Rewarding faculty for commercialization activities and including these successes in promotion and tenure decisions reinforce the importance of economic development. Some universities have developed formal processes that document faculty ownership in companies and manage their other conflicts of interest.

There are also ways to preserve the mission of the research university while encouraging commercialization activities. University foundations can play a central role in the licensing and equity activities surrounding invention commercialization. Foundations are created to support the mission of the university but have more flexibility in such activities to carry out this goal. Venture funds can allocate a portion of income back to the university to support academic activities, which is part of the Georgia Venture Partners Fund mission.

Overall, there are ways to manage conflicts of interest and other unintended consequences while still preserving the mission of the public research university. Examples exist where the commercialization process brought revenues back to the academic institution to

support other teaching and research programs. In other instances, the public health of the population benefits from new medical treatments or drugs or society overall benefits from the technology.

Other Findings

In addition to all of these key components, other findings have emerged regarding university commercialization. In all three models studied, it was very important to have the ability to take an in-depth look at what type of organization and culture already were in place and what other initiatives were planned or in existence prior to determining how a develop a better program. There have been examples in higher education of the "me, too" syndrome, where universities push quickly to adopt a model from another institution without regard for differences in institutional structure and cultures, and not spending adequate time analyzing and assessing the models being considered. Often, the key players who could best weigh in on the factors necessary to make an informed decision are not included in the decision-making process.

Chapter 2 discussed how this "me, too" scenario played out at many academic health centers (AHCs) after the introduction of managed care, and described the devastating results due, at least in part, to the lack of analysis and assessment prior to implementation of new AHC models. Loyola University of Chicago and other academic institutions suffered substantial unintended consequences due to the quick adoption of another institution's model as is.

Biotechnology commercialization is a fluid, complex area that requires much study and review by many experts in order to possibly implement the best model for any institution which is looking to expand, revise, or create a well-designed and effective commercialization mechanism.

To this end, a level of ongoing flexibility in terms of program creation and adaptation was apparent in all three models studied. The Georgia Research Alliance has seen the creation of an ancillary program, the Georgia Venture Partners Fund, which runs in parallel to its own commercialization program. The Pennington Biomedical Research Center is developing a more comprehensive, multi-tiered approach to early-stage biotechnology development due to the realization that having a venture fund in place was not enough on its own for commercialization success. The state of North Carolina is in the process of restructuring its North Carolina Bioscience Investment Fund (NCBIF) after several years of existence.

Restructuring or reformulating the commercialization model can take place while there are ongoing, working, successful components already in place. This ability is important in the biotechnology industry, which is still a relatively young industry which often must respond quickly to numerous marketplace shifts.

In addition to flexibility in the commercialization structure, those who are the key individuals involved in these activities need to be comfortable with risk-taking and thinking in non-traditional ways. This is evidenced in the need for a flexible, non-bureaucratic organizational structure, the existence of a highly entrepreneurial culture, and the ability to change and adapt to a high-paced, evolving industry.

Conclusion

This exploratory study analyzed how to commercialize nascent academic biotechnologies while preserving the mission of the public research university. Although some components were regarded as being key to commercialization success, others were viewed as optional or only necessary in part. At the same time, new components were identified as being instrumental in

the commercialization process. Mechanisms for reducing or eliminating unintended consequences related to the commercialization process have also been studied and discussed.

Since this study has been exploratory in nature, further analysis is recommended. Regardless of which components might be considered for inclusion in a new or revised model, it is recommended that an in-depth assessment of the academic institution itself be conducted prior to the time when that entity creates and implements its own early-stage commercialization model.

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APPENDIX A

Several key individuals participated in this research study. Below is a listing of them by category. Each individual has been assigned to only one category.

Community	3
Consultants	7
Faculty	9
Foundation	4
University Administrators	5
TOTAL	28

APPENDIX B

As described in Chapter 3, this exploratory study contained both individual interviews and focus group sessions. These two interview methods included general and specific questions as described below.

Individual Interviews

Many of the individual interviews were based on a particular topic or issue. The questions in those sessions began with the topic at hand and then broadened to include more general questions. At other times, the questions began in a more general, or grand-or mini-tour fashion and then became more specific, often using probes to gain specific information. Questions included the following:

Community:

How is academic technology transfer perceived in the community?

What advice do you have that would help gain community support?

What are the most significant advantages/barriers to promoting the entrepreneurial culture?

Consultants:

What parts of the commercialization model do you think would work/not work for this particular setting?

Have you seen the same difficulties or roadblocks or successful routes regarding commercialization in the different projects you've seen?

What other commercialization models would you suggest be studied?

Faculty:

What ideas or ways do you believe might help you to move your technology further along in the commercialization process?

What activities could help this transition from your research lab to start-up company?

What topics would you like to see offered in educational and training sessions about technology transfer?

Would you like to see changes made to promotion and tenure in terms of your commercialization activities?

Foundation:

What role do you see the foundation playing in the commercialization process?

Are there specific programs or projects you would suggest be implemented at the foundation level to help in setting up (topic) or in developing (program)?

What other foundation models would you suggest be studied?

University Administrators:

What difficulties/successes have you encountered in your commercialization process regarding early-stage inventions and discoveries?

Does this specific commercialization process work for you or would you change any part of it if you had the chance now to develop it over again?

What specific roadblocks or unexpected difficulties should one be aware of when trying to set up (blank)?

Focus Group Sessions

Focus group sessions were structured around the general topic of technology commercialization. The following exploratory and explanatory questions were asked in a grand- or mini-tour fashion. Time was allotted for general discussion of the topic. After some discussion, more specific questions were asked about some of the comments made. Some of the

individual interviews followed the focus group sessions when individual follow-up was seen as important. Questions included the following:

Exploratory/Explanatory (Grand- or Mini-Tour) Questions:

What has been your own personal experience regarding technology commercialization?

How do you believe the overall academic commercialization process could be improved?

More Focused Questions:

What other commercialization models would you suggest be studied?

How important do you believe the following key components are regarding successful commercialization of early-stage biotechnologies? (included questions based on the list of the 5 key components from Table 1)

Questions Asked in Both Types of Interviews

What have you learned in the commercialization process?

Is there anything else you can think of that we haven't discussed that you believe is important regarding this topic?

Is there anything that you were surprised or did not expect you would learn or realize regarding this topic?

What can be done to help resolve the conflicts regarding (faculty roles, the mission of the public university, academic/industry relationships)?

VITA

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Ms. Jarrett attended Youngstown State University and then received a Bachelor of Arts degree from The Ohio State University in Columbus, Ohio. She went on to earn a masters degree in Health Policy and Management from the College of Public Health at the University of South Florida. She then conducted research at the National Cancer Institute (NCI) Designated Moffitt Cancer Center in Tampa, Florida, focusing on health care cost-effectiveness and quality of life for the terminally ill. Moving to Louisiana, she became the Director of Research and Program Development for the Stanley S. Scott Cancer Center at the LSU Health Sciences Center in New Orleans, Louisiana. In 1999 and 2000 respectively, Ms. Jarrett earned her J.D. and L.LM. (International & Business Law) degrees from Stetson University College of Law in St. Petersburg, Florida, and her MBA from Stetson University Graduate School in Deland, Florida, in 1999. While in law school, Ms. Jarrett was employed by the Patents and Licensing Office of the University of South Florida in Tampa. She will complete her studies for the Doctor of Philosophy degree at Louisiana State University in December 2007 in the Department of Educational Theory, Policy and Practice.