

Profiles of four projects in Biotech Business

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**Copenhagen
Business School**
HANDELSHØJSKOLEN

Biotech Business Working Paper No. 01-2004

Profiles of four projects in *Biotech Business*

By Finn Valentin



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Abstract

In April 2004, Copenhagen Business School opens a centre for research on biotech business. *Biotech Business* includes a number of senior and junior researchers from CBS. Initially the centre takes its point of departure in four projects included in the research program on *Competence, Organisation and Management in Biotech Industries (COMBI)*. Starting in March 2004, COMBI is funded jointly by The Danish Social Research Council, firms and organisations in the Danish biotech industry and CBS. This presentation refers exclusively to four COMBI projects.

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Competence, Organisation and Management in Biotech Industries (COMBI)

A programme for joint research between CBS and representative firms and research organisations in Danish biotechnology.

I	PROGRAMME OBJECTIVES, ISSUES AND ACTIVITIES	3
1	PROGRAMME OBJECTIVES.....	3
2	MOTIVATION	3
3	DEFINITIONS AND FOCUS	4
4	PROJECTS AND THEIR SYNERGIES	4
5	WHO PARTICIPATES.....	8
6	ACTIVITIES AND PROGRAMME MANAGEMENT	8
II	RESEARCH PROJECTS IN THE COMBI PROGRAMME	10
1	INDUSTRY AND FIRM DYNAMICS IN DANISH BIOTECH (BIO-DYN).....	10
2	KNOWLEDGE PROTECTION AND DIFFUSION IN UNIVERSITY-CORPORATE PARTNERSHIPS IN BIOTECHNOLOGY (UNI-COR).....	13
3	ORGANIZATION AND MANAGEMENT IN THE BIOTECHNOLOGY FIRMS (ORG-MAN)	15
4	UNDERSTANDING THE PROFITABILITY OF DANISH AND OTHER BIOTECHNOLOGY INVENTIONS WITH THE HELP OF INDICATORS (IN-PROF).....	18
5	REFERENCES	21

Objectives, issues and activities

Programme objectives

The research programme on *Competence, Organisation and Management in Biotech Industries (COMBI)* will study Danish biotechnology with the following main objectives:

- To generate new data that will allow a comprehensive analysis of Danish biotechnology and its exchange with its key environment of public science, venture capital and the pharmaceutical industry.
- To develop and apply novel approaches in quantitative analysis of e.g. R&D profiles, innovation networks, and the value of patents.
- To expose and develop COMBI research in an ongoing dialogue with the Danish biotech community on issues of managing science-based firms and on trends in the key context of the sector provided by venture capital, public science and the pharmaceutical industry.
- To enhance theoretical understanding of issues of management, organisation and competitiveness in science-driven sectors.

Motivations

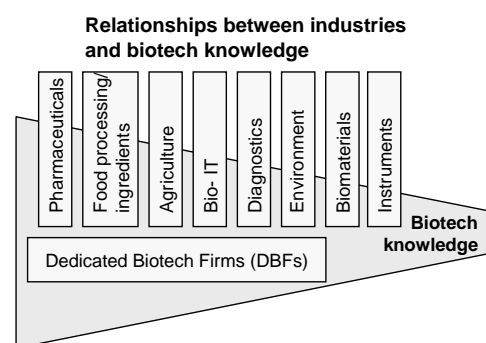
- The Øresund Region, and Denmark in particular, holds one of several agglomerations of biotech firms that have emerged in the US and in Europe since the mid 1980s. Like their counterparts in other regions, Medicon Valley (MV) firms have evolved through a complex interaction between science *opportunities*, venture *capital* and *markets* for research and for research-based products. This project will produce a long overdue systematic *mapping and analysis* of the MV population of firms in terms of these interactions. This mapping will be of interest not only to DBF firms, but also to the VC sector financing them, to science institutions reflecting on new strategic mandates, and to policy institutions.

- Biotechnology, as a wholly science-driven business, brings out *with unusual clarity* a set of issues that increasingly appear also across a broader spectrum of industries. That includes issues pertaining e.g. to i) the management of entirely immaterial/ knowledge-based processes, ii) difficulties in assessing the value of its assets and products and hence in mobilising venture capital, iii) challenges in organising and iv) defining the role of public science in industrial innovations. Biotechnology is a “laboratory” allowing us to study in a pure and early form these issues, the implications of which go far beyond the specific biotech sector.
- Precisely for this reason biotech is a highly informative field for applying and developing theories targeted at these broader issues of knowledge-based firms and economies. That includes theories on the role of science in innovation and firm performance, theories on IPR and appropriability or inter-organisational co-ordination.

Definitions and focus

Biotechnology has become an ambiguous term and needs delimitation. In its modern version biotechnology refers to a body of techniques and technologies applying genetics, immunology, molecular, cellular structural biology for discovery and development of new products. It is increasingly being applied in different industrial sectors, with pharmaceuticals being by far the largest arena for industry-specific biotechnology (Allansdottir et al 2002; Audretsch 2000).

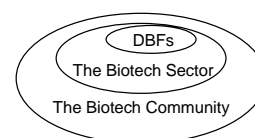
Traditional sectors like agriculture and food processing (ingredients) are increasingly building their industry specific knowledge on biotechnology, and it is also becoming the knowledge basis for new industries, including biomaterials and environmental technologies. Of particular importance is the emergence of a new industry of firms undertaking biotech-based R&D without further downstream activities, normally referred to as Dedicated Biotech Firms (DBFs). They deliver inputs to R&D of pharmaceuticals, and they develop tools and methodologies for biotech R&D.



We use the term “biotech sector” to denote both its core of DBFs and also other firms drawing substantially on biotechnology and having at the same time further downstream activities within specific industries (i.e. including pharmaceutical firms and producers of ingredients as inputs to industrial processes like Novozymes, Danisco, or Chr. Hansen etc.). The biotech sector also includes organisations in public research and health-care in cases where their activities primarily involve biotechnology or rely on its underlying knowledge base.

Finally, the term “biotech community” expands the delimitation to include associations like Medicon Valley, the Øresund Food network and bodies of public administration with a focus on biotech.

Center and periphery in the bioitech sector



As evident from the project descriptions below, COMBI research is focused on several major areas of the Danish biotech sector, but particular emphasis is placed on the study of DBFs.

Projects and their synergies

COMBI research is organised into four distinct research projects:

- *Industry and firm dynamics in Danish biotech* (= BIO-DYN, c/o Finn Valentin) studies developments of DBFs, and their key external relationships to e.g. venture capital,

universities and pharma-firms. The project generates and analyses quantitative data from its proprietary construction of a comprehensive database of all Danish biotech firms, referred to as DABIT.

- *Organisation and management in biotech firms* (= ORG-MAN, c/o Jesper Norus) studies research management and strategy in DBFs, using new structured case-observations and quantitative data from DABIT.
- *Knowledge protection and diffusion in university-corporate partnerships in biotechnology* (= UNI-COR, c/o Lee Davis) studies the implications of university-corporate partnerships as regards the commercial development of valuable new ideas in biotechnology. The project is based on quantitative analysis of proprietary, new data from a survey of public scientists in biotechnology. Data is exchanged with DABIT records.
- *Understanding the profitability of biotechnology inventions with the help of indicators* (= IN-PROF, c/o Markus Reitzig) develops an empirical test of patent indicators as value measures of biotechnological inventions in the structural form.

The theoretical and methodological underpinning of each project will be presented in Section II. In this introduction, we only discuss their shared point of departure. The key characteristics of the biotech sector, and the analytical issues addressing them, may be summarised as follows:

1. Having research as their main activity, biotech firms are directly exposed to the turbulence of global advances in the life sciences. Advances in basic research directly generate changes in the agenda of applied research. The inherent creative destruction of this research frontier (Darby and Zucker 2001) translates almost immediately into instability of both strategies and business models in biotech firms (Stankiewicz 2002).
2. Consequently the biotech industry is highly dependent on early and fast access to scientific novelties, making their linkage to *early insights* a key concern. Studies indicate that public science may provide this early insight (McMillan et al 2000), as long as it operates at the frontier of global science and is well connected to the biotech industry. It matters therefore to have both top quality public science *and* to have it effectively linked up to the biotech industry (Valentin 2000).
3. This linkage takes different forms and varies across countries. The US linkage-model of “scientists-turning-entrepreneurs” (Zucker et al 1994) appears less frequently in continental Europe, as does licensing of patents based on university research in the life sciences (Fuchs 2003). Legal regulation affecting patenting propensity amongst university scientists may therefore significantly affect their outward flow of opportunities towards the biotech industry (Mowery et al 2001). That is the reason why one *COMBI* project undertakes a thorough study of appropriability of university science, including its feedback effects on the agenda of public science.
4. Public science, however, is far from being the only source of “early insights”. With the increasing role of effective *research technologies*, connectivity *between DBFs* with different specialisations assumes growing importance. The division of labour in biotechnology no longer takes the form of a simple vertical disintegration, where DBFs feed discoveries into the processing and commercialisation machinery of big pharma. DBFs bundle discovery activities into several quite different business models (e.g. platforms, pipeline orientations etc.), or they focus on specific research tools or specialised research services to be used by other DBFs and by big pharma in their discovery activities. Complex horizontal and vertical relationships are developing between DBFs (Arora et al 2001). As a consequence, it matters little that a region – like the Copenhagen area – has a concentration of biotech firms. What matters is really *what type* of biotech industry we are talking about: How is it specialised amongst the many different DBF models? What types of inter-linkages and synergies grow

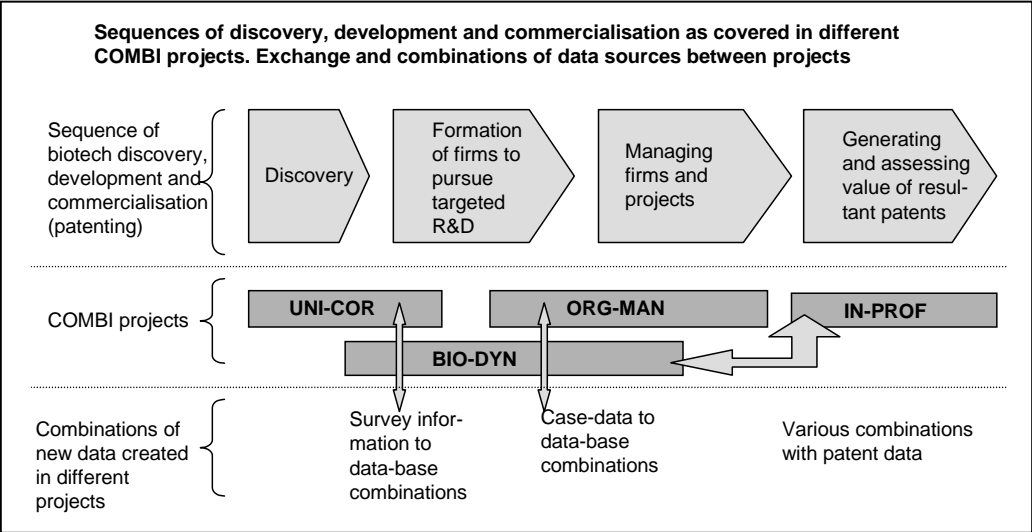
out of this specialisation between firms and between the DBF industry and its infrastructure (e.g. public science, venture capital etc.)? The more exact profile on these dimensions of a specific biotech industry is critical for its long-term development (Casper 2000) (Braunerhjelm et al 2000). Mapping and analysing the Danish DBF industry in these terms appears not to have been undertaken in any previous exercise. Given the significance of biotechnology for the Danish economy and its policy priority, this exercise is long overdue, and it will constitute one of the key research activities in *COMBI*.

- Given the high uncertainties of biotech R&D, *venture capital*, not surprisingly, has come to play a key role. To minimise risks, venture capital increasingly seems to be directing investment flows away from the early, high-risk discovery phases of biotechnology. Instead they focus further downstream, often requiring “proof of concept” to have been reached before investing. Improved methods to analyse both risks and value potential of biotech firms would facilitate venture financing to more firms in these critical early stages (Gompers and Lerner 1998).

These characteristics and issues are highly interconnected, and the COMBI research agenda should reflect these connections. Even though COMBI has four distinct projects they nevertheless form one coherent program, studying closely connected phenomena in the biotech sector and analysing them from related theoretical points of departure. Above all, what gives coherence and synergy between projects is that they address the same underlying issues. The table below gives examples of four such issues (although more could be added) and examples are presented of how they are addressed in each project.

Issues appearing across all projects	How issues are addressed in each COMBI project			
	BIO-DYN	ORG-MAN	UNI-COR	IN-PROF
What types of biotech companies are profitable over time?	Mapping which companies survive and prosper over time (which factors are important?)	Development of production skills and manufacturing capabilities	Do companies that cooperate heavily with university scientists tend to succeed better than those that don't?	Are there specific differences between corporations in the Øresund region and other firms?
What types of biotech inventions are profitable over time?	Mapping the evolution of different categories of biotech inventions	Understanding how markets are created for research outputs of DBFs	How have university scientists contributed to these successes?	Are there specific differences between therapeutic targets and other relevant biotechnology inventions?
What types of collaborations foster success?	Mapping effects of different types of collaborations on company survival rates	Development and management of knowledge in inter-organizational networks	How can partnerships between universities and companies best be structured?	Are patents held by biotech firms that collaborate with public researchers or other firms more valuable?
What are the implications for science and technology policies?	What government incentives are associated with increased success rates?	What government incentives best support successful policies?	What are the larger societal implications of increased collaboration between public scientists and biotech firms?	How does the adjustment of patentability requirements affect innovation incentives?

Furthermore, projects have been selected and designed so that they *together* cover different stages of biotech R&D, going from discovery (e.g. of new therapeutic targets) through development, until resultant patents are claimed and have their value assessed. The figure below positions each project in this sequential logic. The figure also shows how data creation in any one COMBI project benefits from being informed and combined with data from other projects.



Who participates

The program draws on a substantial body of work undertaken not only by CBS researchers but also by managers and staff from nine additional different firms and research organisations.

CBS researchers include three associate professors and one assistant professor, each affiliated with one of the four above projects. Their CVs are presented in Appendix D. They come from two different CBS departments and represent specialised research experience in economics, organisational analysis, and innovation studies.

These four CBS researchers are well connected to the global research environment on the management, organisation and economics of biotech. Several internal visiting scholars will join us for work on specific research issues.

When the program is ready to begin its work (Jan.2004) this team will be extended with:

- Two post docs, one of whom is financed by CBS internal funding to match the one post doc applied for from LOK funding.
- Five PhDs, three of whom are financed jointly by Novo Nordisk and the Fenix consortium of Danish and Swedish firms and research organisations. One PhD is financed by CBS internal funding to match some of the industry funding specifically made available for PhD training in issues relating to biotech business studies. Moreover, one PhD is affiliated through a collaboration agreement with Risø National Laboratories (Research Group on Technology Scenarios).

The nine partner organisations represent a variety of issues and experience. Several DBFs are involved, as are venture capital firms and organisations with particular mandates for contributing to Danish biotechnology.

- Pipeline Biotech
- NOVO A/S
- Bioteknologisk Institut
- BankInvest
- Medicon Valley Academy
- Scan Balt
- The Fenix consortium of Danish and Swedish firms and research organisations, including NOVO Nordisk
- Risø National Laboratory

The PhD collaboration with Risø has not been included as part of program funding, since this would violate LOK requirements not to include other public funding as part of co-financing.

Activities and programme management

The key activities of the programme are to carry out the four research projects outlined in Section II of this proposal. However, this activity will involve substantial interaction with the above partners from the Danish biotech community. From them, data and experience will be extracted and analysed, and each firm receives feedback from the research to which they have contributed. On an informal level there will be an ongoing exchange within each project.

Furthermore, regular seminars will provide a meeting place for programme researchers and the Danish biotech community. Here, progress in research will be reported, international guest researchers will present recent work, and programme partners may share their experiences. Annual one-day conferences will be arranged, in the final year of the programme transformed to an international conference on the management and economics of biotechnology. We hope to make these shared arrangements an interesting forum for researcher-practitioner dialogue, and a substantial share of the sub-budget serves that purpose.

Research stays abroad are planned where substantial programme benefits may be expected, as in the cases of Jesper Norus visiting Prof. David Finegold, Keck Graduate Institute of Applied Life

Sciences, Claremont Colleges, California, or Markus Reitzig further developing his econometric modelling of biotech values in collaborative work with Prof. Bronwyn Hall (UC Berkeley) and Prof. Timothy Devinney (Australian Graduate School of Management).

The programme will be directed by Finn Valentin. An advisory board will be established with representatives from partner companies and institutions. Annual meetings will be held between the advisory board, the senior scientists and the program director.

Research projects in the COMBI programme

Industry and firm dynamics in Danish Biotech (BIO-DYN)

Finn Valentin

Objectives

This project (BIO-DYN) contributes to our understanding of how science-based firms emerge, perform and develop. The project pursues the four following objectives:

1. To improve our understanding of science-based firms and industries by analysing Danish biotech firms in terms of their emergence, development, performance, and their external linkages to the wider biotech sector
2. For this purpose to build a complete panel database of Danish DBFs, mapping each firm in terms of its performance, internal characteristics, and main external relations since its establishment and onwards. This DAnish BIotech Database is referred to as DABIT.
3. Using the database to address theoretical issues at the firm-level and at the mezzo-level of relationships between DBFs and other key actors within the biotech sector, e.g. universities, venture capital, pharmaceutical firms. DABIT data will feed not only into the three BIO-DYN sub-projects summarised below but also into other projects within the COMBI research programme.
4. To subsequently regularly update the database to allow ongoing monitoring of and further research on Danish biotechnology.

Scientific context and motivation

Current advances in the literature provide a general basis for the more confined issues presented below for each of the sub-projects:

Direct utilisation of recent research plays an increasing role for industrial R&D in technology intensive sectors (McMillan et al 2000), stimulating analysis of science as an endogenous component in economic development (Rosenberg 2000).

Science translates into economic activity contingent on institutional arrangements. Institutions shape e.g. how spillovers from academic science migrate into private R&D, or how inventions get connected to finance (Audretsch and Stephan 1999). Adequate venture capital (VC) in particular has been acknowledged as essential for the success of US firms in biotechnology (Henderson et al 1999). But the exact ways in which characteristics of VCs (size, experience, specialisation), shape and influence investment targets have barely been addressed in systematic research (Nilsson 2000). Similarly, the effects of specific institutional arrangements linking academic science to industry are beginning to be explored (Geuna 1999; Larédo and Mustar 2001; Valentin 2000).

BIO-DYN will contribute to further theoretical understanding of the organisation and the economics of science-based business, based on the mapping of how an entire national science-driven sector emerges and develops.

Empirical design

DABIT maps all Danish DBFs (app. 80) on a broad set of attributes, e.g.

- Type of origin (spin-offs from university departments, from other companies etc.)
- Activity level (staff, number of scientists)
- Main type of biotech activity (tool providers, platform, pipeline etc.)
- Research field (disciplines, research specialisation, therapeutic targets)
- Collaboration with external research (in universities, other firms etc)
- Venture capital generated (volume and sources) and burned
- Output: Patents, publications etc.
- Sources of revenue (royalties, research services, products)

With archival data these parameters will be reconstructed for each firm for each year since the firm's establishment (in most cases meaning 1995 onwards), and of course updated systematically. DABIT will draw on multiple sources of data, benefiting from the general high level of documentation that characterises pharma-related activities (e.g. rich patent information and scientific publications in highly effective search architectures, as exemplified in e.g. (Gittelman and Kogut 2003)). Annual reports from firms tend to be highly informative. To this may be added conventional sources like firm records in e.g. The Danish Commerce and Companies Agency. Specific information not available through these channels is retrieved through interviews. This configuration of data, and its coverage of Danish DBFs, exceeds what is offered by existing proprietary databases.

In addition to mapping firm-level characteristics, for a number of variables the unit of observation will be the single project within each DBF, applying the methodology found in e.g. (Henderson and Cockburn 1996). An average of 5-10 projects per firm will generate 400-800 data-points on each variable.

An essential condition for accessing and interpreting information on individual DBFs is the close collaboration with the biotech community. This is where the collaborative arrangement of *COMBI* will offer a unique opportunity for a more fine-grained mapping.

DABIT's data architecture facilitates analysis with both panel and structural approaches, and patterns of morphology of individual firms may be identified. Correspondence and exchange with related database projects in other countries will be pursued (e.g. the Siena University BID-database on global biotech collaborations (Orsenigo et al 2001), or the Ohio-Sweden comparative project (Carlsson 2002)). This potential for a comparative exploitation of DABIT is an attractive platform for research collaboration with the international research frontier in this particular field (Fuchs 2003).

Analysis of DABIT data will allow analysis of a variety of issues. Within the funding from this proposal BIO-DYN will use the database for analysis in the three following sub-projects.

Subprojects

Sub-project 1: Science-based businesses and theories of the firm

CBS allocates one PhD to this sub-project.

Competence-based theory of the firm invites us to examine the basis for value-creation in biotech firms. In many respects the knowledge resources of DBFs, in their constitutive forms, resemble what is found on “factor markets” of advanced public science. Where this is the case, how do biotech firms nevertheless achieve a Penrosian transformation of public knowledge into value creating capabilities? Is differentiating performance of DBFs in research output (and timing) driven by uniquely co-specialised DBF-internal bundling of competencies (Foss and Mahnke 2003), as a competence-based view would have it? Or is it rather driven by transaction cost advantages, derived from superior assessment of external opportunities and from the ability to access them in shifting collaborations and consortia? The latter approach would see superior DBF performance as based on transaction cost advantages, along the lines recently suggested by (Amit and Zott 2001) or (Dyer and Singh 1998). These two theoretical foundations – competence-based views and transaction costs – bring out very different interpretations of science-based value creation in DBFs. DABIT offers opportunities for analysis from either perspective.

Sub-project 2: Assessing value and potentials of DBF

Strategy-oriented analysis referred to in Sub-project 1 also may inform studies of venture capital financing of DBFs. There is a shortage of analytical approaches guiding valuation of DBFs in their early stages. Consequently, venture capital tends to focus on DBFs beyond the stage of “proof of concept”, while investors find it prohibitively difficult to assess the potential value of inventions in their early stages.

With the patent information and the scientific publication details available in DABIT, we may apply standard bibliometric tools (Jaffe and Trajtenberg 2002; Grupp 1998) to explore if the value potential of DBFs may be indicated at earlier stages. Further bibliometric analysis would examine how the knowledge configuration and/or the external network patterns of DBFs (as reflected e.g. in co-authorships) relate to their profitability. This analysis would draw on tools going beyond the standard bibliometric repertoire, using methodologies we have introduced in recent work (Valentin and Jensen 2003a).

Sub-project 3: A systems perspective on the Danish biotechnology

This sub-project addresses issues at the level of “systems of technologies” (Stankiewicz 2002; Carlsson 2002), inquiring how the specific *Danish biotech technology system* affects patterns at both firm and industry levels. I.e. how individual firms extract advantages, or drawbacks, from their surrounding system of innovation, as reflected e.g. in the composition of their networks of innovation (applying tools for quantitative network analysis presented in (Valentin and Jensen 2002; Valentin and Jensen 2003b))? How patterns of specialisation in a research-based industry co-evolve with its institutional framework of science and capital markets? What sources of origin are particularly important for spinning off Danish DBFs e.g. universities or other pharma- or biotech firms? What research fields are pursued, and which type of activity (tool providers, platforms etc.) is their objective? How does revenue formation (type and timing) vary across different categories of DBF activities? How does infusion of new venture capital affect DBFs in terms of focusing their business models?

Key elements in the national framework of Danish biotech are currently undergoing change: New regulations apply to university patenting, and recent reports from the universities indicate effects on commercialisation of academic research to be

significant, although very different from those intended in the legislation. From another angle, venture capital increasingly brings biotech firms to focus their research programmes more directly at highly specific revenue targets, profoundly affecting their scope of research. As BIO-DYN will be carried out over the next three years, we are offered a rare opportunity to observe how the maturation of a science-driven industry may be shaped through its profound interaction with both university science and with venture capital institutions.

Knowledge protection and diffusion in university-corporate partnerships in biotechnology (UNI-COR).

Lee Davis

Purpose

With the rapid commercial development of the biotechnology industry, questions concerning what role academic scientists should play, and how best to organize and manage university-corporate partnerships in new product development, acquire new urgency. This project will explore the appropriability aspects of these choices for the commercial development of biotechnology in Denmark, and their implications for scientists, the biotechnology companies, and society. To investigate how scientists contribute to the biotech industry in Denmark, and the effects of these collaborations, we will conduct quantitative analysis based on questionnaire responses from a survey of scientists in Danish universities and public institutions.

Motivation

Academic research in this area is informed by a central “puzzle” (e.g. Dasgupta and David, 1994, Mansfield & Lee, 1996, Narin *et al.*, 1997, McMillan *et al.*, 2000). University scientists work under a collegiate reputation-based reward system. Success is tied to priority – coming first in the “race” to publish original research in a reputable journal. When scientists cooperate in a corporate R&D program, the main motivation may have more to do with financial gain. Scientific research is (ideally) long-term and motivated by curiosity; corporate research is short-term and profit-motivated. But to what extent is this always – or even necessarily – the case? The issues here are complex. Might not scientists, in some circumstances, be better able to conduct basic research by tapping into corporate budgets? Might not the peer review process tend to encourage work in known areas, to the detriment of genuinely path-breaking discoveries? This project seeks to add to our academic understanding of these issues.

Existing literature on this topic tends to be relatively abstract, country-specific (focusing mainly on U.S. conditions, e.g. Mowery *et al.*, 2001), or highly concrete and policy-oriented. This project seeks to bridge this gap by developing tools, based on the academic literature, which can be applied systematically to analyse cases in the Danish biotechnology industry. University-corporate cooperations can take several forms: patent licensing, contracts for joint development projects, physical presence in a corporate lab.

It is our working hypothesis that the dynamics of university-business partnerships will differ, depending, for example, on whether the scientist is involved in basic or applied research, product or process inventions, or according to particular areas of specialisation. How can such cooperations best be structured? What effects will they have?

Main issues

Several key questions arise. First, to what extent will increased patenting by university researchers decrease the amount of freely available public knowledge – and how will this affect the long-term knowledge needs of the biotechnology industry? Advances in this industry have traditionally been dependent on access to knowledge in the public domain.

Second, how might increasing pressures to patent affect scientists' research priorities, perhaps diverting research efforts away from other, possibly more academically fruitful lines of inquiry? In the United States, for example, leading universities increasingly use patent licenses to fund research. What will happen in Denmark if university budgets become more dependent on this source of revenue? How will this, in turn, affect corporate R&D programs?

Third, patenting is costly and demanding. Companies typically contract with patent agents to help them apply for patents, or hire in-house patent experts. Are university researchers well placed to judge what is patentable and what is not? If university administrators step into this role, who should decide how best to proceed? Who will bear the costs of failed patent applications, or renewal fees for granted patents that no firm is interested in licensing?

Finally, when scientists participate in commercial product development, what is the best way to formulate the contract between the two parties? Given the uncertainties of innovation, how can the parties ensure that the relationship remains flexible – and beneficial to both? How do venture capitalists enter into the equation?

Research design

As a first step, the project will summarize the nature of the central dilemmas described above, and the different proposed solutions, based on both findings in the international literature, and interviews with university researchers and administrators, corporate managers, and policy-makers in the international community. On this basis, the project will generate testable hypotheses to be applied in the Danish context.

A questionnaire will be sent to scientists in the universities, hospitals, and other life sciences research institutions in Denmark, and the responses subjected to systematic statistical analysis. Specific questions to investigate include, for example: What is the relationship between the number of patents taken out by a university scientist, and the number of research publications? Under what circumstances does one activity support the other; under what circumstances is there a negative influence? In-depth, follow-up interviews will be conducted with selected sources in Denmark, enabling the formulation of proposals for reform.

Organization and Management in the Biotechnology Firms (ORG-MAN)

Jesper Ulrik Norus

Objectives

The aim of the project is to explore the globalisation of firm strategies in the biotechnology industry and these strategies' organisational and managerial implications. Recent research suggests that a small dedicated biotech firm (DBF) is best perceived as a loose entity, a temporary meeting place, solely defined by its portfolio of R&D projects and intellectual property rights in the form of patents rather than a well-defined unit with clear jurisdictional boundaries (Norus, 2002). Consequently DBFs are best analysed as loosely coupled systems and as distributed companies, where the basic functions and activities are decomposed and organised in external globalised networks (Powell, 1998). This project examines the globalisation of these networks and their relationships to strategies of DBFs. The two overall questions are:

- 1) What are the important drivers motivating the globalisation of biotech firms?
- 2) What is the role of global networks in the strategies of DBFs to mobilise scarce resources, such as scientific knowledge and capital?

To study and understand the issues of globalisation in biotechnology business, the research agenda is broken down into five theoretical questions:

- How is knowledge created and disseminated in distinct inter-organisational networks, such as communities of practice (Wenger et al., 2002)?
- How do product development and the formation of new markets co-evolve?
- How are managerial roles in network organisations distributed within and across the boundaries of the organisations?
- How is the development of production skills, manufacturing capabilities and marketing functions organised in globalised strategic alliances (Powell, 1998)?
- “Balancing local stickiness and global outlook”: How is management practiced so that it allow firms to undertake a dual position, being attracted and localised in a specific region and at the same time be connected to a globalised system of alliance partners (Hilpert, 2003)?

Motivations

The reason that this project is important is that it contributes to the ongoing research on the formation of innovations and new technologies. The major contribution to the scientific community will be the project's strong attention on how management and leadership is possible in loosely coupled systems where R&D projects, capital, human resources and artefacts are manoeuvred in a variety of globalised strategic alliances and overlapping interorganisational networks.

Scientifically this project is motivated by the source of recent research focusing on the competition between regions to attract and to form new biotechnology firms. Most of this recent research concentrates on institutional mechanisms to foster an attractive innovative climate and to attract companies to specific regions. The mechanisms

typically examined in this research are incentive schemes (tax-packages) and infrastructure like research parks or accessibility to knowledge from world class universities, the existence of a venture capital community and the location of a number reference industries such as pharmaceutical firms in the region (Hilpert, 2003). Instead this project suggest that the role of regions and their institutional mechanisms cannot properly be understood without relating them to the forces of globalisation emerging from the network strategies of single biotech firms. Development of both biotech firms and regions grows out of the dual forces of regionalisation and of global networking, and one important motivation for this research is to understand how the two forces act on the individual biotech firm.

Furthermore, results from the project may offer guidance to biotech firms on how to organise and monitor their numerous network relationships (alliances, research collaborations and agreements etc.). And they may shed light on how production skills are developed when a biotech firm changes from being only a research organisation to also being a producer. Production skills are often mobilised in external networks, based on formalised partnerships models, and results from this project may guide the design of these models.

Research design

The data for the research will be generated from a series of interview studies in Europe, US and Australia in order to develop some longitudinal case studies. This means that follow-up interview studies, e.g. phone interviews, have to take place during the period 2004-2006. From the sample of cases we will identify different types of globalisation strategies and how these strategies develop over time. We examine what are the driving mechanisms behind the strategic forms of globalisation and how are globalised strategic alliances managed and organised. Prof. David Finegold, KGI and Jesper Norus conduct the project, and together they have access to several biotechnology firms around the globe. Finegold has contacts in America, Australia and Asia, whereas Norus' experiences are mainly in the EU and the US biotechnology industries. From a sample of firms, this project will undertake longitudinal cross-national/cross-regional case studies. The reason that these cross-national studies are important is that the organisational dynamics in the firm's external relationships happens rapidly both in time and space, and what is exchanged in the networks is often both immaterial and not quantifiable. This challenges research methodologies to make use of network concepts capable of analysing both the volatility and the stability of the interorganisational relationships in question. The development of the individual case studies in different biotechnology firms in the different locations will be carried out according to a semi-structured interview guide. This interview guide will cover the aspects of the underlying research and at the same time be customised towards the different types of positions that the interviewees occupy in the organisations or networks investigated.

The DABIT database that is developed by Finn Valentin in a parallel COMBI project is an important source of data for this part of the COMBI programme.

Research Partnerships.

A worldwide network of researchers will facilitate data generation in the project and will also provide interesting fora for research discussions about the issues of networks and globalisation. This primarily includes David Finegold and Steven Casper from Keck Graduate Institute of Applied Life Sciences; Walter Powell, Stanford University;

Ulrich Hilpert, Friderich Schiller Universität, Jena and Desmond Hickey, University of Chester, UK. Other key researchers include Malin Brännback, Turku School of Economics; Alan Carsrud, Florida International University; Fiona Murray, MIT; John Mathews, Macquarie Graduate School of Management, Sydney, Australia; and Frank Rothaermel, Georgia Tech. The research partnerships will be used as an opportunity to get access to firms in the different countries, but will also be used as an opportunity to develop different types of research outputs for each of the underlying research questions.

Understanding the Profitability of Danish and Other Biotechnology Inventions with the Help of Indicators (IN-PROF)

Markus Reitzig

Purpose/Objectives

The objectives of this project are

- To provide a large-scale empirical test of what the main determinants of the profitability of biotechnological inventions are,
- To develop and refine existing indicator methods to value (portfolios of) biotechnology patents, and
- To link these insights to the Danish (Southern Scandinavian) biotechnology sector

Scientific motivation

Economists have spent extensive time developing various patent indicators to measure innovative output (Carpenter, Cooper et al., 1980; Griliches, 1981; Narin, Noma et al., 1987; Albert, Avery et al., 1991; Hall, Jaffe et al., 2000; Guellec and van Pottelsberghe de la Potterie, 2000; Reitzig, 2002). Major efforts concentrated on the compilation and interpretation of procedural legal information published together with the disclosure of the technical invention underlying the patent. Nowadays, backward citations, forward citations, family size, and claims (to mention but a few) are standard indicators used to qualify patents and weight patent counts. However, virtually all of these indicators have been validated in the reduced form only. This leaves economists with interpretation problems of empirical estimation results at various points.

One of the fundamental remaining questions is whether certain types of patent indicators signal value because a) an invention is technically sophisticated, or b) because there is a market for it, or c) for both reasons?

Answers to these questions are crucial for two reasons:

- Policy makers need to understand how the adjustment of patentability requirements affects innovation incentives all other variables being equal, and
- Managers and management scholars are interested in the potential of markets independent of the technical value of individual patent rights.

Practical issues and concerns

There seems to be a consensus among R&D managers, analysts, and investors that for various purposes valuation methods for intangible assets are needed that are scientifically valid and practically applicable.

In tight appropriability regimes such as the biotechnology sector, patents represent the most important intangible assets of a corporation. To identify lucrative sectors for investment (through assessing large numbers or portfolios of patents), indicator methods

appear promising. However, as of today, these methods need refinement in that they need more theoretically based empirical validation. Despite its scientific character, this projects therefore simultaneously produces respective empirical evidence directly suitable for corporate application.

Main Issues

The information contents of patent indicators is complex, and the diversity of its potential meanings is far from being fully understood. The main caveat is that the information contained within patents (and respective indicators) is legal of nature and therefore first of all operationalises (latent) legal variables. Only through an additional body of theory can these indicators ultimately be linked to economic phenomena. Our theoretical understanding of the correlations between a patent's *observable* legal characteristics and their economic effects, however, is still very limited. Undisputedly, it is true that a large variety of respective studies in this field has convincingly demonstrated the general suitability of procedural patent data in operationalising a patent's economic value. To the best of my knowledge, however, no empirical study exists that allows us to interpret coefficients of patent indicators as patent value correlates in the structural form. From a scientific and an applied perspective, however, this is dissatisfying for one major reason. The reason is that for a variety of theoretical and practical problems, we are not only interested in *whether* an invention is of commercial value but also *why* it is of commercial value. This problem holds especially true for capital-intensive industries such as biotechnology, where complex allocation decisions have to be made to assure optimal investments to maximize profitability. With the help of custom-tailored estimation techniques, this project seeks to shed light on the following questions:

- Which of the following types of value drivers affect the commercial value of biotechnological inventions: i) Technical quality, ii) Non-technical market factors, or iii) Both?
- How can we use patent indicators correctly to estimate the value of biotechnological patent portfolios, hence lucrative investment sectors?

Research Design

This paper addresses the research problem theoretically and empirically. It starts from the premise (Harhoff and Reitzig, 2000) that observable oppositions against biotechnology patents are driven by two incentives of the opponent that are opposed signals of a patent's value:

- A low technical quality of the patent (leading to an increased likelihood of winning the case on the side of the opponent), and
- A considerable commercial value of the biotechnological invention that can be due to various factors, technical and non-technical.

Applying and refining a recently developed custom-tailored discrete choice estimator (Reitzig, 2003), reflecting the opponent's decision making rationale, to a set of European biotechnology patents shall allow for a structural validation of various patent indicators (backward citations, forward citations, family size, and claims) and answer both of the above questions. In particular, the estimator disentangles the two opposed effects on a patent's value underlying the opposition decision. Refinement shall be

carried out in cooperation with Professor Bronwyn Hall (UC Berkeley) and Professor Timothy Devinney (Australian Graduate School of Management) during research stays at the respective institutions. Finally, through econometric distinctions between Danish (Southern Scandinavian) and other patents, some (very preliminary) international benchmarking of patented Danish biotechnology with respect to technical quality and market attraction could emerge as well.

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