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Development of Intellectual Property Management

- Cases from German and Swedish Biotechnology Companies

Entwicklung von Intellectual Property Management
- Fallstudien aus Deutschen und Schwedischen Biotechnologie Unternehmen

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Abstract

In recent years the management of IP underwent major changes and a rapid recognition in industry has risen that there is a need to integrate IP into strategic management. This thesis aims to contribute to this field of research focusing on the development of IP management in dedicated biotechnology firms (DBFs) throughout the last ten years.

The purpose of this thesis is to describe and explore the history of IP management in selected larger German and Swedish companies operating in biotechnology related fields, while trying to identify measures for IP management performance. Three main research questions were defined in order to accomplish this purpose. (i) How can different stages in a company's IP management be characterised? (ii) What has been the role of different IPRs in different IP management stages? (iii) How to measure the economic performance of IP management?

In order to accomplish these research questions, six case studies were conducted in German and Swedish DBFs, with 'rich experience' in IP management.

Throughout the study different stages of IP management could be identified in all case companies. However, the stages differed in several characteristics. Six criteria were found which characterise an IP management stage best while shifts towards another IP management stage were found to be caused either by internal or external. These events can be said to be single crucial events or an accumulated sum of events. Further, it could be identified that in different IP management stages the roles of different IPRs changed. Further, it was found that in different IP management stages the roles of different IPRs changed.

To assess the performance of an IP department it was found that no single measure fits this purpose, rather a set of quantitative and qualitative measures needs to be developed which aim to judge upon the effectiveness to reach strategic company objectives and efficiency of the current IP management. Three Problems were found when judging the IP management performance. Apart from these problems, this study suggests to assess the IP management performance on the consistence of the company's technology base as well as by the six criteria which characterise an IP management stage. However, these seven criteria need to be broken down further and specifically for each individual company.

Keywords: Biotechnology, IP management, emerging enterprise, Dedicated Biotechnology Firm, Intellectual Property Rights, performance measurement, technology base, Germany, Sweden

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List of abbreviations

CAFC	Court of Appeals for the Federal Circuit
CIP	Center for Intellectual Property Studies
CTH	Chalmers University of Technology
DBF	Dedicated Biotech Firm
DPMA	German Patent and Trademark Office
E&Y	Ernst & Young
EPC	European Patent Convention
EPL	Effective Patent Life
EPO	European Patent Office
EU	European Union
FDA	Food and Drug Administration
FIPCO	Fully integrated pharmaceutical company
GDP	Gross Domestic Product
GSK	Glaxo Smith Kline
HBR	Harvard Business Review
HUGO	Human Genome Organisation
IA	Intellectual Assets
IC	Intellectual Capital
IP	Intellectual Property
IPO	Initial Public Offering
IPR	Intellectual Property Right
IVA	The Royal Swedish Academy of Engineering Sciences
KTH	Royal Institute of Technology
LPL	Lost Patent Life
MDB	Method of doing business
NCE	New Chemical Entity
NIH	National Institute of Health
NTBF	New technology based firm
NUTEK	Swedish Business Development Agency
PCT	Patent Cooperation Treaty
PLC	Product Life Cycle
RBV	Resource Based View
RQ	Research Question
SEK	Swedish Crowns
TBF	Technology Based Firm
TUHH	Hamburg University of Technology
USPTO	United States Patent and Trademark Office
VBU	Association of German Biotech Companies
VC	Venture Capital
VINNOVA	The Swedish Agency for Innovation Systems
WIPO	World Intellectual Property Organisation

Euro conversion rates

Exchange rates[1]:

1 U.S. Dollar = 0.81780 €

1 SEK = 0.11191 €

1 DEM = 0.51129 €

[1] Financial Times, December 9th, 2003

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Frank Tietze

Hamburg, 12.05.2004

1 Introduction to the thesis

The thesis consists of six major parts (see Figure 1). This first part includes the background of why and how the thesis has been written as well as some introductory background on the topic. Further, it explains the focus of the thesis and its three research questions. This part closes with a description of the methodology applied for this study.

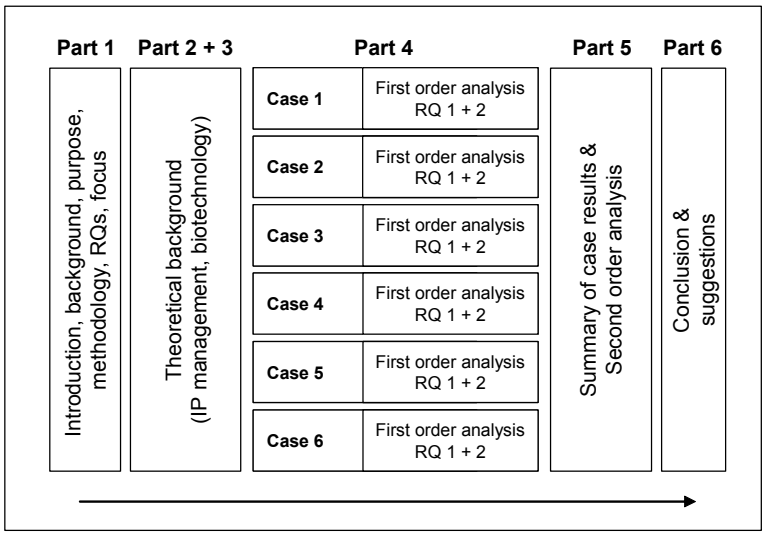

Figure 1: Thesis structure

The second and third part together cover the two major research fields to which this study is related. Throughout the second part theoretical concepts related to IP management are described including the three major elements of the case studies: technology base, IP management stages, and assessing IP management performance. The third part of the thesis provides an introduction to biotechnology, starting with a short history, then giving a description of the term 'Dedicated Biotechnology Firm' (DBFs). Further, biotechnological businesses and common business models are described, while finishing with the meaning of IP management for DBFs. In addition, throughout this part, some theoretical concepts concerning the growth of emerging companies are included.

The fourth part of the thesis gives a short overview of the case companies followed by the reports of the case studies, which are structured almost similarly. At the end of each case report the corresponding company is investigated concerning the first and second research question.

The fifth part of the thesis presents the findings derived from the case studies in an aggregated and comparative way. The results concerning the first and second re-

search questions, which have been presented separately in the previous part, are summarized, while, finally, the third research question is addressed.

The sixth part concludes the study and makes suggestions for further research, followed by several appendices and the references, which close the thesis.

1.1 Development of the topic

Since the end of the eighties there has been a reasonable shift in the economic environment of many industries. Today, as Teece (2000) notes "traditional sources of competitive advantage have been stripped" away. In addition to that shift, as a source for it or even as a result the theoretical literature has introduced many 'new' concepts like "knowledge economy" (Neef 1998), "knowledge strategy" (Hansen et al. 1999; Sveiby et al.) or "knowledge creating company" (Clarke and Turner 2001; Nonaka and Takeuchi 1995). Some authors even started to write about a new fundament of the firm, which they call the "knowledge based view of the firm[2]" (Sveiby 2001; Zack 2003). Major reasons behind this development have been the emergence of new generic technologies (e.g. electronics, ICT, and biotechnology) (Duchesneau and Gartner 1990; Grindley and Teece 1997), which resulted in the foundation of many new technology based firms (NTBF) as well as in an increasing pace of technological change (Granstrand 2000).

Simultaneously, a 'pro-patent era' emerged enabled by a strengthening of the intellectual property regime (Teece 2000) in the U.S. (see as well chapter 2.3). This new era, when IP for many companies became the 'forefront' of competition, is characterised by intensified international competition, global activism of IPRs from industrialized countries, increased international patenting, almost worldwide adoption of the patent system, and, finally, the fact that in many companies the "IP value surpassed the value of physical capital" (Granstrand 1999). Owing to this reshape of economic environments, accelerated by the emergence of new technologies, the "management of IP on the whole … has changed" and a recognition in industry has risen that there is a need to integrate IP into strategic management. Companies have started to manage their knowledge more carefully and "patenting and licensing have become more

[2] Closely related to the knowledge-based view is 'resource-based view of the firm'. See further: (Barney et al. 2001; Grant 1991; Rangone 1999)

strategically managed" (Granstrand 2000). A good conclusion of all these developments was given by Teece and Grindley (1997) when they stated: "the most signifycant emerging business development […] in the last decade […has] been the proactive management of intellectual capital."

Although, Intellectual Capital (IC) has gained major importance for many companies in several industries, IP has become really important only for particular industries: pharmaceutical, biotechnology, electronics, semi-conductors, chemicals, and ITC (Allansdottir et al. 2002; Grindley and Teece 1997; Mansfield 1986). But its these generic technologies that are often seen as the "key technologies for the next millennium" (Thumm 2001) and patents, trademarks, and IPRs "have become a key element of competition" for them (Grindley and Teece 1997).

Even in the early 1980s, Mansfield and Schwartz (1981) showed that "practically none of the drug innovations would have been introduced without patent protection". They state: "Patents are regarded as more important in drugs than elsewhere". Patents have a significant importance in the pharmaceutical and drug development industry (Scherer 2000).

Today, many companies understand IP management as part of their business strategy and have started to generate revenues through out-licensing[3], enable freedom-to-operate by cross-licensing (Teece 2000) and use strategic patents as a 'flexible entry barrier' for potential competitors or partners (Pitkethly 2001; Sullivan 2000) and as a result, IP became critical to companies' competitive advantage. As a consequence, today's companies must either invest in R&D to develop their own technologies or pay license fees for accessing technologies/ patent portfolios of others (Grindley and Teece 1997).

1.2 Purpose and research questions

On the one hand many studies were undertaken on the patterns of companies' development (Churchill and Lewis 1983; Greiner 1998), however, on the other hand IP management and its organisational structure were analysed yet mainly in a static manner, while studying only large multi-technology corporations (Granstrand 2000;

[3] IBM gained licensing revenues, which accounted to 20% of their total profits in 1999 (Lang 2001). There total licensing revenues have accounted for almost 8.2 b€ in the last decade (Shulman 2003). As another example Dow Chemicals is often cited. The company set up an 'Intellectual Asset Function' in 1993 and obtained licensing revenues of 110 M€ (22 M€) in 2000 (1994) (Roos et al. 1997).

Nonaka and Takeuchi 1995). The only study analysing the development of IP or patent organisations which gained major attention in this research area was undertaken by Taylor and Silberston (1973), describing four stages of IP organizations (see further chapter 2.4.3).

As the field of IP management increasingly became of importance for DBFs just recently, but could not be satisfactory accomplished yet, the purpose of this thesis is to describe and explore the history of IP management in selected larger German and Swedish companies operating in biotechnology related fields, while trying to identify measures for IP management performance. Three main research questions have been defined in order to accomplish this purpose.

Throughout a company's history its organization goes through different stages as described by Saemundsson, R. J. (2003), Churchill, N. C. and V. L. Lewis (1983), and Rothwell, R. (1984). Does a company's IP management as well develop throughout stages? This question underlies the main assumption of the following research questions.

RQ1: How can different stages in a company's IP management be characterised?

The aim of this first research question is to identify whether a company's IP management goes through different stages and by which characteristics they can be described and separated. How IP departments are organised throughout different stages, what tasks do they fulfil, which responsibilities appear, etc., are examples of additional, but implicit sub-questions to be answered here. Further, it is a matter of interest which events characterise the interfaces between different stages, or rather how the transformation from one to the following stage of IP management can be characterised. Results from this first RQ may support IP managers to predict and accomplish a transformation to another IP management stage.

RQ2: What has been the role of different IPRs in different IP management stages?

Throughout the different stages probably the meaning of different IPR changes and with them the challenges IP managers face to handle them appropriately. As a company grows from an entrepreneurial venture towards a more mature organisation, the importance but as well the awareness of IP management may rise. IPRs are probably

handled in a more diversified though integrated manner, guided by an overall 'IP-mix' strategy than during the early stages of a company. To identify which IPRs play a distinct role in the different stages identified in RQ1 is the aim of the second RQ. As a result, IP managers might be enabled to be aware in advance of challenges in an upcoming IP management stage. Describing how the IP management is carried out and how it is evolving throughout different stages leads finally to the third RQ.

RQ3: How to assess the economic performance of IP management?

Though judging the economical efficiency and effectiveness is still a 'puzzle' for many companies (Sullivan 2000), the aim of dealing with the third RQ is not to give a comprehensive answer to this question but to try to identify and explore problems with the measurement and to describe the related characteristics of the IP management in order to identify cornerstones of problematic areas which need to be taken into consideration. This RQ addresses companies' top management and may help to stress reasonable and accomplishable goals when supervising the IP department.

Addressing the thesis purpose, backed by the research questions explained above, the overall aim of the thesis is to contribute to the research in the fields of IP management (primary) and the management of emerging companies, e.g. DBFs (secondary). The thesis addresses managers willing to proactively manage their IP and especially those who are curious about extracting value as quickly and economically as possible from their company's technology base (see chapter 2.4.1).

1.3 Focus and limitations

Since in both main research streams –IP management and biotechnology – many interesting research questions are still open and to some extent 'equally' important, it is necessary to maintain a strong focus throughout the thesis. The following section will highlight the core focus of the thesis, draw some attention to closely related aspects, and show clearly which topics have been excluded.

The thesis core focus

This thesis deals with the IP management of 'established' DBFs of 80 to 500 employees in Germany and Sweden and their IP management performance from an economic perspective. As a major research tool, illustrating the main IP management tasks, the concept 'technology base' has been chosen. It distinguishes between "dif-

ferent technology procurement (or sourcing) strategies for building up the technology base and different technology exploitation strategies for exploiting it" (Granstrand and Sjölander 1990). This concept will be further illustrated in chapter 2.4.1.

The development of the company's IP management on the one hand and the development of the company's technology base on the other hand are the two core elements of this thesis. How both these elements develop is analysed throughout the case studies as measures to address the research questions, thereby representing the two main concepts in the focus of the thesis.

Since the thesis is a combination of two emerging research streams there is a large variety of significant research questions, what made it especially important to chose and maintain a strict focus in order to achieve reasonable results in the given timeframe.

Related topics

IP management is concerned with the acquisition of the company's technology base. The creation of knowledge and inventions in-house (the innovation process), but as well with the acquisition of know-how from third parties is an important determinant for building up the technology base, but is treated in this thesis as an upstream process handled mainly by the R&D department. This process is of course linked to the IP management, but not core of this thesis. Further, the thesis does not go into detail concerning the processes of technology exploitation. Only when a single 'case' appears to be of major importance and of influence to a company's development throughout the case studies, this particular situation is highlighted.

A diversification into new resources and/or businesses (product/market combinations) is often accompanied by a company's growth (Granstrand 2003a). This diversification influences the company's growth and vice versa. As well, many changes in the company's competitive/ business strategy are often accompanied with the company's growth. Both the diversification and changes of the strategy are not of par ticular interest in this study, although influenced by or influencing the development of a company's technology base. Though diversification and business strategy are of major importance to this thesis, they are not its main focus.

As described in chapter 2.3 the development of the patent regime on the macro-level has influenced the IP management on a micro-level of the firm, in the past. Since this

thesis takes a management perspective, the patent studies on the patent law or the patent law itself are only studied where it appeared to be of importance.

It has often been reported that in emerging industries research collaborations[4] play an important role for DBFs. Although these collaboration have influence on a company's technology base, this topic is only of minor importance for this thesis.

Limitations

There are many closely related and in some aspects important topics. Some however, needed to be excluded from this thesis. Both fields, IP management and biotechnology, are huge research areas and the areas excluded from this work are probably more numerous than the ones included. In general, one might highlight again that this thesis is limited to its exploratory and descriptive nature (Granstrand 1995). It does not try to explain, predict or prescribe any aspects merely related to the topic.

The thesis is limited to the description of developments in the biotechnology. Other industries (e.g. nanotechnology, ICT, electronics, etc.) are not compared although they might be similar in several characteristics. Further, this thesis focuses only on pharmaceutical biotechnology[5] excluding other areas of application (e.g. industrial, maritime, and agricultural usage). Companies operating in traditional biotechnology or medical fields are excluded as well.

Further, the thesis does not try to link developments of research in biotechnology in every detail to the development of doing business in the 'industry'. A basic understanding of biotechnology related businesses (given in chapter 3.2) is necessary, but it was not an aim to gain a detailed understanding of the business models of DBFs. Two topics of major interest in IP management and closely related with the biotechnology industry are the phenomena of licensing strategies (whether in, out or cross) as it has been done by Bergholtz, C. and M. Svensson (2002), as well as a detailed analysis of the competitive environment in the biotechnology industries. These topics are not part of this thesis.

[4] For further research on this topic see: (Buse 2000; Müller 2003)
[5] Often different terms are used e.g. pharma, health care biotechnology, etc. This thesis uses the term biotechnology synonymously.

In addition, to judge if the development described and explored in the case companies was positive, healthy, and prosperous is mainly left to the reader's interpretation. Although, it was always tried to adopt a critical perspective and some comments might appear indirectly in the evaluation chapters (see chapter 5 following).

Finally, the following key-phrases should give further ideas of issues not addressed, simultaneously giving an idea of possible further, though not yet sufficiently explored research topics: Comparison of European and U.S. DBFs, developments in other countries than Sweden and Germany, communication conflicts of lawyers, scientists and marketing people related to IP management, the role of governmental incentives and clusters, etc.

1.4 Methodology

The exploratory and descriptive nature of the research questions limited the possible research strategy, so that only case studies[6] seemed to be favourable (Granstrand 1995). Due to the explorative nature, it was decided to conduct multiple case studies - instead of trying to identify one single, critical, extreme or unique case - thereby covering a larger frame of ideas (Yin 1989). Six cases seemed to be appropriate and being feasible in the given timeframe. Choosing two countries for this study seems to broaden its exploratory value, while being practicable. Biotechnology companies in Germany, the UK, France, and Sweden represent almost 73% of all European biotech companies (Allansdottir et al. 2002). Of these four countries Germany leads concerning the number of biotechnology companies (Sweden is number four), while Sweden has the highest number of biotech companies as well as technology patents per capita. Additionally, these two countries were chosen due to feasibility and convenience. How the chosen research approach was operationalized is described in detail in the following part. An overview of the research process gives Figure 2.

[6] The case studies rely exclusively on the statements of carefully chosen interview partners and some secondary data. No quantitative analysis were carried out, wherefore this thesis claim to prove any statistically justified evidence as it is of rather qualitative nature.

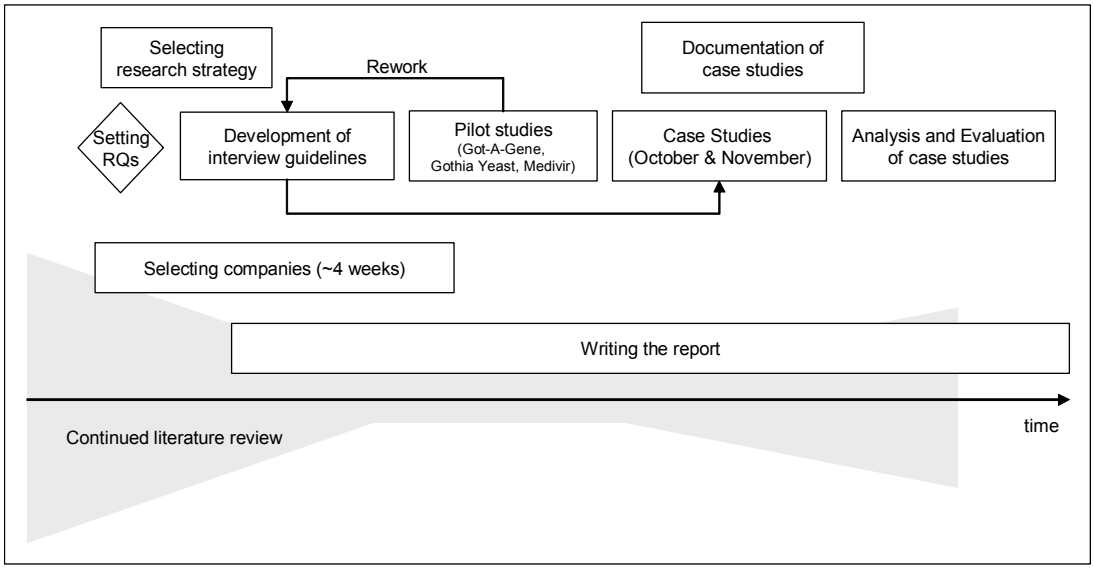

Figure 2: Research process

1.4.1 Sample selection

In regard of the aim of the study and in order to guarantee significant results, appropriate case study objects needed to be identified (Granstrand 1995), wherefore two criteria categories were defined to identify at least 'rich-experience' companies[7] concerning IP management in biotechnology: the 'enabling criteria' and the 'preferred choice criteria'. One can even say that the sample objects are chosen in a two-step sequential process, wherein the first step determined the sampling frame (Remenyi 1998). The process is shown in Figure 3.

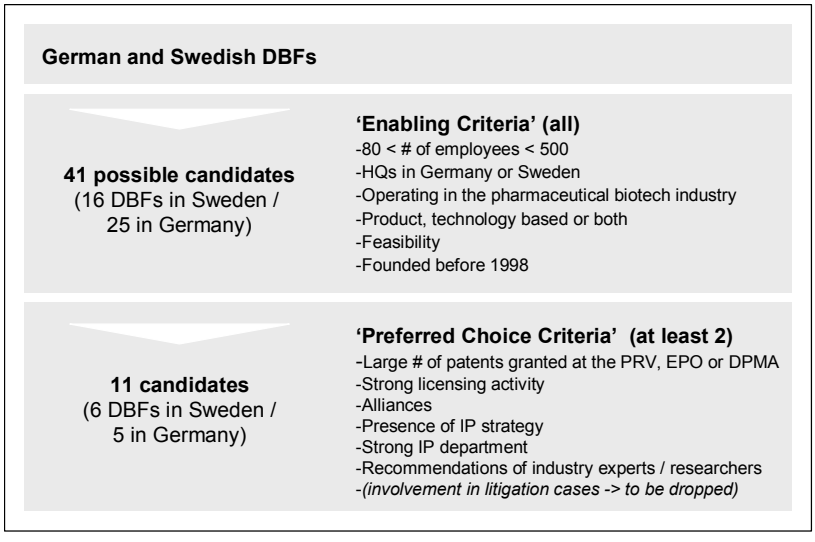

Figure 3: Case selection in a two step sequential process

[7] 'Best practice' could not be claimed for these companies, since an international comparison was not made against other leading biotechnology companies in the UK and the U.S.

As sources for the definition of these criteria interviews were held with industry experts from VINNOVA, AWA Patent, E&Y life science group, PRV, DPMA, EPO, several Swedish and German industry associations (e.g. VBU, BioTop[8], BIOSWEDEN, etc.) and with researchers from CTH, Sahlgrenska Medical University, Charité Medical University (Berlin). Further, a literature review complemented the suggested criteria.

As an outcome of this process, six 'enabling criteria' defined the broader scope of companies suitable for the study. These criteria are only indirectly linked to the IP management experience and were defined as follows: More than 80, but less than 500 employees worldwide[9], based in Germany or Sweden, operating in the pharmaceutical biotech industry, product based company or technology provider or both, feasibility to reach, and founded before 1998. These criteria allowed to identify 16 companies in Sweden and 25 in Germany.

In a second stage, seven 'preferred choice criteria' were applied to the companies which fulfilled the 'enabling criteria'. These criteria were defined as being directly linked to the company's IP management experience. Companies did not have to fulfil all of the 'preferred choice criteria', but at least two of the them: A high number of patents granted or pending at the EPO, DPMA, or PRV, strong licensing activity (reported in industry reports, newspaper articles, or by industry experts), alliances with BigPharma (industry reports, public press), companies are known as 'success stories', presence of an IP strategy, sophisticated IP department. Further, recommendations of industry experts (venture capitalists, patent attorneys, science park or incubator managers) as well as of researchers from biotechnology or IP related fields (CTH, KTH, Sahlgrenska Medical University, Charité Medical University of Berlin, CIP, TUHH) were taken into account. As a result of the second stage evaluation, eleven possible case study objects (six in Sweden and five in Germany) could be identified[10].

[8] A biotech association for the region Berlin-Brandenburg in Germany

[9] However, it appeared that one very valuable case company had significantly more than 500 employees.

[10] The particular industry itself (e.g. diagnostics, therapeutics, bioinformatics), in which the companies were operating, was not a sampling criteria. The approach was to identify biotech companies with expertise in IP management, so that the industries, in which the companies were active, were only of secondary importance. However, it seemed to deliver additional value to the output to include companies from different industries with different needs and requirements of IP management. Finally, it

As the companies were chosen according to the fit with the above mentioned criteria, the sources which were used to accomplish this task should be mentioned. For the 'first step' research of online and offline industry reports was conducted as well as personal suggestions of industry experts and researchers (see above) were taken into account. For the 'second step' the companies' websites and at least the two latest annual reports of almost all 31 companies, which fulfilled the 'enabling criteria', were investigated. If no satisfactory information could be obtained, the companies were contacted personally with detailed requests.

During this sample selection process it appeared that one criterion needed to be rejected. It appeared to be too difficult to generate reliable data for the criterion 'involvement in huge litigation cases' after requests were sent to the German Patent Court in Munich as well as to the Swedish Magazine "Patent Eye" and interviews were conducted with several law firms in Sweden.

1.4.2 Pilot studies

Having identified possible case study objects, an interview guideline for the case studies was designed, while these companies were contacted. To validate and improve the interview guide three pilot studies were carried out. In mid September interviews were performed with the CEO of Got-A-Gene AB, a small company (16 employees) operating in the drug development business, a patent attorney of Medivir AB, a larger biopharmaceutical company (99 employees), and, finally, with the responsible person for technology trade of the fairly small start-up GothiaYeast AB (around ten employees) at the end of September 2003.

The interviews with totally different pilot objects proved to be very helpful, since all interviews delivered insight into different phases of a company's development and thereby illustrating the different needs, requirements, and challenges of IP management. The draft for the interview guideline was modified as a result of these pilot interviews. The final draft proved to be very robust throughout all main case studies.

1.4.3 Secondary sources / gathering data

While contacting the possible case companies took place in the first half of September 2003, further literature was studied and additional data was gathered on the Ger-

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appeared that the selected companies reflected industries in accordance to what Allansdottir, A., A. Bonaccorsi, et al. (2002) found to be the mostly developed biotech industries in Germany as well as in Sweden.

man and Swedish biotechnology 'landscape' by interviewing industry experts from science parks in Germany and Sweden. To gather a deeper understanding of the thesis two main subjects (IP management and biotechnology) several seminars were attended. In June 2003, a seminar held by the Charité, Medical University of Berlin on "Intellectual Property in the Life Science Industries" was attended and the three days CIP Forum 2003 on "Managing the Intellectual Value Chain" was attended in early October. Further, two seminars on biotechnology organised by the Department of Industrial Dynamics at CTH on "Innovations and Entrepreneurship in Biotech/ Pharmaceuticals and IT/ Telecom" and "From scientific discovery to lead product - process of value building within biotechnology companies" were attended in September 2003.

1.4.4 Conducting the case studies

Parallel to the pilot studies, the 'selected' case companies were contacted during August and early September. Since the number of possible companies was quite small, there was a risk of not finding any company to participate in the study (Easterby-Smith et al. 1991). Therefore each company was contacted by phone first, after studying its latest annual report and its website. Finally, three Swedish (Nobel Biocare, Biora, and Pyrosequencing) and three German companies (MediGene, Evotec OAI, and MorphoSys) [11] agreed to participate in the study.

Before visiting the companies the case studies were prepared by studying secondary literature of the company. If available, independent literature was chosen, e.g. for the Nobel Biocare case a PhD thesis could be found as well as a Master Thesis about the Swedish bioinformatics industry for the Pyrosequencing case. For all case studies, as a complement to the interviews and unfortunately as a non-independent source the companies' annual reports of at least the last three years were studied. Additionally, the companies were asked to provide extra material on particular IP issues in advance to the interview sessions. However, only three companies complied. A list of requested information can be found in appendix A.

[11] Out of these three companies MediGene (Evotec OAI) ranks number 28 (31) on a list with largest applicants for biotechnology patents (classes C12N and C12Q) at the DPMA from 1998 to 2003. Source: Request to DPMA on September 4th, 2003.

	Swedish Case Companies			German Case Companies		
	Biora AB	**Nobel Biocare AB**	**Pyrosequencing AB**	**Evotec OAI AG**	**MediGene AG**	**Morphosys AG**
City	Malmö	Göteborg	Upsalla	Hamburg	Munich	Munich
Year of foundation	1988	1984	1997	1993	1994	1992
Date of interview	03.10.2003	13.10.2003	16.10.2003	18.11.2003	03.11.2003	04.11.2003
Interview Partner (years working with company*)	Director, R&D and Regulatory Affairs (17)	VP, General Counsel (1.5); Head of R&D (3); Head of the patent department (10)	Director IP (3)	CSO (7); IP manager (3); VP Core Technologies of Evotec Technologies	Assistant Director IP (5); CEO and co-founder (9)	Senior Director Intellectual Property (10)
Total length of interview	4.5 hours	4.5 hours	4 hours	5 hours	4.25 hours	4 hours

* including 2003

Table 1: Overview of case studies

The case studies were conducted from the end of September to mid November, based on 12 interviews (26.25 hours in total; between 4-5 hours for each company). Each case study is based on one to three interviews, with interviewees who had spent at least three years (except one interview partner at Nobel Biocare) within the company, and held key-positions, e.g. founder, CEO, head of patent department, or head of R&D. Different perspectives through multiple interviews were necessary to achieve reliable results, and construct validity and proved to deliver highly valuable insight (Yin 1989). The interviews with the case companies were conducted as semi-structured interviews following all the same scheme, which can be found in appendix B and C (Dubois and Gadde 2002). Table 1 gives an overview of the case studies. A more detailed overview of the case sources and interview partners' backgrounds is offered in appendix E. After the case interviews were conducted, before publishing the reports were drafted and sent to the companies for review and permission to publish.

1.4.5 Analysis of case results

The case reports were analysed in a two-step process. In the 'first order analysis' each case report was analysed separately mainly in regards to the research questions one and two at the end of each case report, as shown in Figure 1.

In a 'second order analysis' an analysis of the case results was conducted comparing the results from each case on an aggregated basis. This analysis is presented in chapter 5.1 and 5.2 for RQ1 and RQ2. Chapter 5.3 aims to answer mainly the third research question.

The analysis of the cases does not claim to be statistically significant. However, due to the exploratory and descriptive nature of this thesis it aims to show how the IP

management of the companies developed and may give rise to new ideas for concepts assisting IP managers, the top management or researchers in the field of IP management.

2 Intellectual property management

As being a major element in this study some theoretical concepts related to IP management are introduced in this part. First, IP is defined followed by some examples illustrating the importance of IP in today's business environment. Further a short introduction to the development of the importance of IP management throughout the last 25 years is given. Major changes, at least in the U.S. and European patent system, have contributed to today's importance of IP management on a micro-level. This introduction on IP management is followed by the description of the main research tool, the technology base concept, and further by some theoretical background on stages and the development of IP management on firm level.

2.1 Defining Intellectual Property

Throughout literature IP is often interpreted in different contexts of intellectual capital (IC), intellectual assets (IA), organisational capital, structural capital etc. Until today, there is no dominant definition of IC and IA as several authors classify them differently. Sullivan (2000) and Davis, J. L. and S. S. Harrison (2001) define IP in the context of human capital and intellectual assets, while Granstrand (2000) defines IP in the context of material (tangible) resources, which he divides into physical and financial capital and immaterial (intangible) capital, subdivided into IP (as disembodied IC), goodwill and power in internal/external relations, and human (embodied) competence (capital). Further, Roos, J., G. Edvinsson, et al. (1997) define IP in the context of innovation capital together with intangible assets. Innovation capital itself is just one part of organisational capital, this however of the company's structural capital, which is part of its IC.

Although many authors differ in defining of IC, IA, the relations of IP to other kinds of capital, as seen above, the essence of IP is often defined similar, due to its nature as it is closely related to law. As the management of IP and not e.g. its relation to a company's market value is the focus of this thesis the following definition for IP is applied from Granstrand (2000):

> *"Certain creations of the human mind are given the legal aspects of property right. Intellectual property is an all-encompassing term, which includes patents, copyrights, trademarks, trade secrets, right to fair competition, and moral rights."*

However, today IP can be seen in a narrow and wider sense. Although in a narrow sense several authors define IP as certain intellectual assets that have been codified and can be legally protected (e.g. (Davis and Harrison 2001; Sullivan 2000)) in a wider sense IP includes as well trade secrets and the know-how embodied in certain persons e.g. scientists[12].

Therefore IP in the wider sense does not comprise only of codified but as well as of tacit knowledge what is especially important when transferring technology (Granstrand 2003b). This wider definition is applied in this thesis, although its focus is merely on the codified parts e.g. patents, trademarks, etc.

2.2 Introduction to IP management

The number of filed patents has increased enormously, as reported by almost all important patent offices in leading industrialized countries. The USPTO (EPO) recorded a growth of overall patent applications from about 100,000 (60,000) in 1990 up to about 160,000 (100,000) in 1998 (Griliches 1990; OECD 2003).

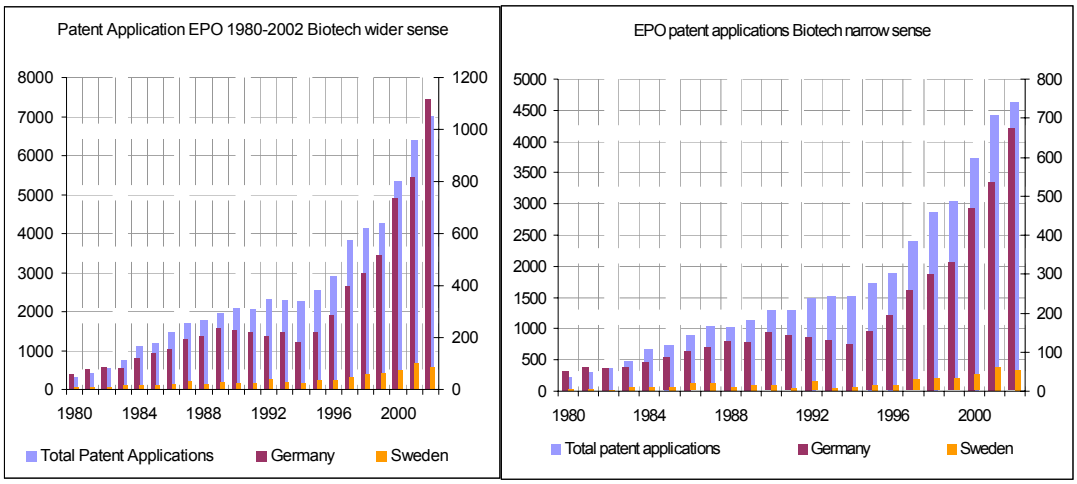

Figure 4: Biotechnology patent applications EPO (1980-2002)[13]

Beside the growth of the number of patents as an economic indicator, there has been an increase in theoretical concepts on how companies create organizational struc-

[12] I follow the definition used by (Nonaka and Takeuchi 1995) as they draw on Michael Polanyi's definition from 1966. Explicit or 'codified' knowledge refers to "knowledge that is transmittable in formal, systematic language… [, while] tacit knowledge is personal, context-specific, and therefore hard to formalize and communicate."

[13] 'Narrow sense' includes IPC categories C12N, C12P, C12Q, A01H, A01K. 'Wider sense' includes further IPC C07G, C12M, P, Q, R, and S. About 90% of all patents in biotechnology are filed in class C12N (Thumm 2001).

tures, deploy a patent or IP culture, and exploit value from patents, IP, and in general their knowledge assets e.g. knowledge-worker (Drucker 1993), knowledge society, and knowledge-based economy (OECD 1996), resource-based view (Prahalad and Hamel 1990), knowledge assets (Teece 1998), etc.

Both trends are backed up, by several examples actually illustrating the importance IPRs and in particular patent protection has in today's global economy; just to mention two:

One of the largest and still ongoing disputes on IPRs is, whether developing countries should be allowed to import generica for curing diseases (e.g. AIDS, hepatitis and cancer) in third world countries, although patent protection is still valid for the 'original' drugs. The world largest pharmaceutical firms are facing risks of heavily dropping profits, and societies of decreasing R&D investments, while ethical rules should argue in favour of it (Cookson 2003; Scherer 2000; Scherer and Watal 2002).

A probably latest example of the huge importance for IPRs, is the legal action the RIAA (Recording Industry Association of America) has taken in September 2003, suing thousands of internet users due to infringements of copyrights through sharing music via the internet. Relating to this action the German government has signed a new copyright law, strengthening the copyright protection. These counter-actions demonstrated once again the threats large multinational (entertainment) companies face due to the digitalisation of today's media[14].

2.3 Recent developments influencing today's IP management

IPRs have always had great importance on the macro level of nations, but as well on the micro level of firms. However, recently the U.S. patent system made a transition from a contra-patent to a pro-patent system, judging in favour of patent holders (Granstrand 2000). The growing importance of IPRs on the micro-firm-level is rooted in several events occurred in the U.S. as well as the European patent system.

The Bayh-Dole Patent and Trademark Amendments Act of 1980 is often seen and cited as the starting point of the strengthening of the patent regime in the U.S.[15] The

[14] As reported in the Business Week, Der Spiegel, Financial Times and many more newspapers in September 2003

[15] Some authors argue the Bayh-Dole act was not that crucial and a starting point for the strengthening of the U.S. patent system. A more comprehensive view is that the Bayh-Dole act has to be seen together with some corresponding events e.g. the emergence of new technologies as biotechnology.

Bayh-Dole Act accelerated the already ongoing expansion of licensing activities from U.S. universities[16] in the 1980s that was further supported by a series of laws, passed by the U.S. congress[17]. In addition, the foundation of the Court of Appeals for the Federal Circuit (CAFC) in 1982 was another major step towards stronger IPRs in the U.S. that "soon emerged as a strong champion of patentholder rights" (Mowery et al. 2001).

Further, the development of the IPR regime was driven by huge litigation cases. A major breakthrough directly effecting the patenting of biotechnology inventions in the U.S. was the case of Diamond v. Chakrabarty[18] when the first patent on 'living organisms' was issued on June 16th, 1980[19]. The U.S. Supreme Court ruled that "the bacterium was eligible for a patent because it had been genetically altered, and was therefore new, not obvious, not in its natural state, and useful for research". As a result patenting of biotechnology inventions increased rapidly after this decision[20].

Further, until the early 1980s, software[21] was considered to be unpatentable in the U.S. The case of Diamon vs. Diehr in 1981 changed this mode, when the U.S. Supreme Court granted a patent on a "rubber-making machine controlled by software." Further, in 1998, a patent was issued for the first time on methods-of-doing-business (MDB) as a result from the case of Boston's State Street Bank and Signature Financial Group. This decision of the CAFC opened the 'floodgate' for software based MDB or sometimes called software enabled business practice[22]. In Europe however,

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However, most authors agree that the Bayh-Dole act accelerated the inevitable development. C.f. (Nelson 2003)

[16] The single most profitable patent during the 1980s and 1990s has been the Stanford-Cohen-Boyer patent, generating about 2 M€ from 1981 to 1997 (Mowery et al. 2001).

[17] Further the government was concerned that U.S. industries had difficulties in protecting and exploiting their technologies, as the competitive pressure by Japanese companies increased (Granstrand 1999).

[18] Case number: 447 U.S. 303, 1980

[19] Some authors claim that it was not the 'first' patent issued on living organisms, but it is often referred to.

[20] Further, major decisions in the U.S. have been: 1987 U.S. Patent office announces that "non-naturally occurring nonhuman animals" are patentable. 1988 The "Harvard Mouse", an oncomouse genetically altered to be especially susceptible to breast cancer, was the first U.S. animal patent issued. 1991 Expressed sequence tag (EST) patent applications filed.
http://www.genesage.com/professionals/geneletter/archives/livingorganisms.html; 2003/09/25; 10:25
http://supct.law.cornell.edu/supct/cases/447us303.htm; 2003/09/24; 16:12

[21] Software is as well important for many biotechnological applications, especially in the field of bio-informatics.

[22] Today major ICT companies as e.g. Amazon, Dell, and AOL have filed such kind of patents (Hall 2003; Lang 2001). Recently, Microsoft was judged by a court in Chicago to have sued a patent filed by Eolas in 1994. Microsoft is supposed to pay 425.7 M€ to Eolas and the University of California.
http://www.spiegel.de/wirtschaft/0,1518,260928,00.html; 2003/09/21; 12:28

the protection of MDB and software was excluded from the European patent law, although just recently discussions on the patenting of software appeared in Europe and many indirect software patents in Europe were granted already.

Although the EPO was established in 1973 after the European Patent Convention was drafted, there has not been a European-wide patent so far. Recently, the European Union approved a 'Community Patent' on March 3rd, 2003. Being filed only once, at one of the national patent offices in any member state, it is becoming valid in all EU member states. The Community Patent should help "breaking down patenting barriers and reducing patenting costs, in particular translation costs"[23]. In addition a Community Trademark and a Community Design was proposed. The first registration date for filing a Community Design was already April 1st, 2003. On July 5th, 2000 the EU also proposed to found a Community Intellectual Property Court (European Union 2003; Lang 2001).

In addition to the U.S. and European developments, international organisations and agreements were established in order to simplify the growing international technology trade, and to establish an international harmonization of the patent system, thereby indirectly but significantly influencing the growing importance of IP for increasingly globally operating companies.

In January 1995, the WTO (World Trade Organisation) adopted the TRIPS (Trade-Related Aspects of Intellectual Property Rights) agreement. This agreement introduced intellectual property rules into the multilateral trading system for the first time, regulating the international trade of technologies and became the "most comprehensive multilateral agreement on IP" so far (WTO 2003).

As a complement to the WTO, the WIPO (World Intellectual Property Organisation) was established, that evolved to an almost worldwide organisation "dedicated to help to ensure that the rights of creators and owners of IP are protected worldwide". Already in 1970, prior to all the major changes in the U.S. patent law, the WIPO concluded the Patent Cooperation Treaty (PCT), which enables inventors to seek patent

[23] As Thumm, N. (2001) reports the lifetime costs of maintaining world-wide coverage for a single patent is in the region of 200 T€. These costs consist in average of 22% for patent attorneys and 33% for transaction costs. Of course costs are of higher importance for smaller firms than for larger ones, but are of "minor importance when making the decision to apply for a patent".

protection in each of a large number of countries by filing an 'international' patent application (Lang 2001) (WIPO 2003a)[24].

During the last two decades the worldwide value of intangible goods and services increased dramatically and of course gave reason to, as well justifying the above mentioned developments. However, currently some authors "raised the warning flag" and started to guard against the risks, which are embedded in these developments (Heller and Eisenberg 1998).

With the developments in the past, two major streams were accompanied. On the one hand, patents became broader and on the other hand, the criterion of applicability ('usefulness' in the U.S. patent system) became less important. Whether, these developments generate sufficient economic benefits, while leading to additional social costs[25] seems to be doubtful. Today, especially in biotechnology, many DBFs just develop upstream inventions, for which the applicability can only be claimed for their "value in performing further research" (Mazzoleni and Nelson 1998). There seems to be a need for a "more cautious and balanced view" on the broadness of patents and their applicability. The National Research Council in the U.S. in 1997 and the study of Nelson and Mazzoleni (1998) raised the point, that today much research is licensed exclusively by universities, while it would have been otherwise in the public domain. Both studies suggest at least rethinking the exclusive licensing strategies of universities. As argued by Heller and Eisenberg (1998) although the strengthening of the IP regime has always aimed on avoiding the overuse of common goods (tragedy of the commons), not finding the right balance of the broadness of patents and the applicability criterion, implies a risk of achieving the counter effect (Heller and Eisenberg 1998).

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[24] On August 25th, 2003 the electronic company Philips was the first "to file a fully electronic international application under the World Intellectual Property Organization's (WIPO) […] PCT". It has now become possible to file international applications either on-line or using physical media such as CD-R, what will probably "translate into significant efficiency gains both for users of the system and for WIPO which administers the PCT" and seems to be a new major breakthrough for IPR matters. http://www.wipo.org/pressroom/en/releases/2003/p350.htm 2003/09/18

[25] Sometimes it even happened that the density of IP for developing a drug became such that drugs are dropped from development due to sheer complexity of the IPR situation (European Commission 2001). As a result companies often face an IP assembly problem, when many technologies are required for embedding in one product. Companies, especially smaller ones facing resource constraints, often are not able to identify all required technologies and involved patents properly (Granstrand 2000).

A good summary was given by Lee Bendekgey from Incyte, when he formulated: "the challenge is to establish policies that provide appropriate incentives, while avoiding protection that is so broad that it inhibits innovative use of IP" (European Commission 2001).

2.4 IP management

Managing several IPRs in an integrated manner in the short-, mid-, and long-term is the primary task of the IP management. Besides dealing only with IPRs developed in-house the IP management is further concerned with the company's total technology base. This concept is described in the following section of this second part of the thesis. Afterwards, properties of the elements included in the technology base, the IPRs, are shortly illustrated. In the third section the IP management is introduced and to which extent it can be sophisticated. How sophisticated actually this 'behaviour' is developed in companies is further subject of this thesis.

2.4.1 The company's technology base

In this thesis the 'technology base' concept (applied from (Granstrand and Sjölander 1990)) is utilized as a research tool that helps to expose the development of companies' IP management. Thereby, it is of reasonable importance for the outcome of the thesis[26].

The 'technology base' is defined as "essentially the asset of the technological competence that […a] company possesses"[27]. Several authors make use of related terms like 'patent portfolio' (e.g. (Ernst and Soll 2003)), 'knowledge base'[28] (e.g. (McKelvey et al. 2004; Ramani and Looze 2002)), or 'technology portfolio', the technology base fits the purpose of this thesis best, as it comprises IP in a wider sense, including all IPRs a company possesses as well as certain know-how and expertise with underlying tacit nature (see as well chapter 2.1).

[26] The technology base concept with related elements (e.g. technology acquisition) is applied as well for research in biotechnology by (Pearson and Ball 1992).
[27] Underlying this definition is the assumption that technologies represent resources. It is widely accepted today that technologies represent resources or assets of major importance for many companies and not at least for so called technology based firms (TBFs) (Connor 2002; Peteraf 1993; Rangone 1999).
[28] The knowledge base "refers to areas of scientific and technological knowledge, including both the knowledge itself as well as its embodiment in techniques and instrumentation" (McKelvey et al. 2004).

Granstrand, O. and S. Sjölander (1990) identified on the one hand five technology acquisition (sourcing) strategies, which add to the current technology base, and on the other hand six technology exploitation (commercialization) strategies, which reduce a company's technology base[29] (see Figure 5). All acquisition and exploitation strategies are concerned with the "generation, combination, transformation, regeneration and recombination of technologies", wherefore they are accompanied by a transfer of explicit (e.g. patents, license agreements, technology descriptions, etc.) as well as of tacit knowledge (personal experience, know-how embodied in specialists, etc.). Further these strategies differ in their degree of organisational integration, as "different contractual forms imply". The current stock of technologies a company possesses - its difference between acquired and exploited technologies - is what is considered to be the company's current technology base.

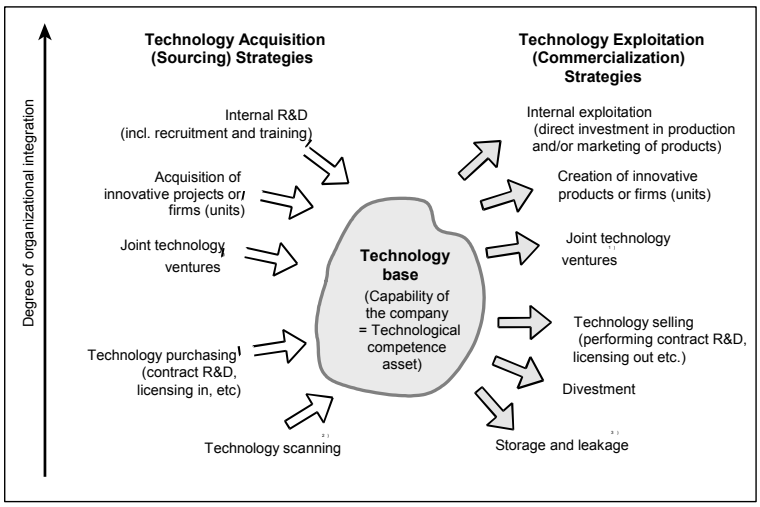

Figure 5: Technology acquisition and exploitation strategies[30]

The choice of these strategies varies widely across companies and sectors. Different acquisition strategies may be combined with different exploitation strategies. Depending on which combination of technology acquisition and exploitation strategies a company follows, the IP management is concerned with different tasks on an operational level (Granstrand 2000).

[29] Edvinsson, L., & Sullivan, P. H. 1996 define almost similar „conversion mechanisms".
[30] Adapted from: (Granstrand and Sjölander 1990)

Technology acquisition[31]

Often the purpose for companies to acquire certain technologies is to complement their core technologies with certain technologies from third parties. Reasons for this could be either that in-house R&D is more expensive in terms of time, costs, opportunity costs, inventing around costs, etc., than a technology acquisition, or even if a certain technology is protected by IPRs to another company. However, different strategies require different degrees of organisational integrating and efforts of the management.

The highest level is the development of own technologies through own/ in-house R&D efforts. However, this implies the recruitment and training of employees and quite often demands a large time frame. The acquisition of a certain innovative company, in order to access its technologies requires certainly a high level of organisational integration. At least to some extent this acquired company needs to be integrated to fully utilize its technologies. The third acquisition strategy – forming collaborative JVs with partners or even competitors is appropriate when huge investments are necessary or know-how from the partners can be complemented in a favourable way in order to develop new technologies. The forth level of technology acquisition is the way of purchasing a technology by in-licensing[32] a right to access a certain patent on exclusive or non-exclusive basis. The lowest level of technology acquisition is scanning for technologies, what includes "legal and illegal forms of acquiring technological know-how from the outside without any direct purchasing from its original source" (e.g. product reengineering) (Granstrand 2000).

Technology Exploitation

Companies exploit technologies for two purposes, either to make direct use of it or to generate further revenues. Important for this decision is the question whether a certain technology can be considered important for the company's competitive advantage - being a core technology or not.

The highest level of organisational integration is in-house technology exploitation, e.g. companies themselves apply directly certain technologies for further R&D, in production or marketing. As well, companies choose to exploit technologies and cre-

[31] This chapter and the following one is mainly based on (Granstrand 2000) and (Granstrand and Sjölander 1990).

[32] Different types of licenses are not core of this thesis. For further reading see: (Grindley and Teece 1997; Pitkethly 2001; Granstrand 2000). For especially objectives of licensing see: (Teece 2000).

ate another company transferring certain technologies to a 'newly' founded spin-off. This may appear for technologies which are of no value any more for the company as it may have made the decision to exit a business, when the top management has decided to refocus on the company's core competences or for other reasons. However, if a single technology is not able to offer a business opportunity, it may be complemented with certain technologies from partners or even competitors by forming a JV. If neither forming a new company nor forming a JV appears to be feasible or advantageous, a company might decide to sell a certain technology as well as related IPRs (e.g. patents and trademarks) (Granstrand 2000; Stewart 1994). If no buyer for a technology or even certain IPRs is available (or even for other reasons) the company can decide to abandon technologies and not further follow their application and development. Companies often drop or often denote patents to non-commercial institutions e.g. universities. Finally, if there is no current but maybe potential usage in the future a company may decide to store the technology in order to apply it in later generation of products (Granstrand 2000; Rivette and Kline 2000; Smith and Hansen 2002).

2.4.2 Properties of different IPRs

Since IP management is concerned with several IPRs an IP portfolio, IP mix or as in this thesis the company's technology base, as a tool comprising all different IPRs, the 'main' IPRs (patents, trademarks, copyrights, database rights, trade secrets and prophylactic publishing) and their properties are describe shortly[33].

1. Patents are often seen as the strongest and probably most important IPR for many companies. According to the definition of the EPO[34] a patent is a "legal title granting its holder the exclusive right to make use of an invention in a limited era and time by stopping others from, among other things, making, using or selling it without authorization"[35]. In all major European countries patent protection is limited to 20

[33] For further readings see: (Granstrand 2000)

[34] There a several different definition, although the one from the EPO fits the purpose of this thesis and is applied quite often by many often cited authors.

[35] www.epo.org; August 10th, 2003. It might be noted that a patent gives a legal right to its owner, but does not automatically grant its owner the right to make use of the invention. In particular for in the pharmaceutical industries a company holding a patent on a drug, is not permitted to sell this drug unless it gains further approvals by governmental authorities (e.g. the FDA in the U.S. and the CE approval in Europe) after extensive tests have proven its compatibility.

years. In order to be patentable an invention has to be novel, applicable[36] and non obvious. Patents can be granted on products (parts, applications, chemical substances, etc.) or processes (production processes, etc.). In addition, in the U.S. software can be patented since 1981 and methods-of-doing-business (MDB) since 1998. In Europe however, software could not be patented until fall 2003 and MDB business patents are not accepted so far (Granstrand 2000; Pitkethly 2001)[37].

Patents fulfil two major functions as being "important as competitive means for the protection and commercial exploitation of new technologies […as well] as a means for technology and competitor intelligence". What differentiates patents against other IPRs is, that the patent system is based on disclosure of information to society rather than keeping information secret. All granted patents are freely available to the public domain after 18 months. In general four main advantages of patents exist: provision of protection, bargaining power, internal advantages, image improvement (Granstrand 2000; Lang 2001).

The value of a patent is dependent upon a number of factors such as the potential for licensing to other businesses thereby generating additional revenues, the quality of the patent, the importance of the market covered by the patent, and the effectiveness and stringency of patent enforcement. Patents have the potential to be transformed into royalty generators through licensing or can be used to negotiate cross-licensing agreement that help to reduce costs of acquiring needed technologies. Further, the quality of a patent is highly dependent on the quality of the technical examination to determine the relative newness of an invention given the available scientific and technical knowledge. High-quality patents can help to attract risk capital and financing for new start-ups as they represent "tangible evidence of earnings potential and competitive prospects to investors and the financial community" (Lang 2001).

2. Trademarks often complement companies' technologies by branding them and creating a certain identity of products. A trademark is defined as "a distinctive mark […(name associated with a company, product, or concept, as well as a symbol, picture, sound, smell or even internet domain)] through which products of particular manufacturers maybe distinguished from those of others". Trademarks often play an

[36] In the U.S. an innovation has just to fulfil the 'usefulness' criteria, which is not that strong. For further explanations and discussions on these criteria see: (Dosi 1988; Eisenberg 1987; Granstrand 2000)

[37] For a description of different patent filing processes see: (Thumm 2001)

important role for companies in the long run success. They are "indefinite in duration, so long as they are used on or in connection with goods or services for which they are registered" (Davis and Harrison 2001; Granstrand 2003b).

3. Copyrights are "intangible, incorporeal rights granted by statute to the author or originator of certain literary or artistic materials", such as plays, books, architectural design, computer software, graphic arts, motion pictures, sound recordings, and videos (Davis and Harrison 2001). Generally copyrights last for a certain period in time - between 50 and 75 years after the authors' life. However, as copyrights are usually not a very strong title of protection they have gained considerable attention just recently with the digitalisation of music and movies and the ease of distribution throughout the internet. Further, design or mask works protect the appearance of articles of manufacture, for currently 14 years in the U.S.

4. As related to copyrights, database rights[38] became increasingly important as a means to protect a collection of specific knowledge as companies but as well countries started to package lots of data in an electronic way with the emergence of ICT[39]. As these databases often represent enormous values to its owners (just to mention the human genome or customer databases of global enterprises) to formulate certain means to protect databases against competitors became necessary. The EU defines database rights as the rights which are provided "for the maker of a database which shows that there has been … substantial investments…, to prevent acts of extraction and/or re-utilisation of the whole or a substantial part… of the contents…" (European Parliament and of the Council 1996).

5. Additionally, companies can apply other means of protection. A trade secret[40] is "a pattern, formula, device or compilation of information which is valuable to a given business and not publicly known" (Granstrand 2000). Trade secrets often complement patents, typically in a way that product technologies are protected by patents while process technologies are protected by trade secrets. The owners of trade secrets do not have the absolute power to exclude others from specific activities except to prohibit the illegal acquisition of the protected secret by the breach of confidence,

[38] During the study it appeared that database rights where not that important for any of the case company. However, database rights play an important role in related fields as e.g. bioinformatics (Bosson and Riml 2002).
[39] Even the EU released a EU Database Directive in 1996 (European Commission 2001)
[40] Probably the most famous example for a trade secret is the formula of Coca Cola. For additional readings see: (Granstrand 2000)

breach of contract, or industrial espionage. Usually, the owner is required to make efforts to keep it secret in order to obtain any legal protection through trade secret rights. If a company can protect its trade secrets against theft, a trade secret may "last for an indefinite period of time" (Lang 2001).

6. Further, companies can apply 'prophylactic publishing', a technique used in order to hinder competitors to patent a certain technology, as publishing eliminates the novel criteria required for patenting. Further, reliance on a market nice and being very specialized and creating a "highly integrated set of activities" can support companies protecting their IP and gaining a sustainable competitive advantage (Granstrand 2003b; Intellectual Property Initiative 2003; Porter 1996).

2.4.3 Stages of IP management

"In a knowledge economy, IP moves from a legal matter to a strategic issue."
(Smith and Hansen 2002)

Today, many companies have understood to fairly handle their R&D in a sophisticated way, thereby "creating innovations and generating more IP than ever before" (Hall 2003)[41]. Due to a growing importance of patents for a company's competitive advantage, as well as the increasing quantity of patents, companies are likely to strengthen their patent management competence. As reported and suggested by many authors (e.g. (Davis and Harrison 2001), (Sullivan 2000), (Edvinsson and Sullivan 1996), etc.) companies are likely to shift towards a sophisticated and even strategic IP management (see chapter 2.4.4). However, companies might not directly enter a level of strategic IP management but rather develop throughout different 'IP management stages'. To explore this development of IP management and its different stages in DBFs is subject of this thesis.

Each shift towards another IP management stage is driven by certain events which cause companies to become increasingly aware of the need for a sophisticated IP management. Each event can be characterised by its length and impact, as shown in Figure 6.

[41] For further readings on the "distinction between an innovation and the intellectual property which embodies that innovation" see: (Teece 2000)

Throughout these IP management stages companies are likely to increase their IP management competence/performance. However, for different companies due to several reasons e.g. a different sequence of different events, various paths of IP management developments are possible. Path A illustrates a development with one crucial event with a huge impact in a very short time period, path B is characterised by several accumulated events with low/ incremental impact. Path C illustrates a combination of both extreme paths A and B.

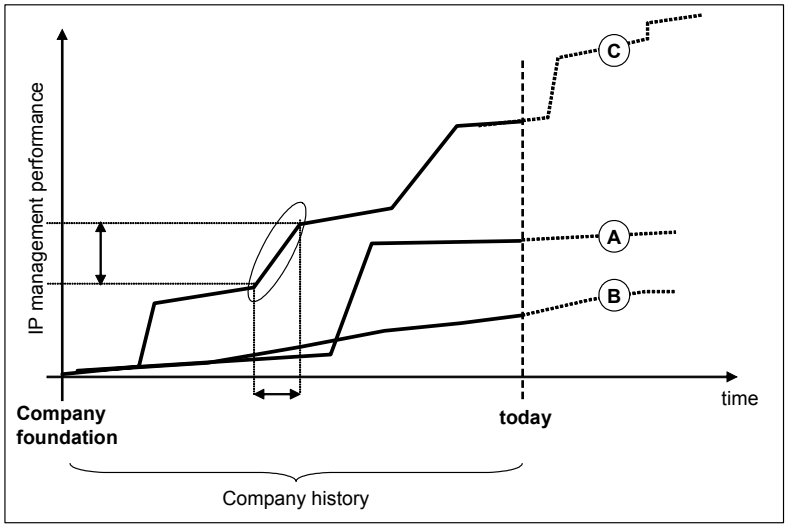

Figure 6: Stages of IP management[42]

Davis, J. L. and S. S. Harrison (2001) introduced the concept of the "value hierarchy" and defined five stages until a company has reached a sophisticated IP management (see Figure 7). Companies are likely to start from a merely 'defensive level' where IP management provides a "patent shield to protect the company from litigation", while viewing IP purely as a legal asset. Throughout the second stage (cost control) companies try to "reduce the costs of filing and maintaining their IP portfolio". IP managers might view IPRs still primarily as legal assets; however, they are likely to have background in business or at least longer experience with IPRs.

[42] Source: own figure. The scale of the y-Axis is still rather subjective.

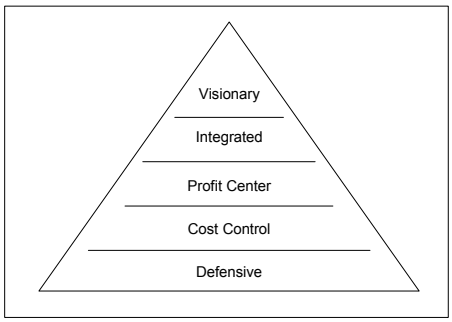

Figure 7: IP management value hierarchy[43]

Entering the 'Profit Center' level, companies start to view their IP as a business asset and often introduce functions like "Vice President-IP". The IP management is now focussed on more "proactive strategies that can generate […] additional revenues while further continuing to trim costs". As Davis, J. L. and S. S. Harrison (2001) report, managing IP throughout this stage requires "a major change in a company's attitude" towards IP.

In the fourth 'Integrated level' an IP department becomes integrated into a company's day to day operations with those of other functions. The head of the IP department often holds a senior vice president title, thereby linking the IP department directly to the company's business strategy.

When companies reach the highest level of IP management (visionary) the IP department's purpose is merely to identify "future trends in the industry and consumer preferences" and to "position the corporation as a leader in its field acquiring or developing the IP […to protect the] company's margins and market share in the future." To reach this purpose the IP department should be headed by a person involved in strategic planning (Davis and Harrison 2001).

In contrast to this model Taylor, C. T. and A. Silberston (1973) characterise four stages of IP management according to the size of the patent department. Since this study has been conducted in industries of the "old-economy", one might question whether this pattern holds true as well for companies in the "new-economy" as surveyed in this thesis. However, characterizing IP management stages according to the number of employees seems to be obviously a possible criterion.

[43] Adopted from: (Davis and Harrison 2001)

Throughout a first stage the patent department is headed by a part-time technology manager who works closely together with external patent attorneys. In a second stage a full-time patent manager[44] merely handles all patent issues together with a small staff, which is not specifically trained on patent matters together with external patent attorneys. Entering the third stage the patent department consists of a specialized patent manager with a corporate patent department working closely together with employees in all business divisions as well as external patent firms. The last stage defined is called "super patent department" which consists of about 35-50 persons working only on patents. The companies having embedded such a department often have a separate licensing department (Taylor and Silberston 1973). These four stages have been expanded through findings during his studies of large Japanese companies by Granstrand, O. (2000) by two additional stages[45]. However, these both stages seem not to be applicable for the six case companies due to their size and age.

2.4.4 Towards strategic IP management

Although, recent studies (e.g. (Schwieger 2002; Sullivan 2000)) proved that the majority of today's companies - larger as well as smaller - still do not integrate their IP as a major capability into their business activities – operational as well as strategic – and handle it in an appropriate manner to achieve and sustain their competitive advantage[46], there is a shift towards a more strategic oriented management of the 'IP mix' ongoing especially in emerging high technology industries as e.g. biotechnology (ETAN Expert Working Group 1999; Smith and Hansen 2002). Today, many companies in emerging industries almost 'rest' on the ability to generate royalty incomes, what becomes particular important during a consolidation phase of an industry, where companies face increasing competitive pressure and in phases of economic downturns, where access to VC is limited (Giovanetti and Morrison 2001). Licensing offers an important instrument for generating revenues through royalty incomes since royalty incomes contribute directly to the company's bottom line profits (Teece 2000).

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[44] Taylor, C. T. and A. Silberston (1973) further mention that one patent manager is able to handle up to a dozen patent applications per year.

[45] A comprehensive 'IP department' consists of 50 to 500 employees with an own patent culture and represents the fifth stage, while a sixth stage is an 'extended IP organization' with the purpose of handling separately technology acquisitions and exploitation, technology intelligence, etc.

[46] In a survey conducted by Schwieger, A. (2002) it appeared that almost 94% of the investigated companies "use their IP only defensively".

Handling IP strategically leads an increasing number of companies to shift from a defensive towards an offensive IP management, as Granat, J. (2003), Granstrand, O. (2000), Sullivan (2000), and several other authors indicate. Granat, J. (2003) defines defensive patenting as to "stop other firms from patenting its invention, even though the firm does not need a patent itself in order to earn a return on its investment in innovation. The firm earns a return through non-IPR appropriation methods". Closely related is the behaviour of several firms to patent inventions to build up bargaining power for cross licensing purposes, for technology trade, or rather to be accepted on a certain technological field. Firms patent offensively to "prevent other firms from patenting inventions that are similar, but not identical, to the invention that they plan to commercialise" in order to prevent other firms from commercialising competitive products, even though the firm does not intend to market these other products itself.

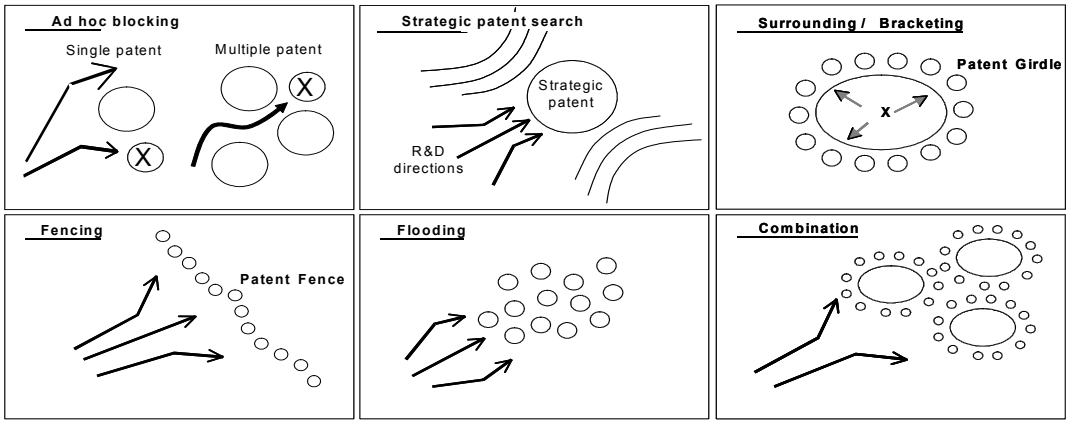

Figure 8: Patent strategies[47]

In order to accomplish a strategic IP management companies (need to) apply several tools[48] (e.g. IP management software and databases) and concepts as an IP policy, IP strategy, and maybe even introducing litigation strategies, trademark strategies, secrecy strategies or even developing a patent or IP culture[49] - as many (large) Japanese companies did in the past as surveyed by Granstrand, O. (2000) - in order to support their 'total' IP management with the aims of cost control, pursuit of profits,

[47] Adopted from: (Granstrand 2000)

[48] (WIPO 2003b) even suggest for SMEs to apply policies for IP exploitation, IP monitoring, and IP enforcement as a minimum when dealing with IP strategically.

[49] A patent (IP) culture is characterised by eight elements: Top management involvement in patenting and IP, patenting and IP as common concern for all engineers, patent policies and strategies integrated in the business plan, clear patent objectives, clear patenting incentives for R&D personnel and organizational units, fostering of behavioural attitudes and norms, visible organizational means, and a common language, methodology and philosophy (Granstrand 2000).

the integration of IP into corporate 'fabric', and the creation of a lasting vision for IP (Davis and Harrison 2001).

An IP policy on the one hand has the purpose to "support the business operations of an enterprise", while an IP strategy on the other hand "defines the principles that IPRs are designed to serve and how patent matters and other IP matters are handled within the enterprise" (Sipilä 1999). An IP strategy has to pay attention to two areas, where IP management is important. First, the internal management of IPR, which largely concerns the running of the IP department and managing its interaction with other departments, and second the IP management concerned with the external management of IPRs, primarily how a company interacts with other companies' IPR and vice versa (Pitkethly 2001)

Since patents are the 'most tangible' form of IPRs and enjoy the strongest legal protection they often have the greatest effect on the commercial success of companies. Therefore patenting becomes of strategic importance when handling IPRs strategically involving the questions: What to patent, when and where to file? How to apply different IPRs to strengthen the company's competitiveness and to develop the enterprise? (Sipilä 1999)

Whether talking about products, technologies, or business models, patents can significantly enhance a company's ability "to secure and defend sources of market place advantage, even in times of rapid technological change" (Rivette and Kline 2000) although a prerequisite for strategic patenting is the "active observation of competitors' patent portfolios" (Thumm 2001). Granstrand, O. (2000) defined six patent strategies, which are illustrated in Figure 8 and explained in the following.

These patent strategies underlies the general idea that a patent blocks certain areas in a so called 'technology space'[50] as a patent gains its holder a monopoly to exclude others from usage. Applying this idea is the simplest form of a patent strategy, what Granstrand, O. (2000) calls the 'ad hoc blocking and inventing around' strategy. Applying this strategy companies patent their inventions as they appear, what happens mainly at companies with "small resources and/or disregard of small patents and

[50] A technology space is a "technological terrain or technology landscape, which is gradually explored by R&D processes" (Granstrand 2000).

portfolio effects". Therefore 'invent around costs'[51] for other companies are relatively low. Applying the 'flooding' or 'blanketing' approach companies file multiple patents in a less structured way in a certain technological area with the purpose to make this area conspicuous for competitors. This approach often appears to be used by SMEs[52] in "emerging technologies when uncertainty is high regarding which R&D directions are fruitful." A more structured approach to patenting is the 'fencing' strategy where companies file series of patents to block "certain lines or directions of R&D." This strategy is often applied, when "different technical solutions […are possible for achieving] a similar functional result". Another more advanced strategy is the 'surrounding' strategy, that is often applied when a core[53] or central patent needs to be protected by 'knitting' a fence around it, e.g. when the central patent will expire in the short run. The patents included in the fence are often less important than the central patent. The fifth patent strategy is the 'strategic patent search' strategy. Searching and designing single patents with a large blocking power is the 'ultimate goal' to block a whole technological area and therefore often a certain business at once. Inventing around a strategic patent often requires enormous R&D efforts and therefore is almost impossible. Often by experienced and advanced IP managers these five patent strategies are applied in a complementing manner in a so called 'combining strategy'.

However, an IP management does not comprise solely of the application of a patent strategy. A sophisticated IP management rather integrates patents with other IPRs and even with a company's structural, relational or human capital and even further in the integration with the company's business strategy to strive for aligned goals. The extent of IP management depends further on the dedication of resources by top management, which is dependent further on the top management's awareness of the importance of IPRs in today's business environments. How the case companies have

[51] The costs for another company to develop an own technology that fulfils the same functionally as a patented one. See further: (Granstrand 2000)

[52] Referring to the definition of SMEs given by the EU small companies have less than 50 employees, medium companies a maximum of 250 employees, while large companies have more than 250 employees (Thumm 2001). However, for this thesis even the largest case company is considered to be an SME.

[53] A core patent has been defined by Rivette, K. G. and D. Kline (2000) as being a patent "that is or will be used in current or future products and is directly contributing to the products value. Non-Core patents are not being used in either current or planned products."

developed their IP management activities and which resources they have dedicated is further shown in parts four and five of this thesis.

2.5 Assessing IP management performance

This chapter is closely related to the third research question of this thesis with the aim to give an introduction of how the performance of IP management or even the IP department can be judged on the micro-level of the firm. Not much literature is available on this specific topic concerning IP management yet, therefore this chapters draws as well on general performance measurement characteristics to assess possible measures of IP management performance[54].

Several purposes for developing a measurement scheme for IP management exist. Having a clear picture of its IP management might support the top management in making uncertain and subjective 'feeling' visible, enabling inter-company comparison, but further enable companies to better signify shareholders the market value hidden in a company's intangible assets. If companies are able to explain the gap between market value and book value, they might even "decrease the vulnerability to certain external events" (Roos et al. 1997).

Today, it is widely accepted by managers, but as well by researchers that it is necessary in "many decision contexts to integrate financial and non-financial measures" of performance and qualitative information (Rangone 1997; Roos et al. 1997)[55]. Non-financial performance measurements are approaches that have been recently proposed as means of overcoming the limitations of traditional management accounting systems in dealing with strategic matters (Rangone 1997). The Balanced Score Card, as proposed by Kaplan, R. S. and D. P. Norton (1992) is just one well known example representing a combination of financial and 'operational' measures.

For assessing IP management it seems to be unlikely to be able to define one single quantitative measure that reflects the intangible nature of IP. Rather a set of multiple, quantitative and qualitative measures, maybe even combined with further indicators

[54] Just recently a more comprehensive project is ongoing on this topic at the Copenhagen Business School, carrying out a study with a much larger sample with the first results to be expected in mid 2004.

[55] The literature of performance measures has mainly focussed on financial measures until the 1980s. In the mid 1980s however, the focus shifted towards measuring qualitative characteristics accompanied by the 'quality movement' (Eccles 1991).

seems to be necessary (Harrison and Sullivan 2000; Roos et al. 1997). However, if companies are able to aggregate further their set of measure to a single index, they might even are able to link the IP management performance to the shareholders value (Kaplan and Norton 1992).

Eccles, R. (1991) defined three prerequisites for measures. The ones to be chosen should be affected 'solely' by the actions of the unit, be consistent with the short- and long-term goals of the company, and be reliable[56]. Roos, J., G. Edvinsson, et al. (1997) further expanded these three prerequisites by four criteria: Ease of use, comprehensiveness, reasonable time and effort required to develop its value, and its comparability. However, it appears that it is unlikely for a measure to fulfil all of these criteria and some "trade-offs will be required" when developing a set of measures. In addition, but as well to fulfil these criteria the relationships between the measures need to be understood, so that the measures can be weighted and prioritised. The measures might be broken down further into precise, robust, and relevant indicators that can be ranked and be expressed as a dimensionless number to be aggregate able. The indicators should take into account interdependences, causalities, and insufficiencies (Roos et al. 1997). The IP management performance is further dependent on clear objectives set by the top management and on the staff that is involved in IP management activities on the operational level, but as well of the people being involved on decisions on the strategic level and of course on the resource commitment of the company towards IP management (Harrison and Sullivan 2000).

Further, a set of measures should reflect a "balanced view between short-term and long-term profitability" it should consist of financial measures, but as well of other "success drivers of the company" (Roos et al. 1997). These circumstances are reflected as well by Harrison (2000) as she notes that IP management adds value mainly to a business on two dimensions. On the one hand companies can use IP to generate profits through licensing (today and in the future) and on the other hand IP can be applied for strategic positioning in the long term. Roos, J., G. Edvinsson, et al. (1997) use the terms effectiveness and efficiency, which need to be reflected by the set of measures and suggest rather to "concentrate on a few […] than to keep track of many different ones simultaneously".

[56] For further discussions on characterisitcs for measures see: (Horváth 2003 ; Reichmann 2001)

Some authors propose another approach than to measure the performance of the IP department to assess its performance. As ‘an’ aim of the IP department is to maximize the value of IP in the company the authors suggest to value the IP (IP auditing) and further assume this value to reflect the ‘performance’ of the IP management in context of the overall company performance (Rivette and Kline 2000; Smith and Hansen 2002; Sullivan and Sullivan 2000). However, it might be questioned, whether the value of IP solely reflects the performance of the IP department. Do ‘revenues reflect a company’s profitability’? This approach is not followed throughout this thesis.

3 Biotechnology

This third part of the thesis introduces biotechnology related issues. After biotechnology is defined, an introduction to the history of biotechnology and especially the German and Swedish market environments is given, and the term 'Dedicated Biotechnology Firm' (DBF) is explained. In a following section, business models and business opportunities are elaborated. Finally, the importance of IP management in the pharmaceutical biotechnology industries is introduced to the reader.

3.1 Defining biotechnology

Biotechnology proved to be an enabling technology, wherefore, a definition of biotechnology does not apply for a particular industry, but rather for a conglomerate of applications of these 'technologies'. Several definitions of biotechnology were proposed by numerous authors in recent years. The following definition was published by the OECD (Beuzekom 2001), is "currently among the most frequently cited" one[57] (McKelvey et al. 2004) (cf. Schüler, J. (2002) [58]), and fits the purpose of this study:

> *"Modern biotechnology means all innovative methods, processes or products which mainly involve the use of living organisms or their cellular and sub-cellular components and which use research results in the fields of biochemistry, molecular biology, immunology, virology, microbiology, cell biology or environmental technology and process engineering within the framework of a causative interpretation."*

In accordance with an interpretation by Ernst & Young in Herstatt, C. and C. Müller (2002) this definition includes innovative products and processes, but it does not include genetical methods, e.g. gene libraries, immunoassays, or sectors, which are not "bio"-technology in its narrow sense. But due to their close relations to biotechnology, they "can be considered elements of the life science value chain [… e.g. bioinformatics, biosensors, combined chemistry, high-throughput-screening, and biomate-

[57] However, the OECD is currently reworking this definition as it is often seen as being to narrow. McKelvey, M. et al. (2004) present a comprehensive overview and discussion of several definitions of modern biotechnology.

[58] As well used in the Ernst & Young biotechnology reports (Germany, Europe, U.S., and Global), which are often cited in scientific papers, reports and textbooks too (Allansdottir et al. 2002; Herstatt and Müller 2002; Senker 1998).

rials] and should be included". This expanded definition takes a broader view of biotechnology and fits very well the case studies included in this thesis.

3.2 Introduction to biotechnology

The initial commercialisation of biotechnology was due to two scientific breakthroughs in the U.S.[59] in the mid 1970s. In 1976, the venture capitalist Robert Swanson recognized the potential of biotechnology and launched Genentech, the first company explicitly and solely devoted to genetic engineering. The foundation of Genentech led to the 'birth' of biotechnology companies and industries and was followed by an 'explosion' of small dedicated biotechnology firms (DBFs) (see chapter 3.3) led by academic entrepreneurs. In 1992, the U.S. pharmaceutical company Eli Lilly, launched the world's first biotechnology drug (the human insulin product 'Humulin'). "Today, more than 90 biotechnology drug products and vaccines have were approved by the Food and Drug Administration (FDA) and global sales of biotechnology-based products […] reached more than 16.4 M€" (Löfgren and Benner 2003).

The absence of venture capitalists in Europe (except the UK), the lack of knowledge about the new technologies, and the rather negative attitude towards industry by European scientists caused Europe a delay in the emerging biotech industry (Senker 1998). Outside the U.S., the quality of research was not available nor sufficiently favourable economic conditions to start a new company, so that a formation of university spin-offs on a similar large scale did not take place (Orsenigo 1989).

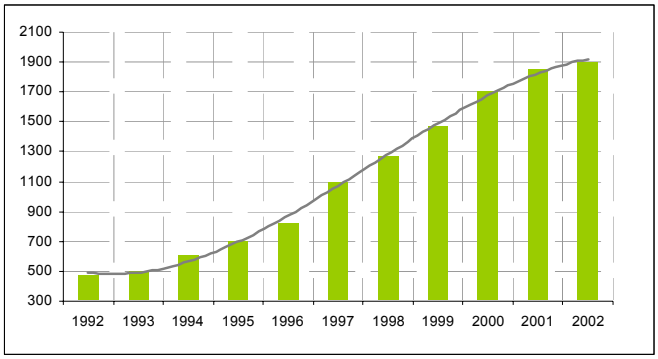

Figure 9: Development of number of DBFs in Europe[60]

[59] In 1973, Herbert Boyer and Stanley Cohen discovered that the DNA can be cut, recombined and inserted into a foreign bacterium and Milstein and Kohler reported the discovery of monoclonal antibodies in 1975 (Senker 1998).
[60] Adapted from: (Crocker 2003)

Although, today, the European biotech landscape still lacks certain competences[61], the number of organisations related to biotechnology grew up to 3,668 at the end of 2001 with around 61,000 employees[62]. Among these organisations there were 1,730 DBFs[63] and 362 suppliers (Allansdottir et al. 2002). Regarding the number of firms Germany[64] (504 firms) leads the European biotech industry, followed by the UK (448), France (342), and Sweden[65] (235). These four leading countries account for 73% of all companies in the European biotechnological industries. However, as Allansdottir, A., A. Bonaccorsi, et al. (2002) report, approximately only 10% of these DBFs have more than 50 employees. The market in Europe for biotechnology-based products has been estimated of about 80 b€ in 2005 (Löfgren and Benner 2003).

German DBFs are mainly active in human health care (therapeutics and diagnostics), while Swedish DBFs focus on human and animal therapeutics. German DBFs entered the industry to "explore the commercial value of recent technological advances in genomics, proteonomics and bioinformatics", while the Swedish companies draw considerable attention to "manufacturing biomaterials and on innovative technologies in drug discovery." In both countries industries seem to be specialized either in terms of technologies or domains of application (Allansdottir et al. 2002). In October 2003, 27 German and 32 Swedish DBFs were listed at the Frankfurt, respectively Stockholm stock exchange.

3.2.1 The German biotech landscape[66]

The German biotech landscape has its roots back in 1993, with the amendment of the Gene Technology Law. When in 1995/1996 the 'BioRegio'[67] competition was initiated by the Ministry of Science biotechnology gained increasing attention in the public and the first biotechnology start-ups were founded. However, the growth of DBFs

[61] In Europe, especially in Germany, innovative activity remains far below U.S. level. European companies make significant use of U.S. research but not vice versa. European DBFs are still much smaller than their U.S. counterparts and much less active in global collaborative relations. It seems that U.S. firms enjoy a first-mover advantage which is likely to provide long-lasting and difficult to erode leadership (Allansdottir et al. 2002).
[62] Compared to 162,000 in the U.S. (Crocker 2001)
[63] Referring to Crocker, 2001 there were only 1,351 DBFs applying a slightly narrower definition.
[64] One might add that according to (Crocker 2001) the number has risen by 150 percent in the past three years, which indicates that the majority of German Biotech companies is still in its infancy. Further German DBFs account for the highest ratio of DBFs per GDP by far.
[65] Sweden ranks number one, when calculating DBFs per capita.
[66] This section is mainly a condensed summary of selected, essential parts from (Schüler 2002).
[67] The BioRegio Competition was initiated to speed up the development of biotechnology clusters and especially DBFs in Germany. It is often seen as the breakthrough of Germany's initial growth in biotechnology (2000).

in Germany started slowly (Momma and Sharp 1999). In 2001, the number of DBFs reached 365, with around 3% of them having more than 100 employees (mainly the companies listed at the stock exchange), and 22% having more than 30 but less than 100 employees (see Figure 10). The total number of employees grew steadily up to 14,408 in 2001 (+35% compared to 2000), with about 55% working in R&D. Almost 65% of all German DBFs are geographically distributed in the major clusters around Munich, Berlin, Cologne, the Rhine-Necar area, and Rhineland (see Appendix F). The growth rate of companies slowed down recently which indicates the entry into a consolidation phase (Schüler 2002; Senker 1998).

The vast majority of German DBFs companies (about 45%) is active in developing therapeutics, followed by 21% operating in molecular diagnostics, about 10% in the drug-delivery field and about 6% in tissue engineering (Schüler 2002).

German DBFs generated total revenues of 1,045 M€ (+33%) in 2001, while the 27 listed DBFs accounted for almost 50% of the revenues. All companies realized total losses before tax of 411 M€ (+66%) and spent 1,228 M€ (+71%) on R&D. Only about 10% to 20% of all companies reached a surplus.

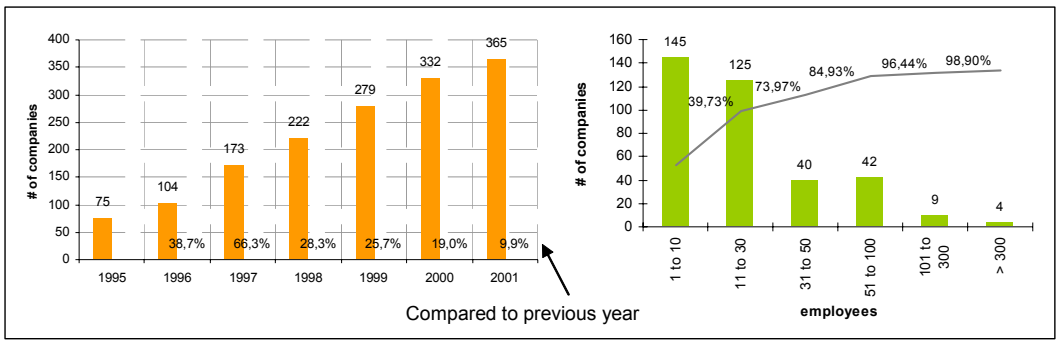

Figure 10: # of 'core biotech' companies (left) and # of employees per company (right) in Germany[68]

In 2001, German DBFs applied for 849 patents (+23.5%). Referring to Ernst & Young, the 27 listed companies, though being only 7% of all companies own 41% of all applied patents and 46% of all granted patents. Since the foundation of these companies 4,817 patents have been applied for and 44% were granted already in 2001. All German DBFs took out about 140 in-licensing deals (+/-0% compared to 2000) and signed about 180 out-licensing agreements (+173%). Almost 63% of the in-licensing (73% of out-licensing) agreements accounted for product-in-licensing,

[68] Adopted from: (Schüler 2002)

and 47% for technology-in-licensing (27% of technology-out-licensing). About 167 DBFs (+96%) signed technology cooperation agreements and 182 companies (+86%) have signed product cooperation agreements. In 2001, there were six acquisitions (-45%), two mergers and one joint venture (Schüler 2002).

Today, there is not any therapeutical drug developed by a German company on the global market. In 2001, there were already three candidates in the approval phase and 183 further back in the pipeline[69]. 238 molecular-diagnostics were established on the market and 29 bio-tissue products have been launched recently. 78% of therapeutical products are focussed on oncology, infections, metabolism, and cardiovascular diseases and are held by privately owned companies. The majority was still in the preclinical phase (67%), 27 products were in phase I+II, while only four were already in phase III of the pipeline (Schüler 2002).

As well as in the U.S. and in many other European countries the government established technology transfer policies and many universities and faculties established increased licensing and spin-off activities. Although governments launched several funding programs (e.g. BTU-program) or start-up competitions and research prizes (e.g. BioFuture), the main source of funds are still the companies own business activities accounting for 45.5% of their resource allocations, VC (15.5%) as well as the IPO (16.3%). In 2001, biotechnology companies raised 548 M€ of equity capital, which is almost only half of the equity capital they raised during the 'boom' in 2000 (OECD 2003).

In 2002, the situation in the pharmaceutical German Biotechnology industries was characterised by a "positive development of indicators, new business models, ongoing product development and a strengthening of existing, while establishment of new biotech clusters. In general, there seems to be a trend away from technology provider to product development companies". However, the lack of available VC slowed down the foundation of new DBFs and forced several companies to exit the market (Schüler 2002).

[69] The drug development process is often called pipeline. See further appendix D.

3.2.2 The Swedish biotech landscape[70]

The three large pharmaceutical companies on the one hand and the universities on the other hand were and still are large resources for innovation during the recent developments of biotechnology in Sweden. Many DBFs in Sweden are spin-offs from the three largest pharmaceutical companies in Sweden, Astra (today known as AstraZeneca), Pharmacia Corporation and Amersham Pharmacia Biotech, though the majority was spin-offs from the largest universities including the Karolinksa Institute (Stockholm), Uppsala University, Lund University, and Sahlgrenska Hospital (Göteborg). The emergence of DBFs in Sweden, starting in the 1980s, was further accelerated with the emergence of a large VC sector (Löfgren and Benner 2003; Sandström and Verket för innovationssystem 2001).

In 2001, there were 235[71] DBFs in Sweden (Allansdottir et al. 2002). In 1999, 41% of all DBFs were active in the drug discovery and development area (therapeutics), followed by 20% in the diagnostics field and 7% in the drug delivery sector. There were 25 biotechnology supplier and eight companies operating in the field of medical technology. 3,000 employees worked in biotechnology, with the majority (41%) in the drug discovery and development field, followed by 22% working in the diagnostics sector, 15% in biotechnology supplier companies, 12% in the drug delivery field, and 11% in medical technology companies. The majority of companies had less than 50 employees (88%) and 57% of all companies had fewer than nine employees (OECD 2003; Sandström and Verket för innovationssystem 2001).

In 1999, 93% of all DBFs in Sweden were clustered in the regions of Stockholm, Malmö/Lund[72], Uppsala, Göteborg and Umea, with a descending number of employees in the same order (see appendix F). The cluster around Stockholm, Malmö, and Göteborg are mainly characterised by drug discovery, drug development, and drug delivery companies, as in the region of Upsalla, mainly biotechnology suppliers (including bioinformatics and technology providers) are predominant.

In 1999, Swedish DBFs generated revenues of 178.2 M€ (+38% compared to 1997). These companies increased the number of patents steadily to 658[73] in 1997.

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[70] If no other source is mentioned, this section is mainly based on (Sandström and Verket för innovationssystem 2001).
[71] Applying a slightly narrower definition there were 179 (Crocker 2003).
[72] Malmö is closely connected to Copenhagen, Denmark. This region is often referred to as 'Medicon Valey'.
[73] These patents are only the ones filed at the USPTO.

Institutions in Sweden supporting entrepreneurial ventures are: NUTEK (formerly called STU), the Technology Link Foundation, and the National Industrial Development Fund. In 2000, there were about 200 VC firms in Sweden. The major ones, investing in Biotechnology were: HealthCap[74] and Ryda Bruk. However, there is a lack of governmental funding and VC in the early phases of start-ups (Sandström and Verket för innovationssystem 2001).

Sandström, A. (2001) notes as being positively for the future development of the Swedish biotechnology the quality and willingness of industry-academia collaboration by scientists, the increasing global orientation, the presence of AstraZeneca and Pharmacia, the strong entrepreneurial spirit, and the fact, that scientists own their inventions personally. However, some obstacles are still present (e.g. the lack of capital and incentives for early stage company foundations, lack of management skills, and the small national market) (Sandström and Verket för innovationssystem 2001). Compared to the German government, Sweden has always been characterised by relative weak state steering (Löfgren and Benner 2003).

3.3 The dedicated biotechnology firm

SMEs, which are solely founded to "explicitly explore and develop new biotechnology products and services" (Nesta and Saviotti 2003), are given several names. However, the most frequent ones are Core Biotech Companies (Schüler 2002), Entrepreneurial Life Science Companies (ELISCO) (Crocker 2000), or Dedicated Biotechnology Firms (DBF) (Nesta and Saviotti 2003). All definitions are quite similar and in this thesis the term 'Dedicated Biotechnology Firm' is used as applied by several authors (Allansdottir et al. 2002; McKelvey et al. 2004; Nilsson 2001; Senker 1998).

Typical DBFs are founded by scientists as spin-offs from universities (Senker 1998) as Technology-Based Firms[75] or even called New Technology Based Firms (NTBFs) in order to further develop and commercialise upon proprietary technologies. Saviotti in Senker, J. (1998) identified that DBFs evolve throughout three stages[76]. During their first stage DBFs are likely to be mainly suppliers of R&D to larger companies.

[74] HealthCap signed 12 deals in 2002 (Crocker 2003).
[75] For further explanations on technology-based firms see: (Granstrand 1998)
[76] Several other models have been proposed for emerging companies as well as for emerging industries. For a more detailed introduction see: (Klepper and Graddy 1990)

For financing issues DBFs often carry out contract research or are funded by VC in their early stage. Throughout the second stage DBFs concentrate on developing their core technologies, while product development is the focus in the third stage. Directly linked to these stages "changes […] take place in the composition of management and the labour force".

Usually, when DBFs grow, they have to acquire or build up additional competences complementing the companies' core (scientific and technological) competences. Teece, D. (2000) calls these additional competences complementary assets. Thereby, DBFs often integrate vertically, at least to a certain extent, although "very few firms reach to complete vertical integration" (Senker 1998). Becoming a FIPCO (Fully Integrated Pharmaceutical COmpany) requires DBFs to make huge investments, e.g. in production capacity, marketing and distribution, human resource, etc., what is very difficult due to financial constraints many DBFs face especially during early years. In order to survive and become successful sooner or later DBFs have to manage to "transform themselves toward a marketing oriented strategy" (Roberts 1991) and to even diversify into additional businesses (Senker 1998). Until today, only a few DBFs (e.g. Genentech, Amgen) managed to become fully integrated (Schüler 2002).

Saviotti, P. in Senker, J. (1998) identified three possible roles DBFs can play in their industry environment. First, DBFs can "behave like a Schumpeterian innovator" introducing a real innovation before imitation becomes widespread, i.e. DBFs often create new niches which later become new sectors. Second, DBFs often enter the market to exploit a small and very specific niche. Most probably these DBFs do not have such a high potential to grow - as the Schumpeterian innovator – and remain fairly small. Finally, DBFs could establish as a supplier of 'knowledge service' by conducting contract research to larger companies or even work closely together in collaborations. Very often, DBFs play several of these roles throughout their development or even simultaneously in certain phases.

As of today an industry landscape has evolved in Europe as well as in the U.S. in which DBFs complement BigPharma rather than replacing them. DBFs played and are still playing an "important role […] in the development of biotechnology" (Senker 1998).

Businesses in biotechnology

Associated with the drug development pipeline as explained in appendix D, DBFs deliver services or products for/throughout certain phases of the pipeline, while biotechnology mainly serves a research tools and process technology (Cockburn et al. 2003). These services or products target four main business segments (see Figure 11). The discovery business segments aim at discovering targets and lead candidates. Targets are molecules which have been identified as the most probable cause of a certain disease. Once several target molecules are identified the next step is to identify possible lead candidates which target the 'target'. Companies operating in this business segment screen huge component libraries against certain target molecules for lead candidate as contract research for other companies or to identify their own candidates for further in-house R&D. To perform this research companies develop technologies for screening large numbers of components in a decreasing time frame (e.g. high throughput screening).

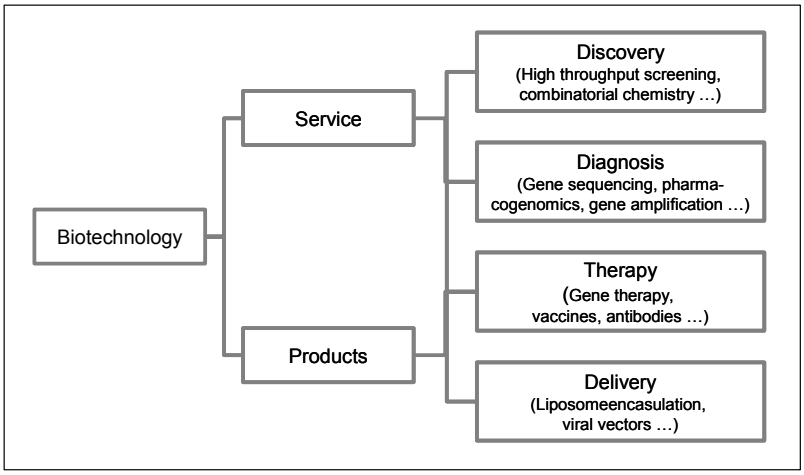

Figure 11: Overview of biotechnology sectors[77]

Companies operating in the diagnostics business aim to identify and interpret molecules or gene sequences causing certain diseases. Companies in the therapeutics business segment develop certain lead candidates throughout the pre-clinical and clinical phases, although some companies are specialized on either the pre-clinical, clinical or both phases. Companies in the delivery business segment develop biotechnological processes to deliver the drug that it reaches its target molecule in the human body (Giovanetti and Morrison 2001).

[77] Adopted from: (Halioua 2002)

In addition to this drug development process, several other businesses are also concerned with biotechnology (e.g. bioinformatics[78]). Since two case companies are operating in the biomaterials business it is shortly explained in the following.

Biomaterials

According to the National Institutes of Health (NIH), biomaterials are "any substance (other than a drug) or combination of substances, synthetic or natural in origin, which can be used for any period of time, as a whole or as a part of a system which treats, augments, or replaces any tissue, organ, or function of the body" (Crocker 2000).

However, since the focus of this thesis is the health care sector, a definition given by Rickne (2000) was chosen, who defines biomaterials as "synthetic or natural materials to be used to treat, enhance or replace human functions. These are materials that are either compatible with human tissue or mimic biological phenomena". Materials that are included in this definition, designed for the use in the human body are: Osseointegration using the material titanium, Silicon and other related materials used, for example, for orthopaedic, dental, hearing and cardiovascular implants, biopolymers used in implants and wound care, proteins used to coat surface and in tissue regeneration, and the technologies of tissue engineering employing biological materials used in tissue healing and regeneration (Rickne 2000).

Biomaterial related technologies are biotechnology, materials science, and biomedical engineering, while there are mainly three related sets of industries. The first group of industries might be called biologics and includes bio-artificial organs (pancreas, liver, kidney, etc.), artificial skin, synthetic blood. A technology of major importance in this industry is tissue-engineering. The second set of industries includes medical devices and implants (e.g. knee repair, artificial joints and hip replacements, as well as dental implants). Pharmaceuticals are the third group of industries with importance to biomaterials including drug delivery, surgical procedures for wound care, adhesion and surgical sealants. For different applications in these industries several technologies can be applied for the same purpose (e.g. artificial skin can be made with tissue engineering using biopolymers as well as biological materials) (Rickne 2000).

[78] Although a highly interesting business segment it is not in the focus of the thesis as no case company is primarily active in this area. For further information concerning bioinformatics see: (Bosson and Riml 2002; European Commission 2001; Vorndran 2002)

Biomaterial companies are more developed and present in Sweden than in Germany (Allansdottir et al. 2002). In 2000, there were ten companies in Sweden working on biopolymer and implants, five on bone-anchored implants, four on tissue engineering, four on drug delivery, four on biocompatible surfaces, and three on cardiac assist systems. The total number of employees was 1,212 working in R&D in this field with an average growth rate of about 50 percent from 1975[79] for 1998 (Rickne 2000).

3.4 Common business models

Though DBFs applied several traditional business models, they invented and 'coined' new ones in recent years. Due to the diversity of business models this section gives only an overview of the most common ones which have been further applied by the case companies.

For their life science reports E&Y have annually surveyed business models of DBFs. In their latest report E&Y defined six general business models being characterised by two major dimensions: the economic perspective and technological perspective (see Figure 12). From an economic perspective DBFs either deliver services or offer products or do both. From a technological perspective DBFs either apply technologies developed in-house or by third parties or develop technologies for their own purposes or offer them to third parties[80]. However, it is often not possible to draw a sharp line through these business models. Throughout their history many DBFs changed their business models a few times and evolved through several of these. In 2001, German DBFs were mainly product developing companies (26%), TechCombi (21%), Combi (20%) or TechProduct (19%) companies (Schüler 2002)[81].

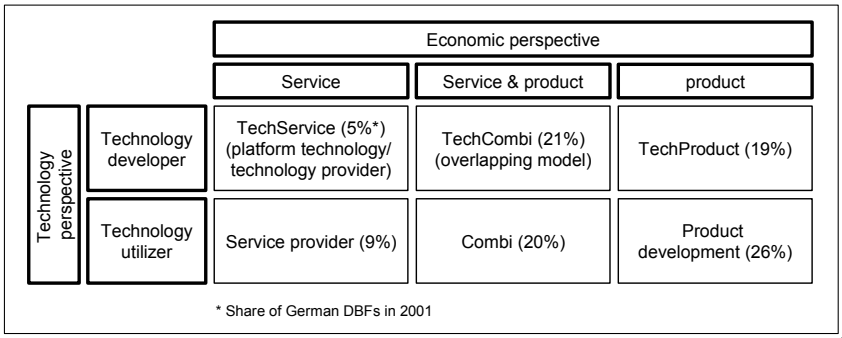

Figure 12: Biotechnology business models (applied by % of German DBFs)[82]

[79] 1975 is often seen as the starting point of biomaterials with the foundation of the worlds' first biomaterials company Nobel Biocare in Göteborg, Sweden
[80] Until 2002, E&Y called this business model "technology provider".
[81] No comparable data was available for Swedish DBFs.
[82] (Crocker 2003)

During the early 1990s, newly founded companies often had the long term goal to become a FIPCO by integrating vertically throughout the whole value chain, but today a trend is shifting that an increasing number of DBFs is turning away from this goal, and rather foster collaborations for product and technology developments as well as for production and marketing capacities[83]. However, during the recently started consolidation in European pharmaceutical biotechnology industries an increasing number of companies is merging, thereby integrating and diversifying at least in related fields of the value chain.

3.5 Intellectual property in dedicated biotechnology firms

Today, there is general agreement that IP and in particular patents play a crucial role in the pharmaceutical, biotechnology, and, in a wider sense, in all knowledge intensive or high-tech industries (e.g. nanotechnology, semiconductors, electronics) (Grindley and Teece 1997; Mansfield 1986; Nesta and Saviotti 2003). Specific 'industry' reports for biotechnology, as by E&Y (e.g. (Schüler 2002), (Crocker 2003)) stress the importance of IP management in the life science industries. As shown by Nesta and Saviotti (2003), a company's market value is an aggregation of "three types of explanatory variable: current market opportunities […]; tangible assets; and intangible assets." Focusing only on intangible assets the authors found that two facts mainly determine the value of DBFs: knowledge capital (including IP) and knowledge integration[84]. As main components of companies' intangible capital were found "R&D stocks, patent stocks and advertising" (Cockburn and Griliches 1988; Hall et al. 1986; Nesta and Saviotti 2003).

As IP is strongly linked to all of these three components, there are several areas in which IPRs are important. Depending on either the competitive environment as well as the awareness of companies' top management IP can serve different purposes in DBFs. As a means to protect the companies' own technologies against imitation IP is important to keep competitive pressure down. Additionally, IP is often an important means to ensure freedom-to-operate, to protect certain technological areas, and further to secure a company's competitive advantage (Thumm 2001).

[83] For further readings on cooperation and collaboration in biotechnology see: (Buse 2000)
[84] Although they prove that knowledge integration has stronger influence on the market value, it is not the focus of this thesis.

Additionally, there is an enormous importance of technology trade throughout all biotechnology related sectors as many DBFs (have to) acquire third party technologies. Unless considerable R&D investments are required most DBFs are unable to develop all necessary technologies in-house. Therefore, the acquisition of IP through in-licensing, M&A activities, etc. (see chapter 3.2.1) is becoming increasingly important the more mature an industry becomes. As IPRs are important when acquiring technologies, they play a similar important role when out-licensing technologies or products to 'partners'. Several business models of DBF even rely on out-licensing for financing purposes through royalty incomes and this trend is even likely to increase than to decrease in the future (Cockburn et al. 2003; Intellectual Property Initiative 2003).

In addition, other facts illustrate the importance of IPRs. Patents were judged "essential to the development of commercially important inventions" in 65% of pharmaceutical inventions. This rate was the highest of 12 industries (Grant 1997). Further, a fact which indicates the importance of IP in DBFs is that in their latest global life science report IP matters appear on page one and in a list of key-factors to enable biotech growth "patent laws that encourage and reward innovation" are top ranking (Szaro 2003).

However, one cannot generalize the importance of IP in all DBFs. Since biotechnology is an emerging technology rather than one particular industry the importance of IP varies even among the different industries. How the importance of IP developed throughout the history of DBFs and which roles IPRs played is further subject of this thesis and elaborated throughout the following part.

4 Case studies

For this study six companies were surveyed during October and November 2003. As described in chapter 1.4 the case companies were selected according to several criteria representing biotechnology companies with 'rich-experience' in IP management in Sweden as well as in Germany. Figure 13 gives an overview of the companies, showing the degree of biotechnology integration, meaning to what extent do the companies apply biotechnological processes, as well as when the companies were founded. Further, Figure 14 shows the business models, which are currently applied by the case companies according to the business models explained in chapter 3.4.

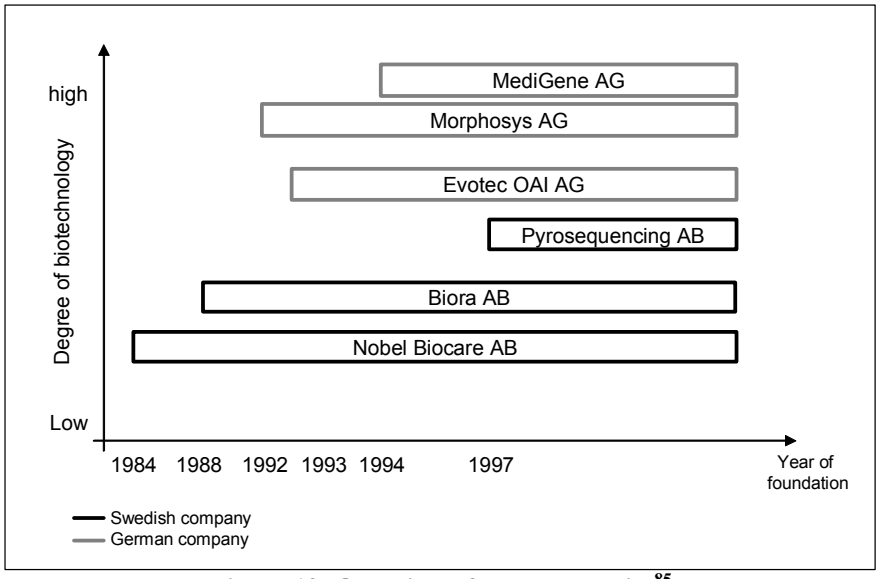

Figure 13: Overview of case companies[85]

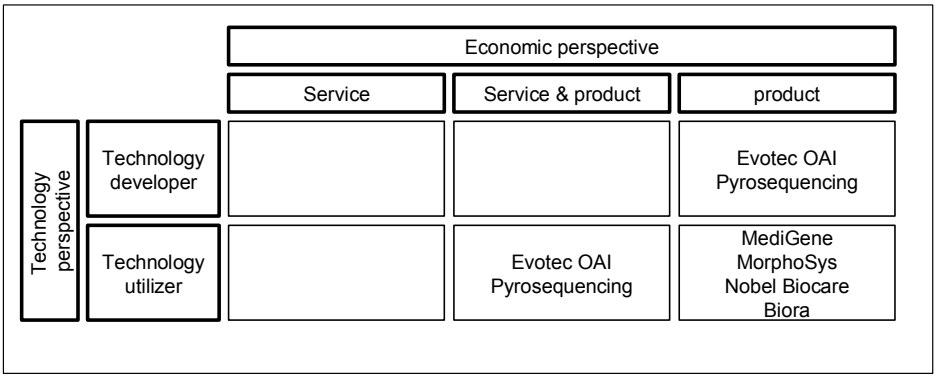

Figure 14: Business models of case companies

The following section of this thesis presents the six case studies. All cases are structured in a similar manner although, in some cases some specific facts appeared to be of additional importance (e.g. huge litigation cases). These are included in the case

[85] The scale of the y-axis is rather subjective, just to illustrate the different degree of application of biotechnology related technologies among the case companies.

reports, but highlighted in separate chapters. However, each case follows generally the structure described below.

In the first part of each case the company's history is described to give the reader a background understanding of the company's business(es), highlighting major events during its development as well as the circumstances of the company's foundation.

The second part contains the development of the company's technology base (see chapter 2.4.1) as a core element of each case study. The company's technology acquisitions and exploitations are listed and its purposes are described.

In the third section the company's IP management is analysed and its development is described. When and why the IP department was founded and how it developed? Which responsibilities (did) have the IP department? A major focus of this chapter is which events occurred and led to changes in the company's attitude towards IP management.

In the closing section of each case study, the development of the IP management is analysed in a so called 'first order analysis'. This analysis mainly answers the research question one and two (see chapter 1.2) individually for each company. However, these results are presented in part five of the thesis together with the findings concerning the third RQ in an aggregated manner.

4.1.1 Biora AB

The company was founded on an initial key patent granted to Lars Hammerström and two scientists from Karolinska Insitutet, Stockholm. The scientists got about 3 T€ from STU (today wrapped up in VINNOVA - 'Swedish Agency for Innovation Systems') for patenting[86] their inventions. The company was founded on December 16th, 1986, and started its operations on January 1st, 1987. Stina Gestrelius combined the positions of VP for Development, Production and Regulatory Affairs and was actually the first employee. Since the company's foundation the founders have stayed in Stockholm although the company operations have been performed in Malmö since 1987, due to an early cooperation with Ferring Pharmaceuticals. In 1988 Biora moved to the newly founded Medeon Science Park.

[86] A second key patent (PT-Nr: EP0337967A2) was filed on March 16th, 1989 and is directly based on some previous work of the company's Director R&D in 1987-89.

Today, Biora is a fully integrated biotech/pharmaceutical company owning in-house production facilities, subsidiaries in Germany and the U.S., having established its own distribution competences, customer networks, and distributors worldwide[87]. It is the largest company in the Medeon Science Park with about 78 employees worldwide and sold more than 500,000 units of its lead product (Emdogain®[88]).

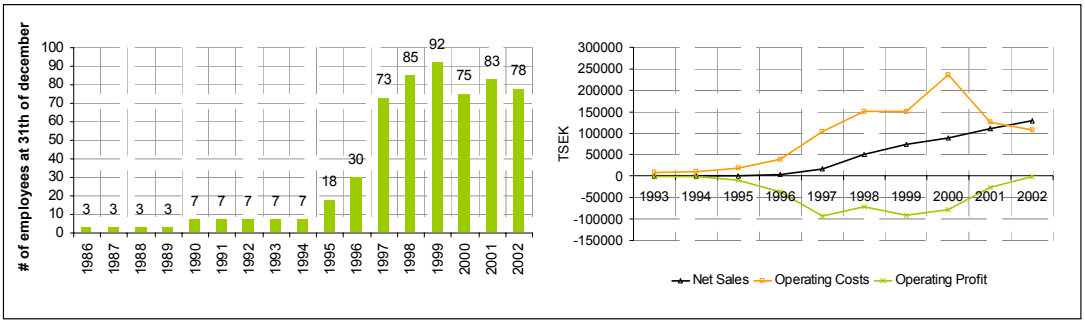

Figure 15: Key figures Biora[89]

In 2002, Biora reached its goal of being profitable with a surplus of 78 T€. Recently Biora announced a merger with Straumann Pharmaceuticals[90] in Switzerland, one of the biggest dental implant companies in the world. Biora will belong to the newly formed Straumann Biologics division in the merged company. This deal is considered to enable further growth due to access to bigger financial resources.

Biora's development

A research collaboration with Astra (today AstraZeneca) from 1989 to 1992 helped Biora in its product development process. Astra performed some valuable testings for Biora in the pre-clinical phase (toxicology) as well as in the clinical phase. Today, Biora still pays 2.5% of its sales as royalty to Astra in compensation to Astra's development costs.

After Emdogain® was approved in Europe (CE-marking in April 1995) and in the U.S. (FDA approval in September 1996), the company's focus shifted totally. The company needed to establish a marketing organisation, start commercial production

[87] At some point in time there were subsidiaries in DE, Benelux, US, UK, South Africa and Switzerland, but only DE and U.S. still had activities in 2002.
[88] The product development time was almost eight years from 1985 to 1993. The costs estimated with the product development are about 11.2 M€.
[89] Source: annual reports 1996-2002
[90] See press release from the April 4th, 2003, at www.biora.com or www. straumann.com

of Emdogain®, and prepare for the IPO. At the end of 1996, the company had grown to 30 employees.

After the CE approval in 1995 Biora established subsidiaries in Germany (Frankfurt) and the Benelux (Amsterdam) and started sales in Europe, thereby generating its first 'own' revenues from product sales[91]. After the FDA approval Biora founded a U.S. subsidiary (Chicago) with its own marketing and sales organisation. After the IPO in February 1997, Biora started expanding worldwide.

The IPO in February 1997 (Stockholm and NASDAQ), flooded Biora with 41.6 M€ and the company was able to escape its financial 'burden', regained financial flexibility and entered a new stage in its history.

In January 1998, Emdogain® was approved in Japan and sales started in France by Laboratoire Pharmadent and in Israel by H.A. Systems[92]. In October 1998, Biora started sales of Emdogain® in Mexico by MediLab and in Spain by UEDA Espanola and signed a sales agreement with Biodenix in Canada.

Beside establishing sales and marketing in key countries, Biora continuously performed R&D to improve its product Emdogain®. On March 30th, 2000, Biora reached approval for its second generation product Emdogain®Gel[93]. Emdogain was substituted by Emdogain®Gel in Europe in spring 2000, in the U.S. in January 2001, and in Japan in December 2001. Emdogain®Gel serves the same function, but is easier to handle for clinics since it is delivered ready to use.

Having started sales and receiving the first feedback from their customers, Biora discovered that Emdogain® causes positive side effects on the wound healing process after dental surgeries. In mid 1997, Biora started further research on this process enabled by the financial resources raised at the IPO. In March 1999, Biora founded a separate company to exploit their expertise on extra oral wound healing, which they called Biora BioEx. However Biora BioEx has always been only a company 'on paper' and never had any employees.

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[91] The company already had revenues from contract work since 1992.

[92] The approval in Israel was unproblematic, since the government accepted the FDA approval. Israel turned out to be an important market in spite of its small size, generating high revenues and having many world class specialists in the dental field.

[93] Although Emdogain®Gel is based on some findings made in 1992.

In June 1998, Biora got clearance from the FDA for another device called PrefGel®. This device is used to clean the surgical site prior to applying Emdogain®. PrefGel® is sold since June 2003 as a bundle with Emdogain®Gel. Today, PrefGel® on its own does not account for significant revenues of Biora but is still offered as a service to the customers. During 2000, 2001 and 2002, Biora applied in the U.S., Europe and Japan for several other indications of Emdogain® and expanded their revenues to almost 14.5 M€.

Biora's organisational structure

After the company had to assign a management team for the IPO in 1997, Biora changed its CEO two times, which has had major influence on Biora's development. In August 2000, Richard Söderberg became the new CEO, who tried to focus Biora on its dental core competences, businesses and markets. In the beginning of 2002, Donna Jansson, former marketing director of Biora, Inc. which is a marketing subsidiary of Biora AB, became today's CEO of Biora with the aim to get Biora profitable.

After the merger with Straumann, Biora is currently in the process of becoming integrated in its Biologics division. Several management positions are about to change, while mainly all members of Biors's prior management team left or will leave the company in late 2003/ early 2004. Only the CEO will stay until March 2004.

Biora's technology base

Today Biora owns about seven patent families at the EPO, seven at the USPTO and two in Japan as well as three trade-marks (Biora, Emdogain and PrepHgel). Biora's patent portfolio is mainly based on two key patents in the dental field. The first patent was filed by the founders of Biora, Lars Hammerström, Sven Lindskog and Leif Blomlof on September 25th, 1986, at the EPO. This patent is based on research performed in 1985. It protects the generic finding of recreating tissues. The second patent from March 16th, 1989[94], was filed based on the characterization work done by the company's current Director R&D and includes the finding that certain proteins are active in recreating tissues. National applications were necessary because the EPC act was not established at that time.

[94] Patent Number: EPO337967

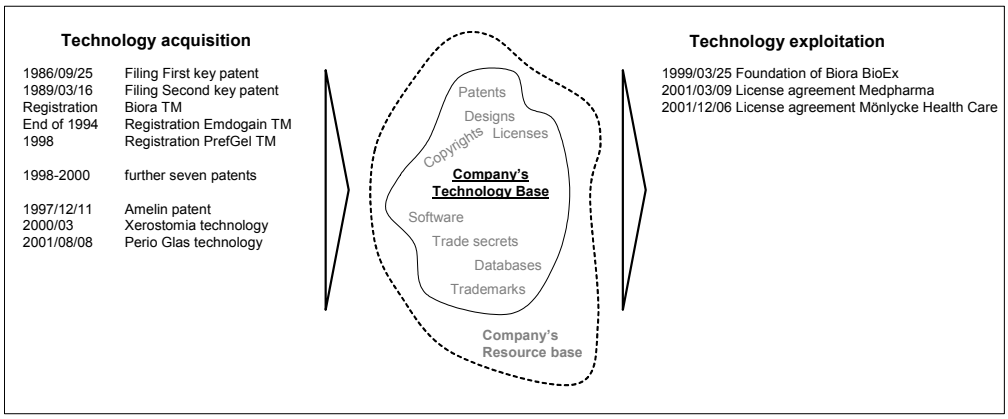

Figure 16: Development of Biora's technology base

At the end of 1994, Biora was required to file a trademark for their lead product in order to comply with the application procedures of NIOM (Nordic Institute for Odontologic Materials). The research group proposed the name Emdogain. Biora also registered its own name (Biora) as a class 5 and class 10 trademark in its main markets (U.S., EU, and Japan) as well as in several other countries of potential importance.

For a supporting device to prepare the surgical site prior to applying Emdogain, Biora acquired an additional patent from Karolinska Institutet in 1995. The patent was filed by two of the three inventors of Biora's key patents. Biora filed a trademark on the name PrepHgel®[95] in 1998 for this device, but discovered some similarities with an existing mark (PrepH). However, PrepHgel was registered using PrefGel® as a substitute.

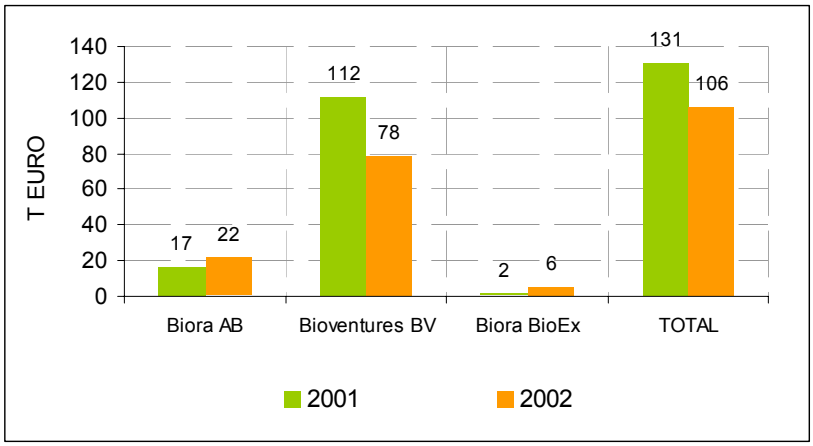

Figure 17: Patent fees in 2001 and 2002 Biora

[95] Biora faced some trouble with this name in Columbia, so that it cannot be used there.

For its second generation of its lead product Emdogain®Gel Biora did not file any additional patents, nor trademarks or other IPRs. The name is protected already through the trademark of Emdogain and the product itself is based on the same initial key patents from 1986 and 1989.

During 1999 and early 2000, the former CEO of Biora, Tomas Hammargren initiated a business strategy focusing on expansion. Biora tried to diversify into the customer segment of general dental practitioners. Therefore, Biora acquired the Xerostomia technology in March 2000 (xerostomia = dry mouth). When the new CEO, Richard Söderberg, took over in August 2000 and Biora business strategy was redefined 'focusing on the company's core competences and key markets'[96] it appeared that the Xerostomia technology was only interesting in relation to dentists. In March 2001, Biora signed an exclusive worldwide (excluding Japan) out-licensing deal[97] with Medpharma for this technology being sold to other medical professionals (mainly to counteract dry mouth as a side effect of drug treatment). Due to outstanding royalty payments of Medpharma of about 409 T€ this licensing agreement was terminated by Biora in April 2003. But renegotiations just a few days later renewed the agreement.

In order to launch Emdogain®Gel TS Biora signed a marketing deal in August 2001 with U.S. Biomaterials permitting co-packing PerioGlas® with Emdogain on markets outside North America (in Europe sales started at the end of 2001).

When Biora founded Biora BioEx in March 1999, Biora transferred patents concerning wound healing to it. In the following years Biora BioEx filed seven patent applications as a result of non-dental research[98]. Biora BioEx also applied for one dental patent in 2000 by mistake of a patent consultant. However, just recently this patent was transferred to Biora. One of these patents war later split up into two[99] and both were out-licensed to Mölnlycke Health Care, Gothenburg, Sweden. Biora BioEx presented a wound healing patent to several pharmaceutical companies. In December 2001, Biora's board of directors finally decided to grant a license to Mönlycke

[96] Press release September 27th, 2000.
[97] Biora tried to out-license another patent in 2001 but without success.
[98] As mentioned earlier, the company did not employ any person. The research was conducted by the R&D lab of Biora, but in the field of extra-oral wound healing.
[99] The splitting of the patent application was required by the EPO as well as USPTO. In other countries Biora still has only one patent.

Health Care[100]. The license agreement implies down-payments at milestones and royalty payments to Biora based on Mölnlyckes sales, while the production is still carried out by Biora. The companies meet several times a year to discuss the progress of the project.

Hitherto, other applicants in the dental field contacted Biora regarding related technologies. Biora has several applications under continuous surveillance. The initial two patents, however, are so broad that it is quite difficult to file another patent in this field without infringing Biora's patents.

IP 'management' at Biora

The patenting process at Biora always carried out by the Director R&D in collaboration with external patent firms. Although some changes in the collaboration partners appeared. First, Biora worked closely together with Bergling & Sundberg in Stockholm. After this company was bought by AwaPatent and some disputes appeared, Biora decided to work with the Copenhagen based patent consultancy Plougman Vingtoft & Partners[101]. The external consultancies were and are responsible for almost the whole patenting process. Neither technical or competitor analysis, nor drafting of patents is carried out in-house today. The R&D Department was originally also responsible for filing the trademarks, and applying for CE marking and FDA approval. The Director R&D has not received any professional training in patenting, but followed a business program at the Stockholm School of Economics. Her experience with IPRs is based on her own research performed at Novo, and also on research management at Astra and Ferring[102]. The Director R&D has always reported to the CEO. Her secretary takes care of the patent archiving. In its annual report 2002, Biora first published to have an 'explicit' patent strategy.

At the end of 2001, Biora reviewed its patent portfolio and decided to abandon several patents. The decision was based again on the change of Biora's business strategy, decided by the new CEO. As a consequence Biora decided not to maintain all the early patents in all possible countries for several reasons: they were costly, some

[100] The Director R&D was involved in the licensing negotiations concerning scientific advice, but the negotiations were carried out mainly by the former CEO Tomas Hammergren and two other board members.
[101] Today, merged with Ström & Gulliksson and called Arator
[102] Stina Gestrelius filed several patent applications herself during her prior work.

were in countries where Emdogain® was not sold, and the protection would still be secured by the follow-up patent from 1989. The cost savings as a consequence of this action were about 78 T€ in 2002 (20 countries discontinued).

The still ongoing merger with Straumann Pharmaceuticals will bring some changes to patenting at Biora. Recently the Director R&D met the internal patent attorney of Straumann and discussed Biora's patent portfolio. It is expected that Biora will continue working together with their current patent firm and Straumann will probably try to regain patent protection of Emdogain® in some of the countries where Biora decided to drop patent protection in 2004. Biora will become a brand of Straumann.

Initial FDA and CE approval for medical device for lead product

From late 1992 until 1996 Biora carried out some subcontracting work, due to some in depth know-how of aseptic manufacture including freeze-drying, for financial purposes. In December 1993, Biora received a loan from Industrifonden. However, during the three-year-long FDA approval stage Biora was running short of money. The application process in Europe for the CE marking of medical devices class III in spring 1995 was an important milestone in Biora's history. Biora decided to wait for a new regulation in 1995 and wanted to apply for a medical device instead of a drug, since such approval was less expensive and time consuming but fitted the product Emdogain®. Biora managed the application process by applying at NIOM, Oslo, a Nordic certification body, for a specific NIOM certificate in January 1994. When NIOM became on official certification body and the new regulation was enforced, the NIOM certificate could be converted into an EC Product Certificate. Biora then managed to get an ISO 9002 certification from BSI (UK), and together with the Product Certificate this resulted in a CE marking in the spring of 1995.

However, the approval was delayed due to a lot of work with the FDA approval in the U.S. during the beginning of 1995. For the FDA approval process Biora worked closely together with Eastham, a U.S. consultancy specialized on Nordic countries and FDA approvals. Biora could not afford to pay them, but later paid royalties during their first years of operations. Biora received the FDA approval in September 1996.

During this application stage Biora was very short of financial resources and still consisted of only seven employees. The approval period between having the product Emdogain® ready in 1993 and the CE and FDA approval all the company's re-

sources were dedicated to the application process and regulatory work, and the production premises were used for contract manufacturing, that generated just enough revenues to pay monthly salaries and rents.

Summary and first order analysis

During the early years of the company, until late 1992, Biora was focused mainly on developing a lead product (see Figure 18) and all resources were dedicated to research (research stage). The collaboration with Astra supported and accelerated this phase and the development of Emdogain®. When the company had a product ready, this product needed to be approved in the U.S. and Europe before sales could start. The approval stage was another phase in the company's history. Financial resources were very short and all employees were working together to get the FDA and CE approval as quickly as possible.

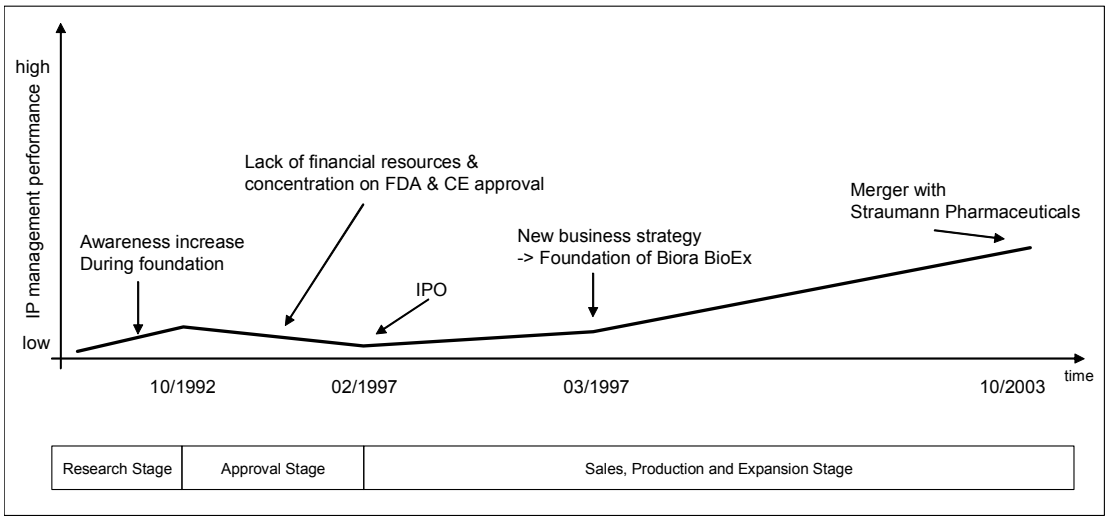

Figure 18: Development of IP Management at Biora

After the IPO in February 1997, however, the company became more aware of patenting when backed up with financial resources. When Biora had set up a management team and could start new research, additional patents were filed for the newly founded business unit Biora BioEx in 1999 and 2000. The company started into a third expansion stage, called Sales, Production and Expansion Stage.

In 2002, however, the patent portfolio went through a critical review and several patents were dropped. In the near future a more extensive patent management seems likely due to the merger with Straumann. However, an integrated approach handling the whole IP mix on a strategic level seems not to be performed yet.

During the Research Stage the whole company was based mainly on two key patents and the attention to further IPRs was low because all resources were focused on R&D in order to get a product ready. The role of IPRs was passive and mainly focussed on the initial technology patents. When entering the Approval Stage, Biora needed to file a trademark for the CE approval, but the company was running really short of financial resources and was facing severe constraints dealing with anything beside the approval. Entering the Sales, Production and Expansion Stage Biora got new financial resources available due to the company's IPO in February 1997. But still the company's main focus was now on production, not on IP issues. During all the IP 'management' stages the company heavily relied on their technologies developed in-house and the need for technology acquisition was relatively low. Only one in-licensing agreement has been signed so far as well as only two out-licensing agreements.

Until today, Biora did not found an independent IP department, although IP issues are handled by a top management member. Biora does control their IPR costs although not monitoring them individually for each single IPR with the aim of tight cost control. However, probably as an outcome of the merger the awareness of proactive IP management for sustaining a competitive advantage and securing future businesses may increase. Further, one might doubt whether a more advanced IP management in recent years would have made Biora even more successful, as the company was always focussed on products, which it wanted to develop and sell by itself.

4.1.2 Nobel Biocare AB

Back in the 1950s, Prof. Per-Ingvar Brånemark and his team studied "blood circulation in bone and marrow, and of bone repair" at the Department of Orthopaedics, University of Gothenburg, Sweden. The findings from this early study are the basis of today's business of Nobel Biocare[103]. In 1978, the Brånemark technology was licensed exclusively to the large Swedish military firm Bofors (today known as Nobel Industries), which was planning to diversify into the medical field. The rights to apply were a major component of this bundle the technology for all applications

[103] Prof. Brånemark detected that titanium does not cause any inflammation when being integrated with bone (Osseointegration). The Brånemark team was a first mover, when fostering the discovery and began trials with titanium based dental implants even in 1965 (Rickne 2000).

above the clavicle. The medical business was run in a subsidiary called Nobel-Pharma. The major shareholder in Nobel Industries (Erik Penser) lost his shares in Nobel Industries in the financial crisis in Sweden during the end of 1980s to the Swedish bank Nordbanken. Nordbanken split Nobel Industries and sold out Nobel Pharma through an IPO in 1994 and changed its name to Nobel Biocare. During its development Nobel Biocare always worked closely together with Prof. Brånemark, thereby benefiting from its research as well as from its "status as researcher with a worldwide reputation giving credibility to its products"[104].

Over the years Nobel Biocare received financial support as well as resources (production facilities, marketing and patenting) from its mother company Bofors and went from a financial loss in 1985 to being profitable with over 700 employees in 1997 after its IPO in 1994 and with the acquisition of one of the leading American dental implant companies, Steri-Oss, Inc. in 1998. Additionally, Nobel Biocare brought in Procera Inc. in 2000. Prior Procera was a joint venture with Sandvik founded in 1984.

Due to a new business strategy, Nobel Biocare started a revision of its product portfolio in November 2002 in order to reduce the number of products from about 3,000 to 800 offering an "integrated platform of dental solutions"[105].

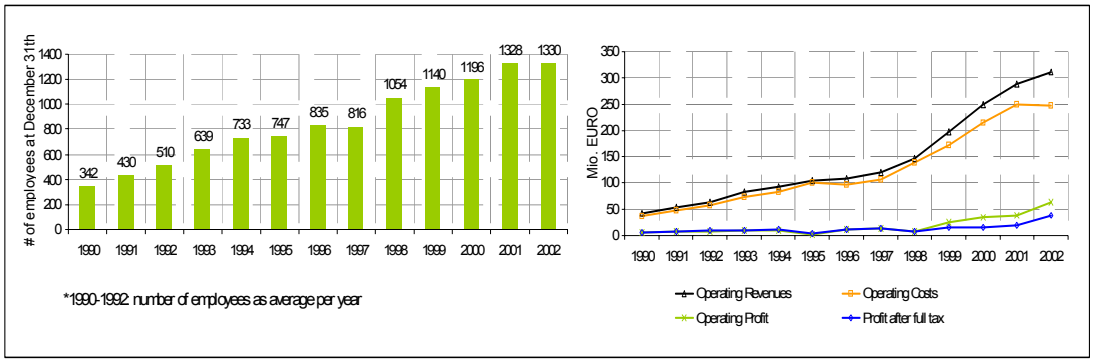

Figure 19: Key data Nobel Biocare

At the end of 2002, Nobel Biocare employed 1,330 employees[106], had subsidiaries in 27 countries, and announced a net-profit in 2002 of about 37.8 M€ (see Figure 19). In June 2002, Nobel Biocare became a Swiss holding company with its headquarters in Zurich, Switzerland.

[104] Source: Case interview
[105] Referring to (Nobel Biocare AB 2002) a concept called C&B&I (crowns, bridges and implants) has been launched.
[106] 80% of the employees worked in Europe, North America and Sweden.

The dental implant industry

Nobel Biocare was a first mover in the dental implant business and had about 27% market share (global market) in 2002. Today, there are about 50 companies competing in the dental implant industry, with five to six of them being global competitors (Rickne 2000). Nobel Biocare's target customer segments are dentists and dental laboratories. Globally there are about 800,000 (~136,000 located in North America and ~276,000 in Europe), whereas Nobel Biocare focuses not on general practitioners, but rather on specialists, which make around 25% of the whole market in its main markets Japan, U.S. and Europe.

Development of Nobel Biocare's technology base

Today, Nobel Biocare rests primarily on two technologies, the mature but well-known Brånemark technology (Osseointegration) as well as on the competences created by the Procera joint venture with Sandvik. Procera JV achieved some breakthroughs from 1994 to 1996, and about 20 patents were filed on this technology. The JV was brought completely by Nobel Biocare when the new CEO Heliane Canepa entered the company in August 2001. By buying out Sandvik, Nobel Biocare secured all of Sandvik's IPRs in this field so that the Procera technology now includes about 50 patents. The JV was based on a user invention, and Nobel Biocare needed to secure total control of it in order to integrate Procera in its new business and marketing strategy.

In order to complement Nobel Biocare's technology trough its own developed implant system, Steri-Oss, Inc., was acquired in 1998 and is today totally integrated into Nobel Biocare. The acquisition brought in six further patents.

In 1999, Nobel Biocare spun-off a company now called Entific Medical Systems AB. The company bases on and applies the same technology as Nobel Biocare but operates in the hearing rehabilitation market. Licensing negotiation took place and involved the former VC, legal affairs Jan Johansson and the patent department.

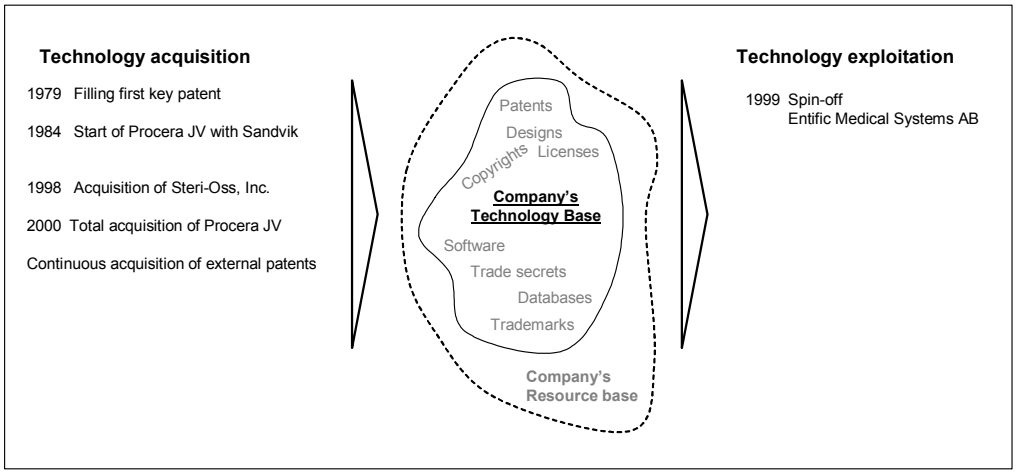

Figure 20: Development of Nobel Biocare's technology base

Today, Nobel Biocare owns almost 200 patent families, with about 1,000 patents worldwide, but primarily in the key markets U.S., Europe and Japan. The development of the patent portfolio is shown in Figure 21.

IP Management at Nobel Biocare

Prior to 1993, all patenting work at Nobel Biocare was carried out by the mother company's (Bofors) patent department, employing three to four patent attorneys. Gunnar Olsson, one of these patent attorneys, was partly responsible for Nobel Biocare's patents at Bofors and founded the patent department at Nobel Biocare in 1993 when he changed from Bofors to Nobel Biocare. A lot of patent work had piled up at Nobel Biocare due to increased R&D results, external patent work and thereby complicated information flows. Having an in-house patent attorney at Nobel Biocare resulted in an increase of efficiency in filing patent applications and an increase in new patent applications in 1994 (see Figure 21). During the years between 1993 and 1998 the newly formed patent department worked out a company's patent policy describing issues like countries to file, rules for inventor payments, etc. Today, the patent department employs one additional assistant and is reporting directly to the company's head of R&D.

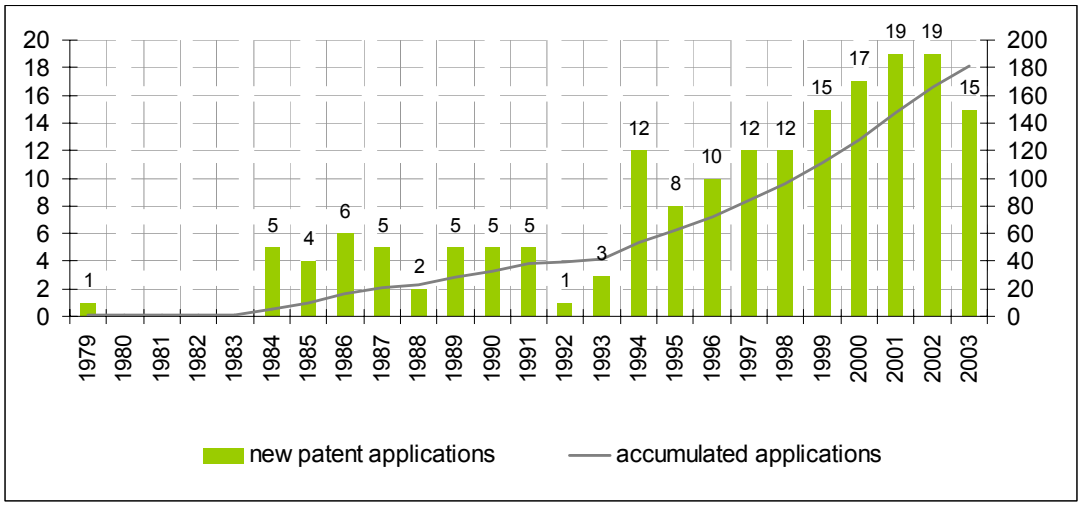

Figure 21: Development of patent portfolio of Nobel Biocare

The actual patent filing was and still is done in cooperation with several external patent firms especially for the filing in the U.S. and other countries outside Sweden. The patent drafting as well as the patent searching is carried out in-house using several databases. Patent watch of competitors is done by external patent firms.

When a new head of R&D came to Nobel Biocare in 2000, the attitude towards patents changed. Having realized the recent developments in the U.S. patent system, that several companies filed the first MDB patents and bringing in a rich experience with IP from the consumer white-goods industry, the new head of R&D tight up the relationship with the patent department and fostered a more progressive approach of patenting even setting an (even if implicit) goal for filing about 20 new patents a year. The patent policy was reviewed and, when the new VP legal affairs (Michaela Ahlberg) entered Nobel Biocare in April 2002, the focus shifted to an even more integrated approach of the whole IP mix including not only patents, but trademarks, designs and maybe upcoming software patents (software copyrights). Especially, more importance was drawn to the Procera technology due to the complexity of its components involved. An explicit patent strategy was formulated at Nobel Biocare in 1999. The company follows a brand strategy as well, but is about to develop a total IP strategy initiated by its new VP legal affairs.

Nobel Biocare constantly built up a patent portfolio until 1997. Although, once a year the company reviewed its patent portfolio, the company actively dropped just a few patents until 2002. However, during recent years the budget for maintaining the patent portfolio increased significantly so that in 2002 the patent department and the

head of R&D decided to review the patent portfolio and to drop several patents, due to the parallel product revision as Nobel Biocare reduced its product portfolio. As a consequence, some patents which were related to products which were not offered any more were dropped[107].

Trademarks and other IPRs

Until today, Nobel Biocare filed several trademarks on their three major brands (Brånemark System, Replace and Procera) as well as on the company name and their new business concept C&B&I (Crown & Bridges & Implants). Prior, when the new VP legal affairs[108] entered Nobel Biocare, the decision to file trademarks was made by the marketing department, whereas the actual filing of trademarks was carried out by the patent department. Today, an integrated IP approach is fostered and the VP legal affairs is involved in the decision whether to file trademarks.

Litigation cases

During its history, Nobel Biocare was involved in a few litigation cases, from which some are still ongoing (less than five). One case should be noted at this point, since it represents a significant change in the company's competitive environment.

In 1993, Nobel Biocare became involved in a litigation case in the U.S. on the initial 1979 patent licensed from Brånemark. It turned out that the patent which protected the implant surface structure did not hold through in the U.S. After the court decided against Nobel Biocare competitors entered the market immediately.

Summary and first order analysis

Today's business of Nobel Biocare is more exposed to competition than almost twenty years ago; although the market is not fragmented, it is divided by a few major competitors (oligopolistic market). The market for dental implants grew from a niche market to an almost "mass market", which required some redirection of Nobel Biocare's business strategy. Although Nobel Biocare was by far the first mover on the market, the company faces some severe competition today. Due to the change of Nobel Biocare's competitive environment, the importance of IPRs and its active management has increased steadily. The company became aware of the possibilities

[107] Since they were mainly product patents, referring to very specific components, it did not seem to be of any value to donate them to some other parties, e.g. universities.

[108] Before Michaela entered the company Jan Johansson was responsible for legal affairs. He was with Nobel Biocare from 1994 on.

IPR's offer for sustaining a competitive advantage almost four years ago. In the early days of Nobel Biocare (after the initial technology was secured by patent protection) patents were filed with the purpose to protect single elements of their products against imitation. Today, Nobel Biocare follows a more active and business oriented approach when filing patents. Patents are used primarily to secure today's but to a certain extent to protect future businesses as well. An integrated IP management was started recently.

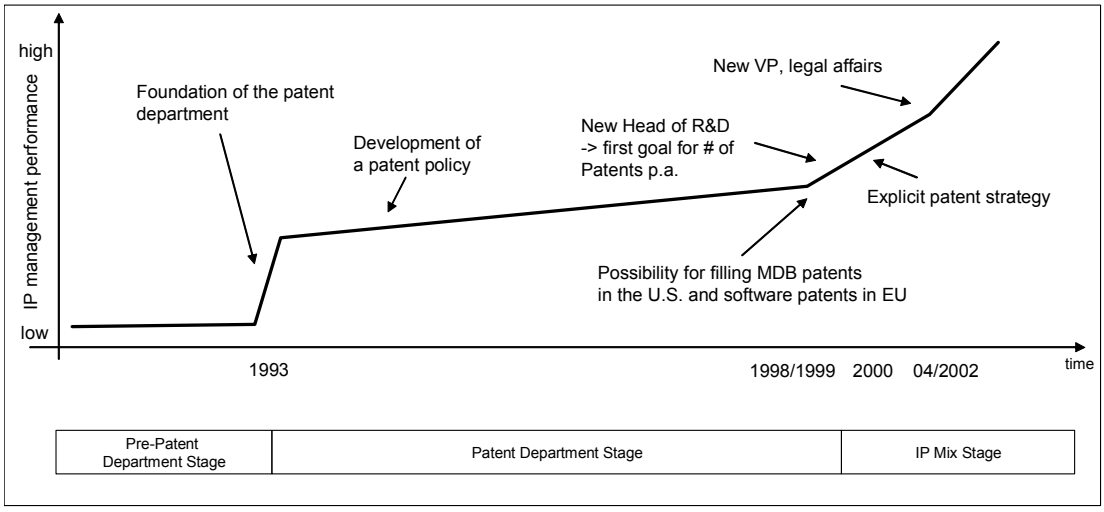

Figure 22: Development of IP management at Nobel Biocare

Summarizing the developments of Nobel Biocare described above one can find that the company went through three major stages[109] in its history (Figure 22). The first stage can be seen from its foundation in 1984 until the formation of its own patent department in 1993. During this stage the company had nearly no IP competence of its own and there were no competitors on the market. During this stage (the Pre-Patent Department Stage) there was hardly any 'IP management'. When in 1993, due to available financial resources and a need for internal patent work the patent department was founded by a well experienced patent attorney, a second so-called Patent Department Stage was initiated. In the following years a patent policy was established and patent applications were drafted and filed in-house, while there was growing 'relationship' between the R&D manager and the patent department; although the patent department was still very small. This second stage started very abrupt by and with it a performance increase in 'IP management'. Initiating the third stage of IP

[109] Although the company changed the CEO two times it does not seem to have had significant influence on the IP management at Nobel Biocare. Leif Ek was CEO from its foundation until 1989. Jack Forsgren took over leadership in 1994. Heliane Canepa entered Nobel Biocare August 2001.

management was driven by several accumulated events and not just only one major critical event. The shift is still ongoing and cannot be characterised as abrupt as the first one. When the new head of R&D entered the company in 2000 he fostered a more proactive approach on patents to secure future businesses, being aware of the possibility to file MDB patents in the U.S. since the first cases of Amazon and Dell in 1998/1999. When the new VP legal affairs started at Nobel Biocare in April 2002, the management of patents started to become an IP management fostering an integrated approach (IP-Mix Stage) of different IPRs including trademarks, designs, etc., to make use of the economic properties of IPR in order to differentiate its products against competitors and prevent them from imitation[110].

During these three stages different IPRs can be assigned different roles and importance. In the Pre-Patent Department Stage the company owned a few key patents, which were the fundament of the company's technology base. Trademarks and other IPRs were not so important beside the company's name, which was secured as a trademark. In the Patent Department Stage the main focus was still on patents. A patent portfolio was built up steadily, without really managing it (e.g. dropping patents or licensing-out technology). However, to build up a technology competence complementary assets were acquired by licensing-in, joint venturing or acquiring companies. Further, trademarks were filed to build up brands and establish them on the target markets against rising competition. When the company entered the IP-Mix Stage it moved to a stage where beside product patents and trademarks as well MDB patents, copyrights and design rights became important. Although this stage is just ongoing, the company will move from a patent to an IPR portfolio trying to establish synergies from aligning different IPRs and protecting future businesses. During this stage the meaning of IPR is changing from a pure legal perspective to entirely economic assets.

4.1.3 Pyrosequencing AB

Pyrosequencing was started as a newly founded company in March 1997 by four scientists[111] of the Royal Institute of Technology, Stockholm. From its beginning the

[110] This approach seems to be partly due to the background of the new VP legal affairs having worked within the computer software industry.
[111] Mathias Uhlen, PhD; Pal Nyren, PhD; Mostafa Ronaghi, PhD; and Bertil Pertersson, PhD.

company has been aiming at analysing DNA sequences targeting the market of applied genomics as a supplier of genetic analysis[112]. Björn Ekström (today Pyrosequencing's Executive VP) was the first employee actually starting operations of the company. In April 1997, the company was able to raise 1.75 M€ from the Stockholm based VC organisation HealthCap, which helped it to invest in producing prototypes and to become fully operational in June 1997.

During 1998 and 1999 the company raised 7.9 M€ and 10.5 M€ respectively in private placements while the company kept developing its prototypes. In September 1999, the company presented its instruments at the Genome Sequencing and Analysis Conference (GSAC) in Miami and sold its first instrument, the PSQ^{TM}96 in November 1999. The company was able to raise almost 87 M€ through their IPO on June 7th, 2000, which gave the company sufficient financial backup.

After the IPO, the company experienced continuous growth as to be seen in Figure 23. However, in 2000, the company's top management decided to change the business strategy and to diversify into the molecular diagnostics business. Therefore Pyrosequencing entered several collaborations mainly with universities (e.g. Harvard University, Université de Reims Champagne-Ardenne, Stanford University) and built up molecular diagnostic competences in 2001 and 2002. However, this strategy was dropped at the end of 2002, as it turned out that enormous costs for entering this market[113] would collide with the corporate objective to "shorten the time to profitability"[114].

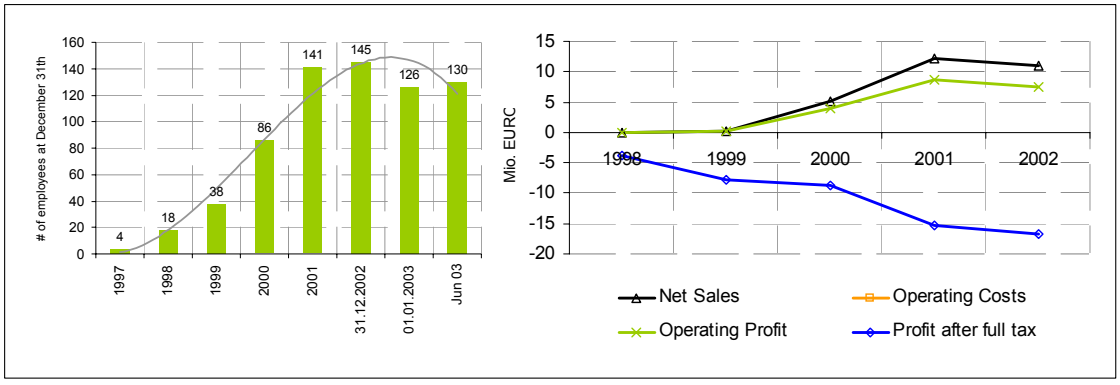

Figure 23: # of employees and key financials of Pyrosequencing

[112] For a detailed description of this technology see: http://www.pyrosequencing.com/pages/demonstration.html

[113] This is mainly due to the requirements for getting an FDA approval in the U.S. for drugs or medical devices.

[114] Source: (Pyrosequencing AB 2002)

In 2002, the company launched its second generation of products and continued to experience growth in sales of units. Pyrosequencing sold about 60 units in 2000, more than 80 in 2001 and about 100 in 2002. During these years the customer group of universities continued to buy the company's products, while the commercial bio-tech sector faced some complicated economic environmental conditions (e.g. lack of availability of VC for second and third round financing - start of consolidation in Europe), wherefore the demand slowed down. Although the company expanded its product portfolio by signing a distribution agreement with Corbett[115] for the U.S. market, Pyrosequencing needed to cut down its staff by about 35 in October 2002. Mainly administrative and R&D staff was reduced and all top management was consolidated to the headquarters in Uppsala. The majority of the reduced staff was involved in software development. This business unit was cut down as there was only restricted need for further software development in the near future. The other part of R&D staff was marginally affected of the head cut. When the company did not reach its profitability goal in 2002, the top management decided to lay off another 30 employees during a second head cut in August 2003.

In August 2003, Pyrosequencing announced to merge with Personal Chemistry, a 1998 founded and Uppsala based company with around 86 employees selling a "new technique for organic chemical synthesis." The main objective of the merger was to create a company with "improved prospects to reach profitability…through joint purchasing and production organizations"[116]. Additionally in mid October, Pyrosequencing acquired Biotage, a U.S. based DBF and changed its name to Biotage AB in December 2003 with a turnover of about 48 M€ (pro forma) in 2003. These three companies complement technologies ranging from applied genomics (Pyrosequencing), purification and separation (Biotage), and microwave synthesis (Personal Chemistry)[117].

Development of Pyrosequencing's technology base

When Pyrosequencing was founded in March 1997, its initial technology base consisted of one patent, which was filed in March 1988 by Mathias Uhlen and assigned

[115] Corbett is an Australian based company "developing specialized equipment for the life science industries". Its products are "excellent complements" to their own products (Pyrosequencing AB 2002).
[116] Press Release Pyrosequencing, September 10th, 2003.
[117] Press Release Pyrosequencing, October 14th and December 4th, 2003.

to his former company Cemu AB as well as of two patent applications filed in September and December 1996. Cemu became integrated in Pyrosequencing during its foundation together with the patent and the patent applications. The two patent applications in 1996 formed together with the acquisition of a fourth patent (not just a license) in January 1998 from the New York Medical College[118] the core technology base of the company. This fourth patent was needed to ensure 'freedom to operate'[119].

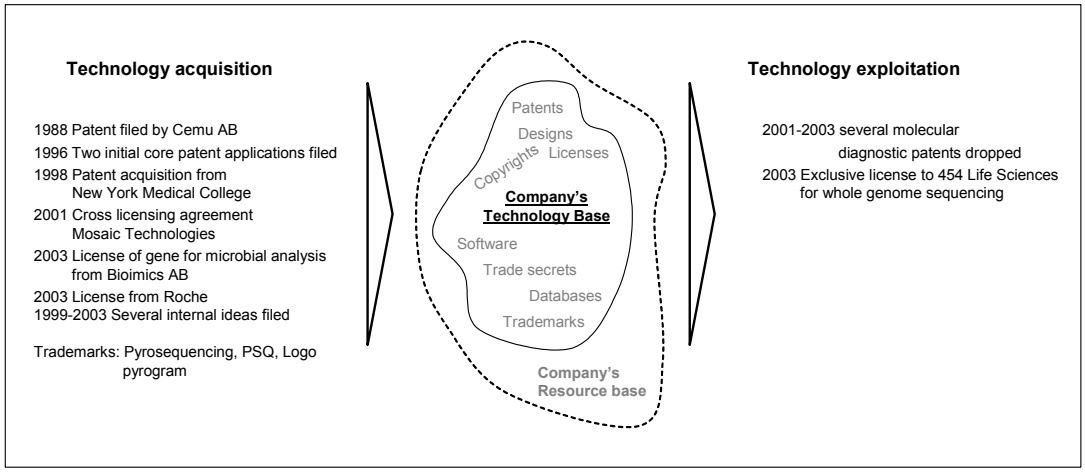

Figure 24: Pyrosequencing's technology base

During the following years the company continued filing new patent applications protecting their core technologies, applications, software, and processes. Especially when the company decided to enter the molecular diagnostics business in 2000 and started collaborations with universities, Pyrosequencing started to file patents in this field and intensified its search for potential licensees.

Pyrosequencing in-licensed a technology in March 2001 by entering into a cross licensing agreement with Mosaic Technologies to get access to a chemical compound needed for "dye labelled sequencing-by-synthesis development"[120]. In addition, Pyrosequencing acquired three further licenses in 2001 and eleven in 2002. However, most of the molecular diagnostics patent applications were dropped or will be dropped in the near future, as the company decided to exit this business.

[118] Sequencing-by-Synthesis; USPTO Nr: 4,863,849; filed on July 18th, 1985.
Note: The filing dates are the dates the priority documents filed in Sweden, not the filing dates in the U.S.
[119] Björn as well as all the founders have always been aware that they would need this patent.
[120] Pyrosequencing press release of March 20th, 2001.

Until today, Pyrosequencing signed only one out-licensing deal in August 2003. Pyrosequencing sold an exclusive five-year license to 454 Life Sciences, which applies a similar technology, but in different fields of use[121]. Pyrosequencing will receive a minimum of about 4 M€ in up-front payments and minimum royalties[122].

So far, Pyrosequencing secured the company name as a trademark as well as four others. These trademarks were filed in the U.S., Japan and Europe. The company holds one software patent application, as well as 19 method patents and 9 application/product patents.

The change in the company's business strategy in mid 2000 had a major influence on the development of the company's technology base. The company started looking systematically for research collaborations mainly with universities. Due to this process several patents were filed in the field of molecular diagnostics. As mentioned above, most of these patents were dropped in 2002 as shown in Figure 25.

In the near future, due to the mergers with Personal Chemistry and Biotage, the new company's technology base and patent portfolio will rise and this new IPR mix needs to be carefully evaluated in order to identify how different IPRs from the different companies complement each other.

IP Management at Pyrosequencing

Due to his prior work experience at Amersham, Björn Ekström was well aware of the importance of IPRs and has from the beginning drawn considerable attention to IP issues, although just on patents. When he started to work with patenting at Pyrosequencing, he realized the fact that the acquired patent from New York Medical College was filed in 1985 and will expire already in 2006. Since this patent is protecting one important part of the company's core technologies, he took care that all further patent application would refer to this particular patent, thereby trying to expand the protection time frame.

[121] Pyrosequencing's focuses on gene sequences, while 454 Life Sciences analyses whole genomes.
[122] Pyrosequencing press release, August 19th, 2003.

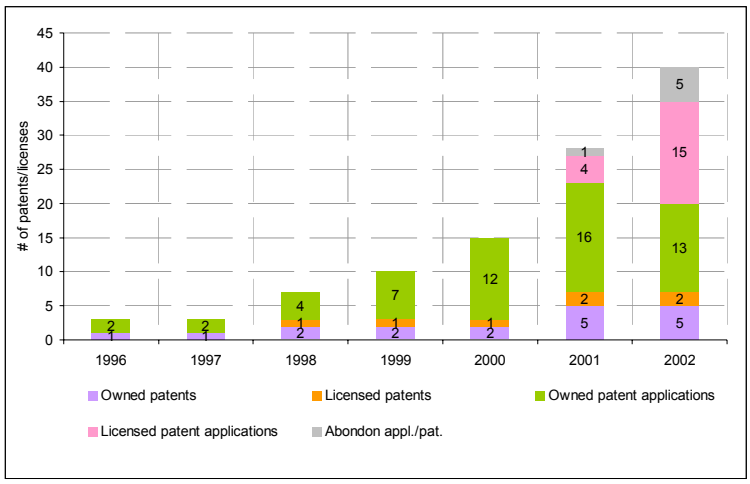

Figure 25: Development of Pyrosequencing's patent portfolio

When, due to the change in the business strategy to enter the molecular diagnostics business, new patent applications increased in 2000 and with it the corresponding workload, the top management team decided to hire a separate employee dedicated to IPR issues[123]. The company had not had an explicit IP strategy so far, although Björn Ekström was aware of the need of dealing in a more sophisticated manner with IP from a business perspective. Pyrosequencing hired Per Johan Ulfendahl, who became the Director IP at Pyrosequencing. His tasks included the whole patent work, but as well issues concerning other IPRs. Björn Ekström wanted him to set up an IP strategy, but first Per Johan Ulfendahl needed to receive training in IPR matters.

Since June 2001, Per Johan Ulfendahl has received considerable and still ongoing training as a Swedish patent attorney with a strong focus on becoming a European patent attorney. He started visiting IP related conferences (e.g. the CIP Forum 2001 at CTH) and came up with a first draft of an IP strategy in autumn 2001.

Today, the responsibilities of the IP Director are to "handle the existing patent portfolio, to participate in R&D projects to identify internal and patentable ideas, to support with IP knowledge during in- and out-licensing deals, to support the marketing groups regarding trademark search, to secure that printed material fulfils IP standards and security, and to establish good connections to Patent and Trademark Attorneys"[124].

[123] A newspaper advertisement was placed offering explicitly the occupation "Director Intellectual Property".
[124] The responsibilities are written down explicitly in an internal document from February 2002.

During the development process of the IP strategy the Executive VP and the Director IP worked closely together and started to recognise that there is a need for an 'IP steering group'. On February 12th, 2002, the 6th draft of the IP strategy was decided on, which took place on the first meeting of the IP steering group, which is called 'IP Council' since then. The IP Council meets regularly once a month and includes the CTO (Chairman), Director IP, VP R&D, VP Marketing Life Sciences, VP Marketing Molecular Diagnostics and Corporate Business Development. Its objectives are to "advise the Director IP regarding IP questions and to support the Director IP in the idea handling process"[125]. From this time on, the company follows an explicit IP strategy fostering a surrounding strategy[126], as illustrated in Figure 26, in the fields of technological improvements, applications, and different genes. This surrounding strategy protects Pyrosequencing's core business area (based on the three patents Apyrase, Real Time Sequencing and Sequencing-by-Synthesis) by referring to these patents when filing new patents and draws considerable attention to strengthening the IP "platform on upstream (e.g. sample preparation) and downstream (e.g. result analysis) processes". The aim is to apply for new patents to protect the existing patent portfolio or, if not possible, to acquire or in-license patents to support this strategy[127].

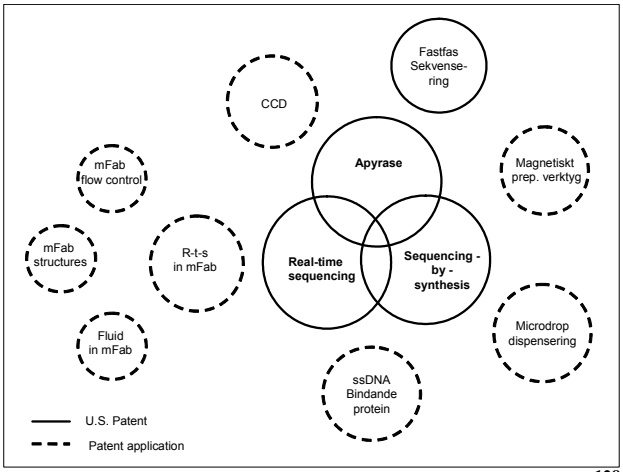

Figure 26: Surrounding Strategy at Pyrosequencing[128]

[125] Source: 6th draft of Pyrosequencing's IP strategy; February 12th, 2002.
[126] According to the interviewee the company was pursuing almost a surrounding strategy implicitly during all previous years, especially protecting the Sequencing-by-Synthesis patent, which expires in 2006.
[127] Source: Internal document, February 2002.
[128] ibid.

Additionally, it was explicitly 'enshrined' that the company should "set up an agreement with at least one commercial IP search web site"[129]. As of today, Pyrosequencing uses the 'Delphion' patent database. The Director IP is continuously monitoring patent and trademark costs on an individually patent level. He is assigned a budget each year.

During the following years Pyrosequencing started to protect software and algorithms in the U.S. too, while before the focus was on technical improvements, product designs, applications and some processes.

In addition, the company has developed some formal procedures how to deal with ideas of employees. The company is not searching continuously for external ideas. Since the company does not have a direct competitor yet, Pyrosequencing does not monitor their IP portfolios.

Relationship with external patent attorneys

Mathias Uhlen, one of Pyrosequencing's founders had worked with Frank B Dehn & Co, a London based patent firm, when he filed its Cemu patents in the 1980s. During that time not much competence for filing biotech patents was available in Sweden, so that he looked over to the UK. Björn Ekström continued working with Frank B Dehn & Co when Pyrosequencing started in 1997. Frank B Dehn & Co was responsible for almost all patent related tasks including drafting, technical analyses, freedom-to-operate, and the actual filing of an application. Almost no patent related work was carried out in-house, although supervised by the Executive VP until April 2001. Pyrosequencing continued to file new patents, mainly product patents (e.g. on their reagent kits) on single design elements, and filed some trademarks on the name Pyrosequencing, PSQ and the logotype.

When the company hired a Director IP the situation in Swedish patent firms had already changed. Some firms realized the rising need of patenting in the emerging biotechnology sectors and had started to train their patent attorney's for the specific needs of DBFs, some even set up own life-science teams. In May 2001, the Director IP evaluated different patent firms and invited three of them (AwaPatent, Albihns, and Ludwig Brann) for a final evaluation. Since Albihns had a whole life-science team as well as an office close to the EPO in Munich, Pyrosequencing decided for

[129] Source: 6th draft of Pyrosequencing's IP strategy; February 12th, 2002.

them and all patent applications after autumn 2001 were filed by Albihns. By this decision Pyrosequencing was able to reduce its patent filing costs by about 50% and to improve the communication with its patent attorneys, due to their local presence.

Summary and first order analysis

The development of the IP management at Pyrosequencing can be said to be driven by a very open minded management team, which was aware of the importance of IPRs in today's business environment very early. However, from the company's foundation until April 2001 IP management was only implicitly and subliminally carried out by the Executive VP although with 'above average awareness'[130]. Throughout this period the IP management was carried out part time by the Executive VP with external patent attorneys. This stage (Pre-IP Director Stage as shown in Figure 27) was characterised obviously by some learning effects increasing the IP performance continuously but only incrementally.

When the company hired its first employee being particularly responsible for IP matters, today Director IP, in April 2001 this decision can be said to be a gateway into a new IP management stage (IP Director Stage). Within a short period, Pyrosequencing increased its IP management performance drastically, although it took some time until the Director IP was fully trained. A next milestone in this stage was the project to work out an IP strategy. When the Director IP started to work on the different drafts together with the Executive VP on a top management level, the IP awareness spilled over to other employees. The Director IP further held patent seminars for several departments in order to increase the knowledge and the awareness of the need to protect new ideas. These seminars supported the increase of patent applications filed the following years based on employees' ideas.

[130] There are several further indicators that underline the strong awareness of IP importance at Pyrosequencing. Even in 2000, the company's CEO reported on the first page of its first annual report as a publicly traded company about its IP and referred to it as a "key component" of its business model. He further pointed out the importance of IP in order to be "free to pursue all aspects of the technology."

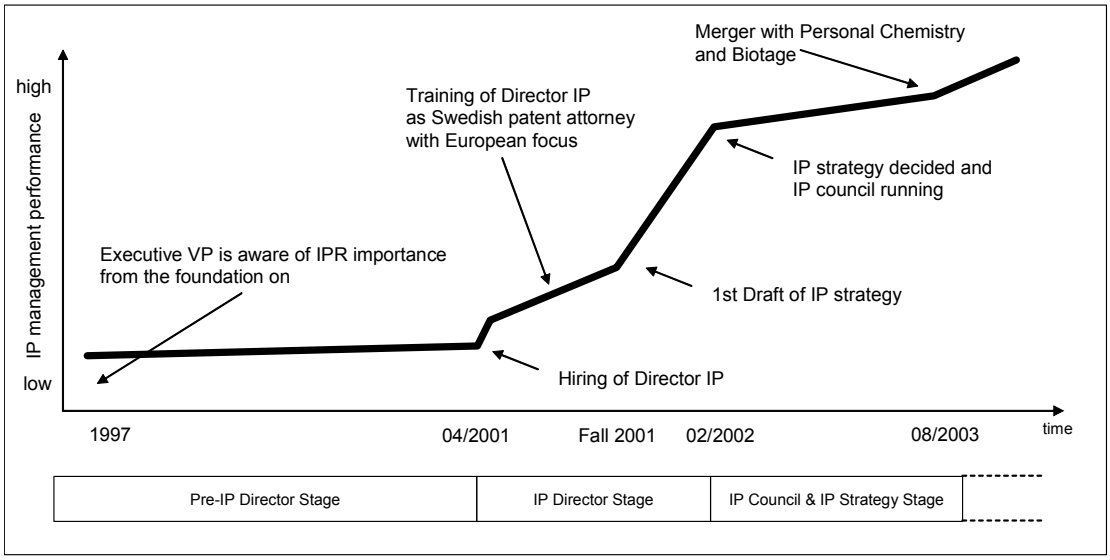

Figure 27: Development of IP management at Pyrosequencing

With the decision on the company's IP strategy in February 2002 the company reached another milestone and set a reliable fundament for its future competitiveness, thus entering the IP Council & IP Strategy Stage. The company started to establish an additional instrument (the IP Council) to carefully and proactively work with IPRs handling them as business rather than legal assets.

The mergers with Personal Chemistry and Biotage in (late) summer 2003 will enable the company to broaden its product portfolio as well as its IP portfolio and IP competence. Personal Chemistry has its own internal European patent attorney as well. Both of them, the Director IP of Pyrosequencing and the patent attorney of Personal Chemistry will stay with the 'new' company, so that there is much IP competence in a company with about 250 employees. However, operational structures are still uncertain.

During these different IP management stages the role of IPRs changed. During the Pre-IP Director Stage, the company owned mainly core patents and a few patents on applications as well as trademarks on the company name. Although the Executive VP was aware of the importance of IPRs, they still had a more 'passive' role.

When the Director IP brought in IP competence during the IP-Director Stage this role changed. IP assets became more business assets when new patent applications were filed to protect the company's (future) businesses and when additionally, software and process patents were filed. When the company had an explicit IP strategy and the IP council met regularly (IP Council & IP Strategy Stage), IPRs became even of

'strategic importance' as top management became involved in decisions concerning IP matters.

It should be noted that when setting up the IP council in February 2002, many employees became aware of the importance of IP so that one might suppose that there is at least a very early stage of a patent culture embodied in the company's employees today.

Finally, it should be highlighted that Pyrosequencing never struggled with financial problems as many other, especially small start-up companies had during recent years. Therefore, financial constraints were never crucial and a force against the development of IP management in Pyrosequencing.

Summing up, in its European Biotechnology report in 2001, Ernst & Young called Pyrosequencing a 'success story' and it seems that the above described developments do not refute this statement. One might even suggest that its decisive progress towards a sophisticated IP management is a reason of or at least has contributed to this success.

4.1.4 MediGene AG

MediGene was founded in 1994 by a group of four scientists as a spin-off of the Munich Gene Centre[131]. The four founders realized the ongoing developments in the U.S. where the first DBFs were founded and started to grow (e.g. Amgen, Genentech). They became aware of business opportunities and the emerging market potential of biotechnology applications. However, the founders had just an idea of a technology which was not ready to commercialise upon at that point in time[132].

Since the early days, MediGene's business model was and still is to become a FIPCO operating in the business of cancer therapeutics. The company's aim was to continu-

[131] Prof. Winnacker, president of the German Research Council (DFG, Deutsche Forschungsgemeinschaft), Dr. Heinrich, today's CEO of MediGene, Prof. Domdey, regional responsible for Munich as the later winning region in the BioRegio Competition, founder of the Munich Technology Park and today's CEO of BIOM AG, and Prof. Hallek, who was working as a clinician at the Ludwig-Maximilians-University of Munich.

[132] This was a technology based on AAV (Adeno-Associated Viruses), which was invented by Prof. Hallek. Today, this technology is in the clinical phase 1/ 2.

ously scan for and to acquire technologies and to take those through the clinical phases, as well as to develop its own technologies[133].

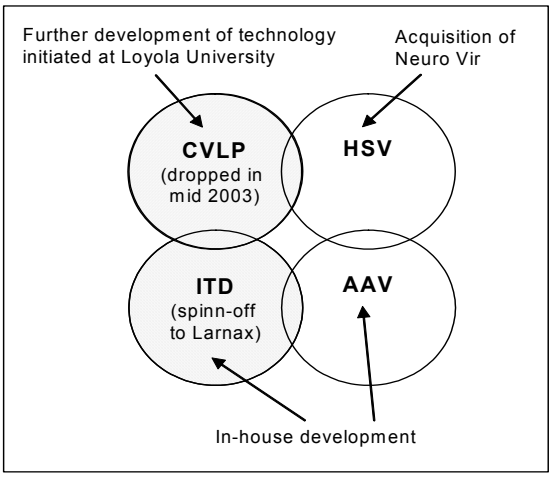

Figure 28: Core technologies of MediGene

During the early days of MediGene there was a lack of VC in Germany and the company needed to finance itself by offering DNA sequencing services. At the end of 1997/ early 1998 the company was forced by investors to spin-off their 'service unit' into an independent company called MediGenomics. Investors wanted to invest in MediGene's core business, but at the same time not to subsidize the service business. The 'service unit' was entirely sold to an investment fond (Eurofonds) in 2002.

MediGene went public on June 30th, 2000. The IPO flooded MediGene with about 110 M€ utilized to broaden the company's technology base by securing another technology platform based on HSV (Herpes Simplex Viruses) as well as two cancer drugs[134] in the clinical development by acquiring the DBF NeuroVir Therapeutics in January 2001. The integration process started immediately and NeuroVir became totally integrated in March 2001 as MediGene's U.S. subsidiary, MediGene Inc.

Later, MediGene started to develop the Integrated Target Definition (ITD) technology in-house, aiming at heart diseases (cardiology). Resulting from this technology in 2000, MediGene announced its first lead candidate 'Etomoxir' that became a "cornerstone"[135] in MediGene's technology base in the cardiology field. However, in June 2002, when Etomoxir was already in the clinical phase II, the company was

[133] Cf. (MediGene AG 2002)
[134] G207 for the treatment of brain tumours and NV1020 for the treatment of liver metastases
[135] (MediGene AG 2000)

forced to abandon this "lead candidate", when a "small number of patients showed some unforeseen side-effects" (MediGene AG 2002).

Until March 2003, MediGene operated in three drug market segments: HPV[136]-indications (based on the CVLP technology and Polyphenon), oncology (rAAV, HSV technology and hormone treatment of prostate cancer), and cardiology (ITD technology platform). Although MediGene's business model was always to become a FIPCO, the technology base varied throughout its history. The company used the money raised at the IPO to broaden its technology base by acquiring NeuroVir. Later, MediGene dropped two technologies. In March 2003, the company spinned off its cardiology segment (including the ITD technology and the lead candidate Etomoxir) to a company called Larnax GmbH, and MediGene had to drop further developments of the CVLP technology due to litigation with Loyola University in mid 2003 (see Figure 28).

The numbers of employees developed continuously (see Figure 29), with a slight decline in 2003. MediGene employed 165 employees at June 30th, 2003 with revenues of 3.5 M€.

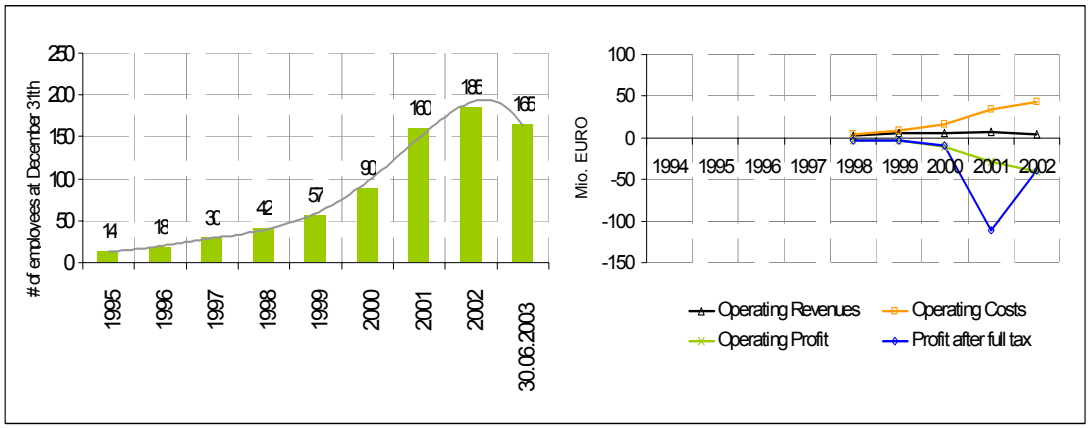

Figure 29: Development of employees at MediGene

Development of the company's Technology base

Until today, MediGene developed two technologies in-house: The AAV (Adeno-Associated Viral Vectors) technology was brought into MediGene from the early days due to prior research by one of the founders and the ITD (Integrated Target Definition) technology to identify targets for developing therapeutics. Further, MediGene acquired two technologies: The CVLP (Chimeric Virus-Like Particles)

[136] A virus that infects humans and triggers genital warts as well as cervical cancer and its precursors

technology and the HSV (modified Herpes Simple Viruses) technology[137]. However, as of today the company's technology base constitutes only out of the HSV and AAV technologies (see Figure 28). Recently, the company developed two drug candidates from the HSV technology and one out of the AAV technology.

Technology acquisition

The AAV technology was developed in-house based on some prior discoveries by Prof. Hallek. The first patent on the technology was filed in 1996. Until today, the company got seven patents on this technology granted by the USPTO.

As mentioned above the HSV technology was acquired when MediGene acquired NeuroVir in January 2001 as well as all related IPRs. This acquisition was possible since the U.S. market was already in the consolidation phase and share prices dropped, while the European market was still growing. MediGene was able to acquire NeuroVir through an equity exchange.

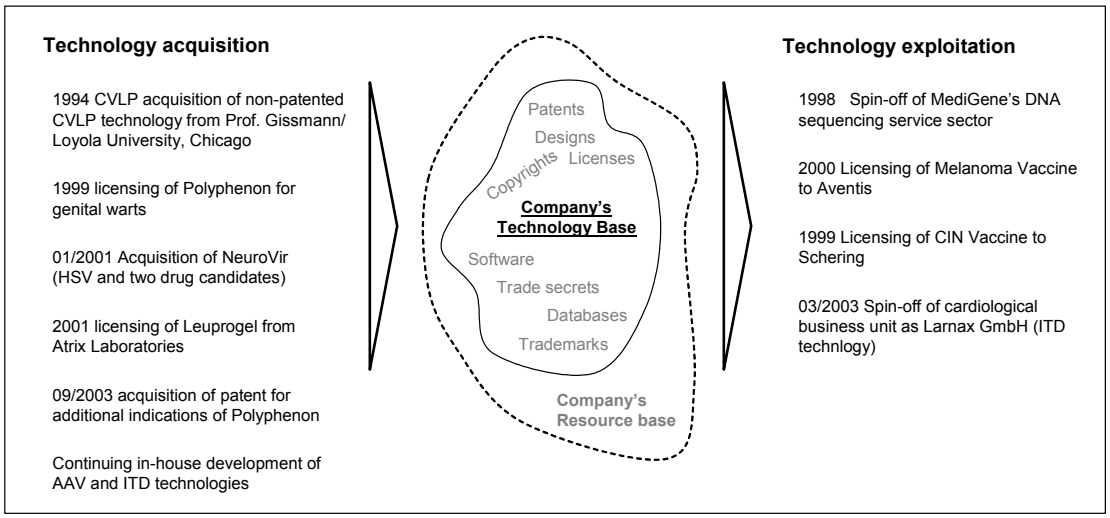

Figure 30: Development of MediGene's technology base

The CVLP technology was invented by Prof. Gissmann[138] and colleagues at the Loyola University of Chicago. He offered the so far not patented CVLP technology to MediGene in 1994, and MediGene immediately filed a patent application. However, a litigation with Loyola University arose in 1998 (see further the special section on 'litigation cases') on the ownership of the patents. Mainly due to this litigation

[137] For an illustrative explanation of these technologies see: (MediGene AG 2001), p.24ff.

[138] From 1993 to 1996 he was head of viral oncology at the Department of Gynaecology and Obstetrics at Chicago's Loyola University, U.S.

MediGene decided to abandon the technology together with its lead product for the treatment of cervical intraepithelial neoplasia (CIN) in April 2002, which was already in the clinical development.

MediGene licensed Polyphenon, which aims at genital warts, from the Canadian based company Epitome in September 1999. Epitome had licensed the technology from the Japanese company MitsuiNorin.

Additionally, the company in-licensed exclusive marketing rights for a drug called Leuprogel (known in the U.S. as Eligard) from the U.S. based company Atrix Laboratories Inc. This drug aims to treat prostate cancer and is sold in the U.S. since its FDA approval in January 2002. The European approval was obtained recently.

Technology exploitation

The first technology exploitation happened when MediGene spinned off its DNA sequencing service unit in early 1998. Since investors were just willing to invest in MediGene's core businesses an independent company called MediGenomics was founded. In May 2001, MediGene sold its remaining 30% share in MediGenomics to Eurofins Scientific.

In March 2003, a second spin-off took place when MediGene spinned off its cardiology sector into the independent company Larnax AG, due to one unsuccessful trial with its lead candidate Etomoxir in spring 2002. Etomoxir was a result of the company's own ITD technology. In order to further finance R&D for the underlying ITD technology it was necessary to found an own company, which could apply independently for VC.

In addition, MediGene out-licensed two vaccines for further development. A development agreement was signed with Schering in September 1999 for the clinical development of a vaccine developed for cervical carcinoma. The contract includes a worldwide license with the option for sub-licensing. After joint development until clinical phase-I Schering will conduct further clinical developments and the approval process. In February 2000, MediGene signed a second joint development agreement with Aventis for a rAAV tumour vaccine. Aventis received almost worldwide marketing rights (incl. Japan, the U.S., and Europe), while MediGene retained marketing rights for Eastern European countries and a number of countries in South America, the Middle East, and East Asia. Aventis will carry out all clinical trials after the

clinical phase II and take care of the approval process. In return for both these agreements MediGene expected to receive maximum payments of 32.5 M€ (Aventis) and 48.3 M€ (Schering). However, in September 2001 the licensing agreement with Schering was amended. Thereby MediGene was able to delete possible payment obligations to Schering, which might appear when losing the litigation against Loyola University.

IP Management at MediGene

When MediGene was founded there was no employee particularly assigned to work on IP issues. However, since the company's business concept was not primarily based on a single initial technology on which the company tried to develop a drug, there was a strong orientation towards potential in-licensing candidates from the early beginning. The company was always actively scanning for drug candidates to acquire and develop further. During its early days the administration of IP was handled by the company's CEO. In March 1998, the responsibility shifted to the VP Business Development[139], who, besides his responsibility for 'classical' Business Development, became responsible for public relations and patenting as well.

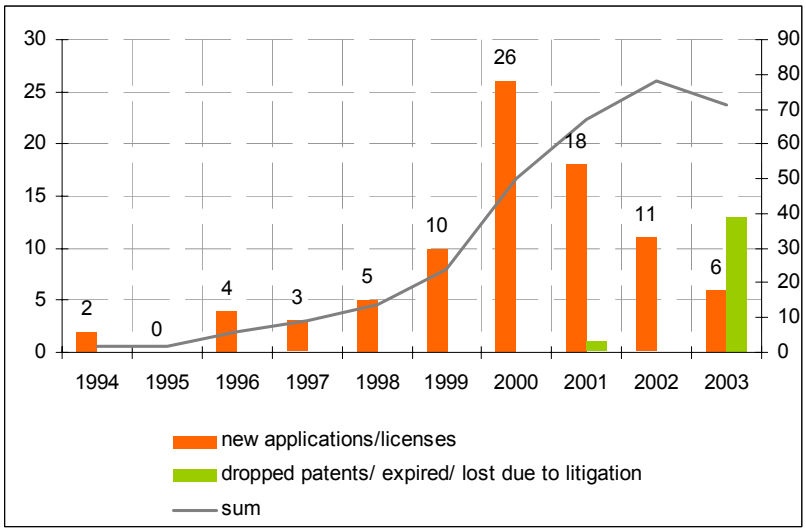

Figure 31: Development of patents at MediGene

As a consequence of the litigation with Loyola University as well due to the piling up of patent work, the top management decided in 1998 that the company needed to develop internal IP competence. They decided to appoint one of their researchers, who had gained considerable experience with patent work. However, when this re-

[139] The former VP Business Development left in April 2001. At the end of 2001 Dr. Claudius Wamlek started to work for MediGene.

searcher left the company in spring 1998, the top management hired an external person to become responsible for IP matters.

Dr. Rehfueß was employed at the end of 1998 as the "Manager Patents and Licensing" and became "Assistant Director Patents and Licensing" in 2001. Soon after his employment, he started to become trained as a European patent attorney. To hire an experienced IP manager was too costly, therefore the only possibility was to train their own patent attorney. When patent work piled up in 2000 MediGene hired an additional IP manager in May 2001, who currently receives training as a European patent attorney. Both are assisted by a part-time employee, who was hired in August 2002.

The 'IP group' (as the IP department is called today at MediGene) is responsible for filing patent applications, handling trademarks as well as for negotiating plain patent licensing contracts. Larger partnering and co-development contracts are handled by a separate 'licensing group' headed by the VP Business Development supported by input from the 'IP group'. The licensing group consists of one licensing director and two licensing managers. The business development department further employs one analyst.

The current structure has developed since the end of 1998 when the business development department had grown continuously from three to eight (today seven) people (not including any assistant) and a higher degree of specialization was desirable. However, both 'groups' report to the company's VP Business Development. Additionally, MediGene employs a lawyer in the U.S. subsidiary who, among others, is responsible for managing IP of the subsidiary.

MediGene registered its name as a trademark in 1995 and further registered trademarks for the ITD technology as well as on 'integrated target definition' which were transferred to Larnex when MediGene spun off its ITD technology. In addition, MediGene holds a trademark on the name 'Economizer'. The company has not filed any trademarks for its close-to-market products yet. Trademarks for the substances Leuprogel and Polyphenon were filed already by MediGene's licensors.

So far, the company filed two utility models as well as one method of treatment pat ent[140] in the U.S. In the threat of the litigation the company had filed a design, in order to get enforceable protection earlier than just after the long approval period for a patent. In general, the company is more likely to keep process know-how secret than filing process patents, since an infringement is difficult to prove and in most cases it is not difficult to invent around just making slight changes. In case single steps of a process are independently patentable, without the need to disclose information about the whole process, such protection is seen as highly valuable. The company filed three patents for such processes.

Until today, the company has not explicitly formulated an IP strategy. It is not seen to be necessary since all persons involved meet regularly but informally and work closely together in one central location, the headquarters. Only one IP manager is working in the U.S. at the MediGene Inc. site, but there is a strong information exchange too. The IP portfolio has been reviewed a few times so far. If IP issues grow further and more people work with IP and the fluctuation of IP managers increases, the company is aware that an explicit IP strategy or policy may become necessary.

As tools supporting the IP management and the prior art search the company basically uses two external, commercial patent databases (Derwent World Patent Index, and CAS (Chemical Abstracts) besides the freely available EPO, Depatisnet and USPTO databases.

Executing patent application filing

Initially, MediGene worked closely together with several patent firms[141]. Today, the company mainly works with three German based patent firms: Isenbruck and Partners (a spin-off from the biotechnology team from Bardehle and Partner, which was one of the largest patent law firms in Germany), Zimmermann and Partners (a spin-off from Diehl and Partners), and Vossiuss and Partners. There were some miscommunications resulting in double-efforts and inefficiency with some previously used patent firms. As a consequence the Assistant IP Director decided to consolidate the

[140] Patenting methods of treatment is not possible in Europe, yet.

[141] Compared to Sweden there was no lack of patent competence specialized on biotechnology in Germany. According to Dr. Rehfueß the density of patent firms was and still is the highest in Germany in the whole of Europe.

IP work to a limited number of patent law firms – the three mentioned above. With this decision communication could be significantly improved and the application process streamlined. However, due to potential conflict of interests of one law firm three patent law firms are still used.

International filing is mainly done by these patent firms as well. They take care of contacting local patent attorneys in other countries, as working directly together with patent firms abroad often turned out to be inefficient and costly.

Usually, patents are filed first at the DPMA and later internationally using the EPO as 'receiving office' to keep costs low and to make use of certain procedural advantages. In general, international patent applications are then further pursued in Europe, the U.S., Japan, Canada, and Australia. Depending on foreseen markets additional countries are pursued. If it is important to create 'state of the art' as fast as possible in the U.S. in a highly competitive field, patents are filed first with the USPTO as provisional applications.

Litigation: MediGene vs Loyola University

Prof. Gissmann and colleagues invented the CVLP technology during their research at Loyola University, Chicago. In the U.S., all inventions are usually owned by the university where the invention is made, but in this particular case Loyola University was not interested in patenting the CVLP technology. When Prof. Gissmann asked the university to patent the technology, the technology transfer department rejected his proposal due to unavailability of financial resources at that time. Prof. Gissmann was 'allowed' to try to exploit the commercial potential of his technology himself.

When Prof. Gissmann[142] offered the CVLP technology to MediGene in 1994 they recognized the commercial potential and decided to buy-in the technology. MediGene filed a patent application, set up a project for developing this technology further and entered into negotiations to obtain the full rights to the technology.

Before coming to a definite licensing contract Loyola University appointed a new technology transfer manager, who realized the value of the technology and signed an out-license agreement for the CVLP technology with MedImmune Inc., a U.S. based

[142] Prof. Gissmann started working for MediGene as head of R&D later in 1997.

biotechnology firm, which almost directly out-licensed the technology to Glaxo Smith Kline (GSK).

When it appeared to MediGene that GSK was working on the same technology they had purchased, MediGene "filed an action at the United States District Court for the Northern Dirstrict of Illinois against Loyola University of Chicago and MedImmune, Inc."[143] in spring 1998.

In March 2002, MediGene appealed in the dispute against Loyola University, but when it turned out that Schering, which had previously worked together with MediGene on product development of an HPV vaccine based on the CVLP technology, terminated the collaboration agreement, MediGene decided to settle the dispute since a litigation against GSK without having Schering's financial backup would be almost impossible to succeed. MediGene "settled the patent dispute with Loyola University […]" in January 2003. The "disputed ownership rights were assigned to Loyola" University, but MediGene "still possesses patents for the protection of elements of the vaccine". Shortly after that decision MediGene dropped the research project on the CVLP technology as one of its core technologies[144].

Summary and first order analysis

Today, MediGene operates an IP department consisting of 2.5 employees. The department was continuously built up after the company realized that a professional in-house IP management is of importance, not at least after the difficulties which appeared after the company filed litigation against Loyola University in 1998. This litigation represents a critical event in the company's history and since then the awareness of the necessity of a sophisticated IP management was much larger. Referring to the company's CEO, the aim was and still is to build up a "strong" IP department.

Until today, the IP department has no explicit mechanisms (e.g. IP or patent strategy, IP policy, etc.) in place. The patent portfolio was reviewed a few times so far, although not in a constant time frame. Licensing issues are handled by a separate department which works closely together with the IP department when dealing with in-licensing, negotiations, etc.

[143] For more detailed information see: (MediGene AG 2002), p.98f
[144] (MediGene AG 2002)

Interpreting the litigation case against Loyola University as a major event in the history of MediGene, one can identify two different IP management stages which the company went through so far (see Figure 32). The company was in the Pre Litigation Stage from its foundation until they filed the infringement claim against Loyola University in spring 1998. As difficulties appeared MediGene's Management became aware to better try to avoid litigation cases in the future and/or settle them in an arbitration court and build up a "strong IP department."

The litigation as a disruptive event led to a change in the awareness of the necessity of IPRs. All upcoming projects had to be carefully evaluated concerning substance protection and freedom-to-operate and no project with uncertainty concerning these criteria and with an uncertain patent situation could be started any more[145].

Since the end of 1998, MediGene started to continuously build up a sophisticated IP management. As a consequence the company hired their first in-house person being particularly responsible for IP matters, who was trained to become a European patent attorney and continuously expanded its IP management incrementally, hiring additional IP managers when necessary. MediGene changed its organisational structure and responsibilities for patenting and licensing at the end of 1998 (IP Department and Licensing Stage).

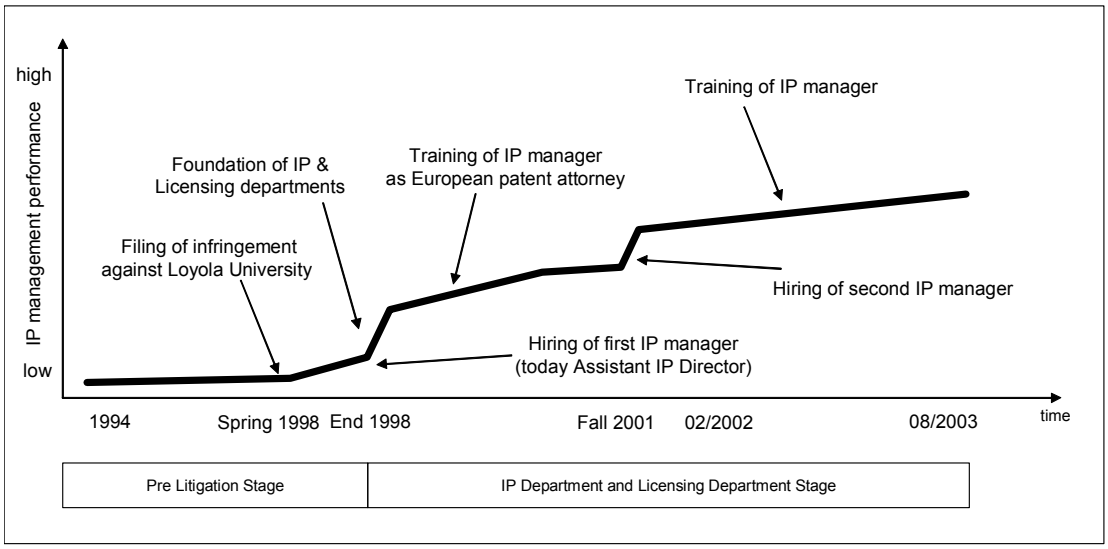

Figure 32: Development of IP management at MediGene

Throughout these two stages the role of IPRs changed. Since the company was not founded on the basis of one core technology during the Pre-Litigation Stage the

[145] Comment from the CEO on the litigation during the interview.

company was aware of the need to handle IPRs carefully, but did not gain much experience quickly. Patents were necessary to be obtained, especially for the IPO, but were not actively managed. In addition, only few trademarks were filed, e.g. the company's name.

When the company experienced the effects of a litigation case it started to attach more importance to patents. When the first IP manager (today's Assistant IP Director) started to receive training as a European patent attorney, the company begun additionally to file process and method of treatment patents.

Recently, MediGene started to foster an integrated IP-mix management seeing IPRs as active mechanisms to secure future businesses and not just as legal assets. The licensing and IP departments together are specialized on certain tasks, but work closely together although no explicit mechanisms for guiding the IP management are in place.

4.1.5 MorphoSys AG

MorphoSys was founded as a limited liability company (GmbH) on August 5th, 1992 by Dr. Simon E. Moroney (today the company's CEO), and Dr. Schneider, who met as post doc and doctoral students at the ETH in Zurich, as well as Prof. Andreas Plückthun, from the Max-Planck-Institute for Biochemistry in Martinsried, today professor of biochemistry at the University of Zurich and member of the company's advisory board. After its foundation the company was first situated in an in-house laboratory at the Max-Planck Institute in Martinsried. In 1993, the company moved into its own laboratories in the Munich Technology Centre and in 1997 into the newly built innovation centre for new biotech enterprises (IZB[146]) in Martinsried and finally occupied its own building in November 1999 close to the IZB.

MorphoSys was founded on the idea to exploit the opportunities deriving from the emergence of biotechnology, but not based on a specific, already existing technol-

[146] The IZB (Innovations- und Gründerzentrum Biotechnologie) was founded in November 1993 by the Ministry for Economy, Transport and Science from the state Bavaria, Germany. The first companies moved in on October 15th, 1995.

ogy. The company's management team early decided to target the antibody market as the founders realized the growing importance of antibody treatment[147].

Between 1992 and 1997, MorphoSys established its technology platform by developing technologies for the generation and screening of protein libraries with a focus on antibody fragments, and the construction of special multimeric antibody fragments. During that time frame, MorphoSys and its ongoing R&D was mainly financed by venture capital until the first generation of its lead product, the HuCAL®[148] (Human Combinatorial Antibody Library) was ready in early 1997, which led to the first commercial agreement with Pharmacia & Upjohn. The company went public on March 9th, 1999.

In January 2000, MorphoSys released its second generation antibody library, HuCAL®-Fab, with about 10 billion antibodies. On the 12th IBC Antibody Engineering Conference in San Diego, California, in November 2001 the company launched its third product generation called HuCAL®Gold with about 13 billion antibodies.

In early 2000, the company founded its U.S. subsidiary in North Carolina for the purpose of "assisting […] in marketing and commercializing its technologies". However, as a consequence of the restructuring process, which started at the end of 2002, activities of the U.S. subsidiary were transferred back to the German headquarters and the operations were "substantially closed by the year-end 2002"[149].

From 1997 until 2001, MorphoSys was commercialising on its HuCAL® library through

either offering collaboration agreements to collaborative partners for developing drugs throughout the pre-clinical stages on behalf of its partners and/or offering companies the opportunity to use the HuCAL® library whether in-house or by fully licensing the technology to their customers[150].

However, in 2001 the company decided to diversify in the drug development business willing to develop "therapeutical antibodies for its own account by taking drug

[147] In 2002 twelve therapeutical antibody drugs were approved for sale in the U.S. Total sales had experienced growth of 40% in 2001 up to 4.3 b€ (MorphoSys AG 2002) Revenues are forecasted to grow until 27.5 b€ in 2010 (MorphoSys AG 2001)

[148] The HuCAL library is a "concept for the generation of highly specific and fully human antibodies. [It is applicable for a] broad range of purposes reaching from target validation to drug development. […It] is also a direct source of antibodies for all kinds of diagnostic and therapeutic applications."

[149] (MorphoSys AG 2002)

[150] The company was able to sign eleven licensing deals until 2001.

candidates to proof in human clinical trials before seeking a commercial partner"[151], wherefore the company founded a pre-clinical and clinical development team. But, as it appeared that "new capital through a planned equity-based strategic partnership was not possible"[152], when would have been necessary for carrying out expensive clinical trials, MorphoSys had to re-adjust its strategic plans at the end of 2002. In November 2002, the company started to restructure its business with the "principle aim of reducing expenditures related to the development of proprietary drug candidates, in addition to refocusing its commercial strategy"[153].

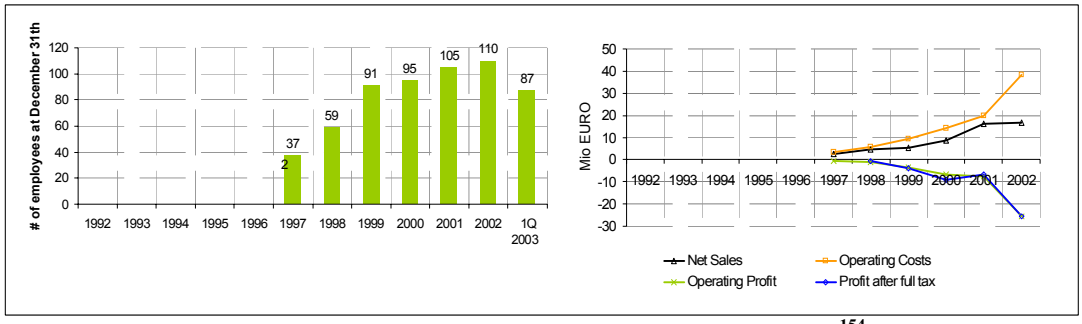

Figure 33: Key financials and # of employees, MorphoSys[154]

Today, the company is still developing proprietary drugs throughout the pre-clinical stages. The company has three own drug candidates (MOR101 against deep second-degree dermal burn, MOR102 for treatment of inflammatory diseases, e.g. rheumatoid arthritis, and MOR201 targeting haematological malignancies).

As a consequence of the restructuring process, the company reduced its headcount by 29 to 87 in March 2003[155]. At the end of 2002, MorphoSys had about 20 drug development programs ongoing with collaboration partners and generated revenues of 16.8 M€ in 2002 (see Figure 33). Today, the company's strategy is to "apply its proprietary HuCAL® technology to generate therapeutic antibody candidates that will be developed and commercialised with partners"[156].

Currently, MorphoSys is producing research quantities of antibodies from the HuCAL® library in-house but signed a supply agreement with Lonza Ltd. in the UK in

[151] (MorphoSys AG 2001)
[152] ibid
[153] (MorphoSys AG 2002)
[154] For the early years of the company's development no data could be obtained as the data was not open to the public.
[155] "No further plans for headcount reduction are foreseen" (MorphoSys AG 2002)
[156] ibid

January 2003 for the production and supply of clinical grade antibody drugs derived from MorphoSys HuCAL® technology within the next five years.

Development of MorphoSys' technology base

Today, the HuCAL®[157] technology is the company's core technology which is complemented with several other technologies (see Figure 34), which have mainly been developed in-house. Other complementary technologies were licensed-in from third parties (see Figure 36). Since the company's business strategy is partly based on making its HuCAL® technology available to partners for R&D purposes, the company signed several out-licensing agreements for the usage of its libraries, wherefore MorphoSys needed to negotiate sublicense agreements with the technologies embedded in the individual HuCAL® libraries.

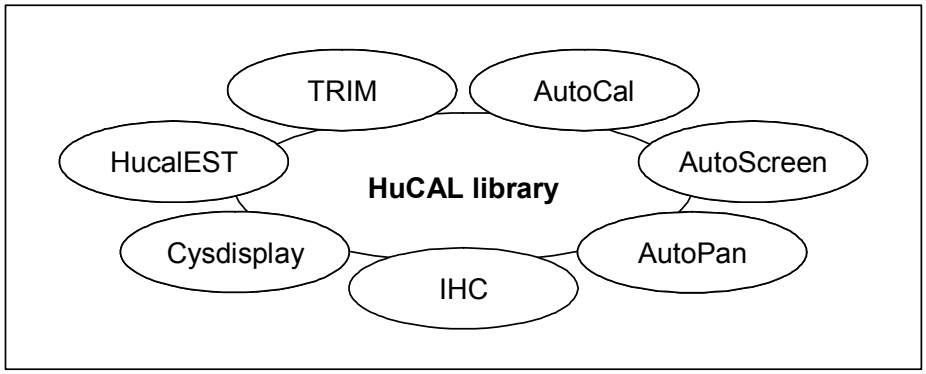

Figure 34: MorphoSys's core and complementary technologies

In House Development

In order to protect the technologies developed in-house, MorphoSys filed several of its own patent applications. How the patent portfolio developed can be seen in Figure 35. The company had received its first HuCAL® patent granted by the USPTO on October 9th, 2001[158].

[157] HuCAL® is a 100% synthetically derived library, or collection of antibodies. These natural proteins are part of the human immune system. With the aid of antibodies, the human body fights off agents which trigger illnesses. Antibodies are said to have a have huge importance for future therapeutic treatments; (MorphoSys AG 1999; MorphoSys AG 2002)

[158] U.S. Patent: U.S. 6,300,064 based on an application submitted to in 1998

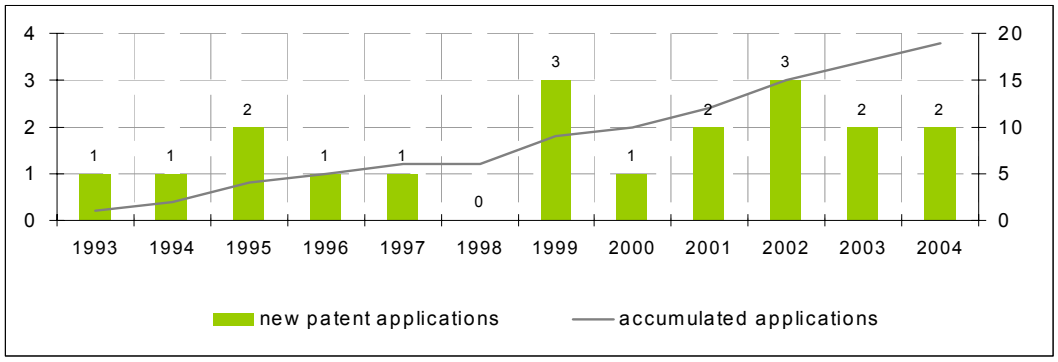

Figure 35: Development of MorphoSys' patent portfolio[159]

Technology Licensing

MorphoSys licensed-in third party patent rights either to complement its core technology to fully practice its HuCAL® library or in order to secure target IP as the basis for developing antibodies directed against that target. When licensing technologies for the usage of its library, it was always important to receive the right to sublicense the patent rights to the company's commercial partners as well. Morphosys has not acquired another company so far. In 2002, MorphoSys had total license expenses of about 8.6 M€, which equals 51% of its revenues.

In 1993, MorphoSys signed its first in-license (see Figure 36) agreement and received a worldwide, exclusive license from John Hopkins University, Baltimore, U.S., for the TRIM (trinucleotide-directed mutagenesis) technology.

In October 1996, MorphoSys signed a second important in-license agreement with Dyax Corp and received a worldwide, non-exclusive license for the Dyax phage display technology. Additionally, in December 1999, MorphoSys received a non-exclusive license from SCA Ventures for a technology encompassing single-chain antibodies as an important complement to its first HuCAL® library.

[159] The figure includes only the first applications of new patent families. Resulting PCT and national applications are not shown.

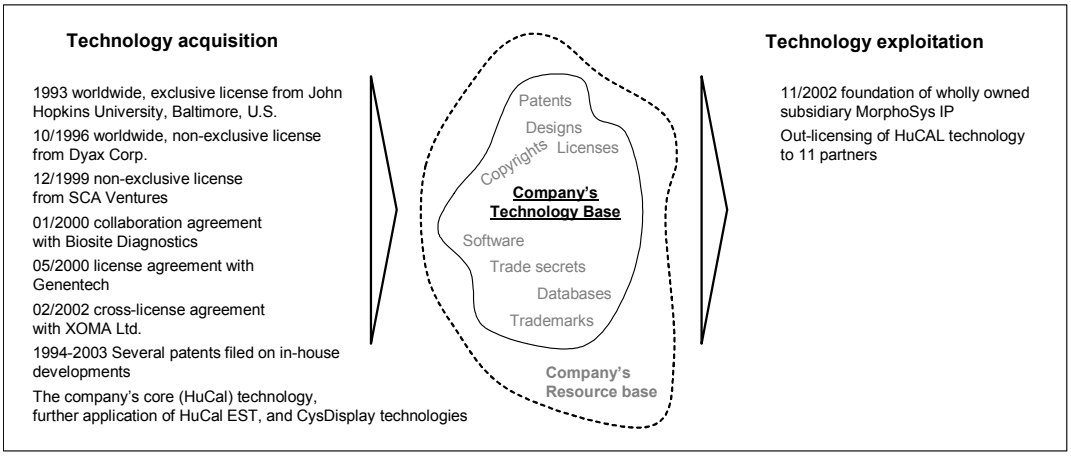

Figure 36: Development of MorphoSys' technology base

In order to make full use of its second-generation antibody library (HuCAL®-Fab) MorphoSys needed to access several patents of Biosite. Therefore MorphoSys signed a collaboration agreement in January 2000. In May 2000 as well, MorphoSys signed a license agreement with Genentech, Inc. In 2002, MorphoSys entered a cross licensing agreement with XOMA Ltd.

Technology Exploitation

In November 2002, MorphoSys founded a wholly owned affiliate called MorphoSys IP GmbH with the purpose to "administer the internally generated intellectual property of MorphoSys AG". The mother company sold rights of certain internally generated IP to MophoSys IP GmbH, but still holds sublicenses for certain technologies required to commercialise HuCAL®. Furthermore, MorphoSys had signed eleven out-licensing agreements in 2001 for the usage of the HuCAL® library to several partners.

IP Management at MorphoSys

From the early beginning MorphoSys was involved in drafting patent applications supported by a professional patent firm[160]. At the end of 1995, three internal researchers participated in an IP seminar offered by the patent firm Vossius & Partner. Since the laboratory project of Dr. Virnekäs had just finished and he was looking for another task at Morphosys, he was selected to be trained as a European patent attorney and became the head of the newly founded IP department in early 1996.

[160] MorphoSys worked closely together with Dr. Jaehnichen of Vossius & Partner in Munich, Germany.

When a patent dispute with Cambridge Antibody Technology (CAT) (see special section on litigation) 'exploded' with the first lawsuit in the U.S. in 1999, the company realized that they would need to provide more internal IP resources. An additional employee (who left the IP department in 2001) was transferred in-house to support the IP department, and was additionally carrying out SWOT analyses for new projects. In mid 1999, when the litigation became too extensive, a third employee was hired who started to receive training as a European patent attorney. In 2000, a U.S. lawyer was present at the company's headquarters and assisted in the day-to-day work and additionally carried out an internal audit of the patent department with focus on U.S. IPRs. The size of the IP department increased further, as work piled up, to a maximum of four people (incl. the Senior Director IP) in the course of 2002.

At that time, a U.S. lawyer from MorphoSys U.S. patent counsel was part of the team supporting mainly the IP department concerning U.S. patents. This lawyer became employed by MorphoSys Germany in July 2003, but his main area of responsibility is now in the Business Development department, although he is still in close contact

with the IP department due to some overlapping tasks. Today, the IP department consists of the Senior Director IP and one employee. Prior to spring 1999, the IP department reported directly to the company's CEO. Later they reported directly to Dr. Thomas von Rüden, CSO of MorphoSys.

In the past, licensing issues (in-licensing, out-licensing, and licensing negotiations) were in the area of responsibility of the Business Development department as it was always an integral part of the company's business strategy. At the beginning of 2003, the company's CSO became Executive Vice President of Business Development, so that Business Development and IP are today both in the responsibility of this VP. Today the licensing department consists of a lawyer (handling contract design) and two to three assistants reporting to the Director Business Development.

Until today, the company has never laid down an explicit IP strategy in writing. However, the company's goals have always been (i) to secure freedom to operate for itself and its commercial partners, and (ii) to obtain the best possible protection for its technology platform. Thus, it is fostering an 'active' screening for new as well as competitive technologies and tries to apply 'foresighted' patenting to strengthen their

IP portfolio against competitors. The company follows the approach to file applications, only when it is likely that the application will be granted. The company reviews its patent portfolio, but not on a scheduled basis. No patents or patent applications have been dropped actively so far, but the company is planning to adjust its patent portfolio in the near future. As tools supporting the patent work, the company has used, beside various publicly available databases, one commercial database (Thomson Derwent former called Delphion[161]) since the end of 2000. So far MorphoSys did not file any design rights or patents on software algorithms. The company is carefully deciding on a case-by-case basis, whether to file patent applications concerning processes or whether to keep the respective know-how secret.

Litigation Cases

During its history MorphoSys was involved in litigation against two parties: Cambridge Antibody Technology (CAT) and Applied Molecular Evolution[162] (AME). In 2001 (2000), the company had capitalized costs of 7.3 M€ (5.5 M€) resulting from these two litigation cases.

As a starting point for several disputes and infringement cases between CAT and MorphoSys, MorphoSys initiated "opposition proceedings against [… a patent[163]], licensed exclusively to Cambridge Antibody Technology Ltd."[164], in the European Patent Office in Munich, Germany in 1994. A further opposition against a second EPO patent[165] was launched by MorphoSys in 1997. On September 24th, 1998, CAT sued MorphoSys for patent infringement of the German counterparts of these two European patents in the Munich District Court. The two oppositions were decided by the Opposition Divisions in October 1999 and July 2000 respectively. In both cases appeal proceedings were started subsequently.

After the grant of a U.S. Patent in March 1999[166], MorphoSys filed a 'motion' for seeking a Declaratory Judgement (DJ) in April 1999 against CAT in the U.S. District Court in Washington, D.C., This case went to trial and finally was decided by the

[161] Previously, this database was offered free of charge by IBM.
[162] Eli Lilly and AME recently announced "to AME's merger into Lilly."; press release AME; November 21st, 2003
[163] The Winter-II patent covers antibody gene expression libraries; EP-B1 0 368 684 granted by the EPO on April 9th, 1994.
[164] (MorphoSys AG 1999)
[165] McCafferty patent EP-B1 0 589 877 granted in December 1996
[166] The 'Griffiths' patent; U.S. patent: 5,885,793;

judge in Summary Judgement in favour of MorphoSys. A similar DJ action at the same court was filed by MorphoSys when the first U.S. McCafferty patent was granted in October 1999. In both cases CAT filed counterclaims for patent infringement. On June 19th, 2001, the U.S. patent corresponding to the European Winter-II patent was granted, and on the same day CAT sued MorphoSys for patent infringement in the U.S. District of Southern California in San Diego. However, the case was dismissed by the court, and MorphoSys was again able to file a DJ action in the Washington, D.C., court. However, when additional patents were granted CAT and other parties sued MorphoSys in September 2001[167] at the same court.

Finally, both parties settled the dispute in December 2002. MorphoSys gained rights to apply CAT's technologies, but CAT will receive an annual payment of 1 M€ from 2003 to 2008 (at a total of 4.17M€[168]), as well as other "financial consideration from MorphoSys' activities related to its HuCAL®Gold libraries for a defined period of time."[169] CAT will receive milestone and royalty payments for previously developed products as well as an equity stake of about 600,000 shares. However, MorphoSys has an option to buy out its obligations for a "predefined fixed amount at any time during the duration of the agreement"[170].

The CAT litigation cases were handled at MorphoSys mainly by the company's CSO, Dr. Thomas von Rüden, and the head of the IP department (today's Senior Director IP) together with an external German attorney, and in close interaction with four to five U.S. lawyers from the U.S. law firm representing MorphoSys.

In June 2001, AME initiated a lawsuit against MorphoSys in the U.S. District Court for the District of Massachusetts in Boston that MorphoSys is infringing some of their patents[171]. Morphosys counterclaimed that the patents are "invalid and/or unenforceable" or not infringed by MorphoSys's activities. Although the Magistrate Judge issued a Report and Recommendation in January 2003, recommending that the District Judge should grant Summary Judgement in favour of MorphoSys for non-infringement, the case is still pending since the District Judge has not yet finally ruled.

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[167] Two U.S. patents: 6,291,158 and 6,291,161
[168] http://uk.ilfnews.com/storyID=460122302.htm; 2003/12/14; 12:02h
[169] (MorphoSys AG 2002)
[170] ibid
[171] Matter of this dispute is the so-called 'Kaufmann' patent family.

Summary and first order analysis

Throughout its history MorphoSys went through three major stages (see Figure 37). During its early years the company needed to identify and develop a technology to commercialise upon (Technology Developing Stage). Therefore, it needed to develop its core technology and to complement it with third party technologies to be able to fully utilize the technology. During this stage MorphoSys acquired licenses to several technologies from outside, but developed some technologies in-house. Further, MorphoSys initiated the first dispute relating to a third party patent. When the company was invited to participate in a seminar held by their patent firm, the company's awareness of the need for a sophisticated IP management increased.

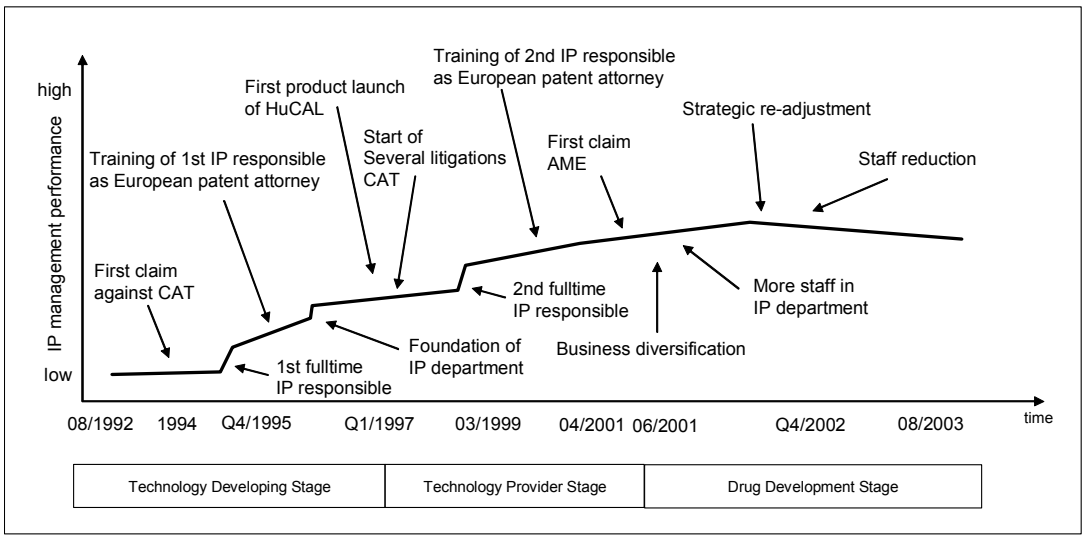


Figure 37: Development of IP management at MorphoSys

When the company launched its first HuCAL® library in early 1997 the company's focus shifted and the company entered its second stage (Technology Provider Stage). At that time the company needed to deal with the licensing agreements with their collaborative partners. During this stages the company's IP department was founded, which can be interpreted as an additional increase in awareness concerning the importance of IP by the top management. Since both the complexity of disputes with CAT as well as the number of in- and out-licensing agreements increased, the company consistently built up its patent and licensing departments.

When the company decided to apply its own technologies for diversifying in the drug development business in 2001 the company entered its third stage (Drug Development Stage). Although the company decided to re-adjust its strategy at the end of 2002 and not to follow its strategy to develop drugs throughout clinical trials, it is

still preceding development work in the pre-clinical stages. In this stage IP management is mainly concerned with analysing and securing freedom to operate with respect to the antibody product programs to be pursued.

During these three stages the role of different IPRs changed. In the first stage mainly product patents and in-licensing agreements were important in order to 'assemble' all technologies which were needed to ensure freedom-to-operate, and to protect in-house know-how through patents. The company filed mainly patent applications on either methods for generating antibody libraries and the libraries as such or methods of screening and using such libraries.

When the company entered its second stage and started to offer its services, technology development was still ongoing to improve its HuCAL® library, but collaboration agreements became predominately important. During this stage trademarks became to some extent important to protect their lead product, although the customer base is small and brand awareness is not seen as being so important.

When the company diversified its business in 2001 it became important from an IP management point of view that the huge investments to be done in the course of development of a pharmaceutical product could be protected by securing appropriate freedom to operate and working towards adequate protection of the final products.

The top management has been aware of the importance of IP since the foundation of the company, and although the company has not developed an explicit IP strategy, its focus has 'always' been to secure freedom to operate and to obtain the best possible protection for its technology platform. As part of that (implicit) strategy, the company files applications "only when patenting is very likely". While initially the company was not managing the IP mix as a whole, this changed in 2003 with Dr. Thomas von Rüden being responsible for both IP and Business Development, including in- and out-licensing so that today IP management and licensing are done in an integrated form, although both departments do not meet regularly.

4.1.6 Evotec OAI AG

Evotec BioSystems GmbH (Evotec) was founded on December 8th, 1993, by Dr. Karsten Henco, a prior founder of Qiagen[172], Prof. Manfred Eigen, Dr. Ulrich Aldag (first CEO), Prof. Freimut Leidenberger, Prof. Heinrich Schulte, Prof. Rudolf Rigler, Prof. Charles Weissmann, and the Max Planck Society. The company's aim was to commercialise upon FCS (Fluorescence Correlation Spectroscopy). This technology was invented and developed by Prof. Manfred Eigen[173], director of the German Max Planck Institute for biophysical chemistry in Göttingen, Rudolf Rigler and their co-workers. The technology detects compound interactions at the molecular level.

Dr. Henco was in close contact with Prof. Eigen and convinced the Max Planck Society to sell the FCS technology as well as its whole IP related to it, to Evotec in exchange to an equity stake, while Prof. Leidenberger and Prof. Schulte raised the start-up capital of about 6 M€.

Initially, Evotec tried to apply the FCS technology in order to optimise functional properties of biomolecules (evolutionary technology), but soon realized that the technology had a much greater market potential when used for screening of large number of molecules in order to identify new drug candidates. Today, the initial application is carried out by an independent company called Direvo Biotech AG, which was founded in 2000 in Cologne, Germany.

At this early point of time, Evotec's aim was to apply the FCS technology to offer drug discovery services, enhancing the "efficiency, accuracy, and velocity of the drug development process for the life science industry"[174]. However, before the company could commercialise upon the technology, it needed to develop the tools and instruments first. Therefore, Evotec went into R&D collaborations with Novartis in April 1996 and with GSK in December 1996. As an outcome of these collaborations its first prototype was ready in 1998, called EvoScreen®. The company went into an additional collaboration with Pfizer in June 1999 to develop the technology

[172] www.qiagen.com
[173] Manfred Eigen received the Noble Prize in Chemistry in 1967 together with Ronal George Wreyford Norrish and George Porter "for their studies of extremely fast chemical reactions, effected by disturbing the equilibrium by means of very short pulses of energy"; http://www.nobel.se/chemistry/laureates/1967/; 2003/12/08
[174] C.f. (Evotec OAI AG 1999)

further, so that a first fully working prototype was ready at the end of 2000 followed by a more mature and improved one in 2001.

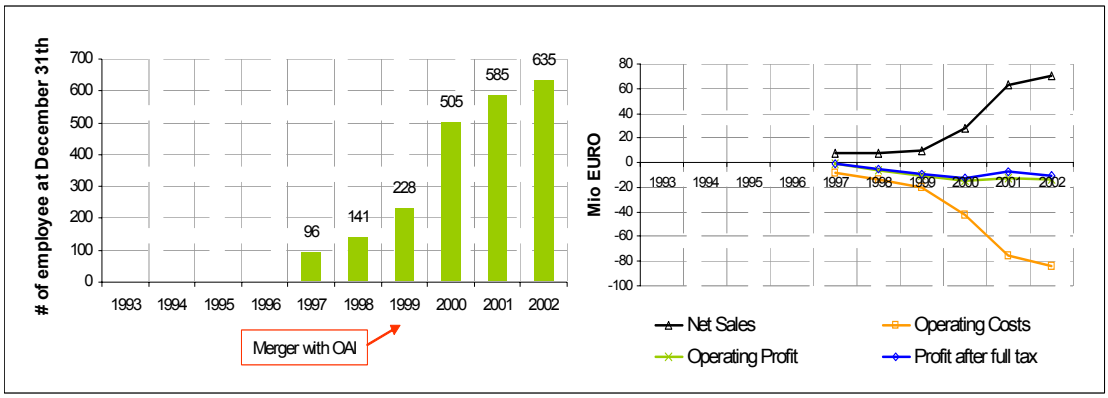


Figure 38: Key financials and # of employees Evotec OAI[175]

Besides developing the tools to commercialise upon the FCS technology, the company diversified into the diagnostics business, when it founded its affiliate called Evotec Neurosciences GmbH with the aim to identify targets for the Alzheimer disease in Mai 1999. In November 1999, Evotec was listed at the "Neuer Markt" at the Frankfurt Stock Exchange as Evotec BioSystems AG.

In late 2000, Evotec merged with a UK based company called OAI (Oxford Asymmetry International) in order to expand their service offerings, to be able to present their customers a "one-stop-shop" from target validation until clinical trials. OAI brought in further competences and capacities to "produce larger amounts of chemical substances for further pre-clinical or clinical trials"[176]. The resulting company was named Evotec OAI and is nowadays listed at the "TecDax" at the Frankfurt Stock Exchange.

As the EvoScreen® technology proved to be successful Evotec OAI founded its independent affiliate Evotec Technologies GmbH in order to handle the "instrument and technology business"[177] in early 2002. These days, Evotec Technologies GmbH works on improving the EvoScreen® technologies but has further developed more compact instruments for direct sale (e.g. Opera™ and Elektra™). Founding this subsidiary, Evotec OAI was able to sustain its competences since most of the develop

[175] Data for earlier years could not be obtained.
[176] (Evotec OAI AG 2001)
[177] ibid

ment team of EvoScreen® went over to Evotec Technologies to secure the know-how and expertise.

Today, Evotec OAI is focussed on its core business with two business segments called DDS (Discovery and Development Services) and DPD (Discovery Programs Division). For DPD Evotec OAI is working closely together with several external partners, preferably universities. The company had 635 employees at the end of 2002 and annual revenues of around 70 M€, with an operating loss of around 14 M€ still remaining.

Development of Evotec's technology base

Evotec's initial technology base comprised of the FCS technology acquired from the Max Planck Institute in Göttingen, Germany in early 1993. How this initial technology base developed is shown in Figure 39 and further explained in the following.

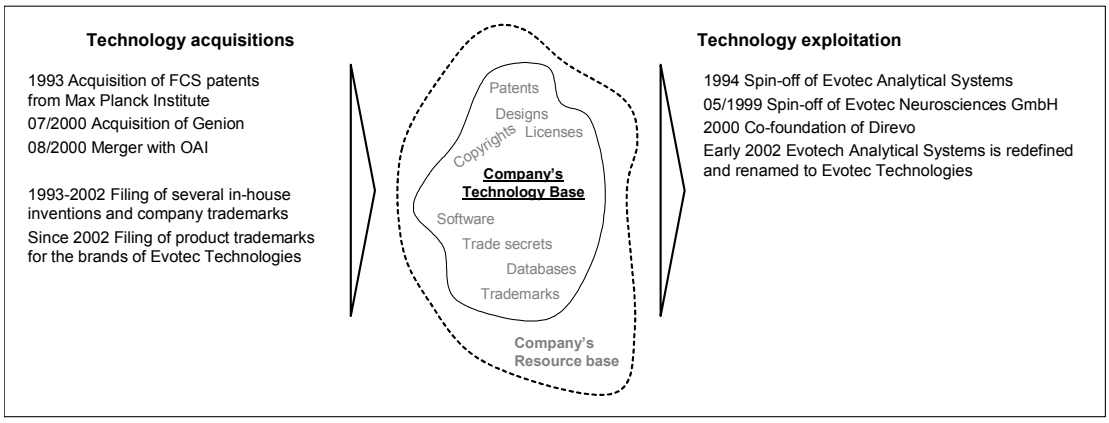


Figure 39: Development of Evotec's technology base

Technology acquisition

During the following years the company worked on developing tools and instruments to get the technology working for high throughput screening. Therefore, Evotec expanded its know-how and built up competences in related areas mainly by in-house R&D. When the company started to develop software for analysing and evaluating the screening results[178], the company started to file patents on these processes as well.

Although the FCS technology and related con-focal techniques remained to be Evotec's core technology, the company further invented new technologies to improve the efficiency in related areas (e.g. optimizing sample carriers, therefore mini-

[178] Mainly done by the subsidiary in Tallinn, Estland.

mizing the amount of costly fluids needed for the test). Additionally, Evotec acquired few but less important patents when the research team discovered that it would need a particular patent to run certain applications (e.g. sample carriers).

In July 2000, Evotec acquired Genion Forschungsgesellschaft mbH (Genion), a spin-off from the University of Hamburg, Germany, in order to be able to use its competences and technology related to ion-channels for offering additional services. Genion was later totally consolidated in Evotec.

As a second acquisition Evotec acquired "all shares of OAI"[179] in August 2000. The purpose of this acquisition was again to "[…] expand their service offerings relating to chemical synthesis." Through this merger the company acquired additional know-how as well as IPRs which were needed to ensure freedom to operate and offer its services. Today, the former company OAI is represented by Evotec OAI's subsidiary in the UK.

Technology exploitation

Even in 1994, Evotec founded an independent company with the purpose to "explore additional areas of application" for its core FCS technology called Evotec Analytical Systems GmbH (EAS). EAS primary task was to develop applications, i.e. biological testing systems, relating to the FCS technology. EAS therefore used parts of Evotec's patent portfolio relating to such FCS technology. And in 1999, Evotec founded its affiliate, Evotec Neurosciences GmbH, to explore targets for Alzheimer's disease.

Still in 2000, Evotec out-licensed some of its early core technology to Direvo Biotech AG (a recently founded company), which took over the business of optimising bio-molecules. Direvo builds on some of Evotec's initial IP in this area while Evotec OAI still holds equity in this company.

When the company had fully developed its EvoScreen® system, the management decided to focus on its core business service offerings to pharmaceutical or biotechnology companies. In order to further develop their technologies, it redefined the purpose of its earlier founded Evotec Analytical Systems GmbH and renamed it to Evotec Technologies GmbH in early 2002. Evotec OAI transferred product and instrument related patents to this recently founded company, but only granted non-

[179] (Evotec OAI AG 2000)

exclusive licenses for the use of their main technologies. Evotec Technologies then continued to file additional patents on devices and processes for its new product ranges of more compact screening systems.

In addition to the trademarks Evotec had filed before (EVOTEC, the logo, EVO-Screen, EVOfactory, EVOseek, NANOSTORE, ALGOCHEM), Evotec Technologies now started to file trademarks to protect the new products of Evotec Technologies, which were to become 'brands' in the future. At the same time they filed some industrial design applications to protect against imitation.

IP Management at Evotec OAI

During the first three years all patent work was mainly done through external patent attorneys. The company worked closely together with the patent attorneys of "von Kreisler Selting Werner" based in Cologne, Germany. As Mr. Henco, the founder of Evotec, had some experience with IP from his prior work with Qiagen, he was aware of the importance of a strong IP portfolio form the beginning. He wanted to deal with patent issues in-house but during the early days of the company no resources were available for such tasks. However, when patent work piled up, he decided to hire someone internally responsible for IP. Evotec's first IP 'responsible'[180] had some prior experience with patenting and started early with his training to become a European patent attorney. Since these days the company has grown continuously, but no critical event appeared forcing the company to draw exceptional attention on IPRs, i.e. the company has never been engaged in litigation.

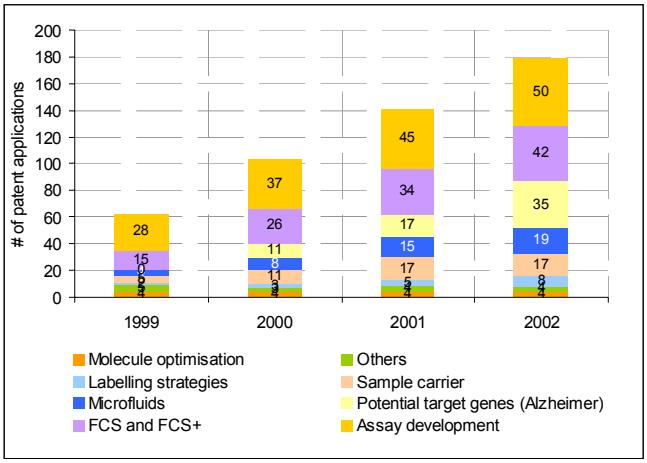


Figure 40: Development of patent portfolio of Evotec OAI

[180] Dr. Martina Leimkühler is today the head of IP. She holds a Dr. degree in biology from the University of Osnabrück and has become a European patent attorney in 2002.

However, the patent work constantly increased and the company hired step by step three and 'a half' additional IP 'responsible' as well as one internal lawyer until end of 2002. A full time IP 'responsible', which nowadays works only part-time, was hired in 1999 and two fulltime employees in 2000. All of them have background either in biology or chemistry. Apart from the lawyer, none of them had management experience before. Two of them already became European patent attorneys, whereas one of them is about to finish his training.

At the end of 2002, the company owned 179 patent families in eight major areas, of which 35 are used mainly by Evotec Neurosciences. How the patent portfolio developed is shown in Figure 40. Today, the company's IP department is headed by an IP director (head of Intellectual Property). Prior to the merger with OAI the IP management team reported directly to the CEO (Mr. Henco). But after company's board changed as a consequence of the merger, the IP department started to report to the CSO, since the new CEO was the company's prior CFO, who was not so familiar with IP matters. Due to the fact that OAI is providing a special type of fee-for-service services, it only owned a small patent portfolio as most of the IP used and/or developed during the chemical services belonged to the customer.

The IP department is centrally organised for Evotec OAI, Evotec Technologies, and Evotec Neurosciences in the Hamburg headquarters. Virtually all patent work is carried out in-house. Almost ready-for-filing drafts are sent to patent attorneys just for a final review and the actual filing. The company works with an additional patent firm based in Munich (Von Betzold & Sozien), because one acquired technology relating to microchips was administered by them. Both law firms are responsible as well for filing foreign applications. The company files its patents mainly in the U.S., Europe and Japan. Patents are always filed in Germany or with the EPO first in order to keep costs low and to get a first examination report on patentability.

The IP department does not meet regularly with the executive board, but is in close contact with the R&D departments of Evotec OAI as well as with Evotec Technologies and Evotec Neurosciences. Regular meetings take place with the heads of the

different R&D departments. The IP department handles IP issues of all companies within the Evotec OAI group[181].

During its daily business the IP department monitors the IP expenses though only on an aggregate level. For prior art search the IP department mainly uses the commercial database "Delphion" in addition to the freely available databases from the EPO and USPTO as well as scientific databases such as Medline.

The company has not yet carried out an IP audit or dropped any patents. However, such an audit was planned in 2001, but when the company decided to spin-off Evotec Technologies as a separate company, this audit was postponed. No 'explicit' mechanisms are in place to guide the IP 'managers' through their daily decisions (e.g. IP policy or strategy) today.

Summary and first order analysis

The development of the IP management at Evotec OAI can be characterised as very smooth and without major disruptive events. The IP management team was continuously built up due to a steady increase of patent work. Due to the above average awareness of the prior CEO, the company hired its first full-time IP 'responsible' already three years after its foundation. The development is represented in Figure 41.

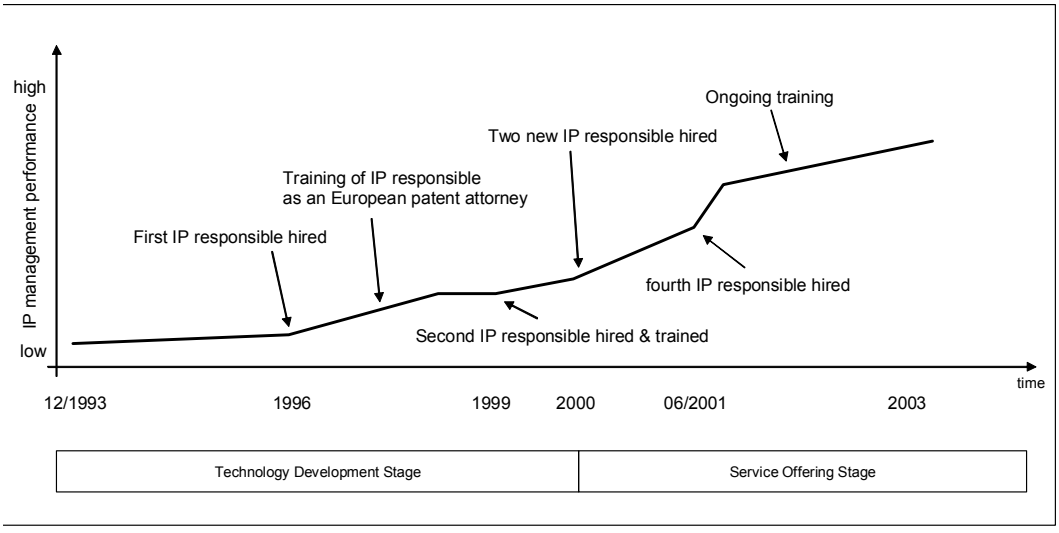


Figure 41: Development of IP management at Evotec OAI

However, the company's history can be roughly divided into two major stages. During the Technology Development Stage IP management was mainly done in or-

[181] It might be necessary to notice that this is possible, because all three companies are located in the same building.

der to secure the company's in-house inventions and secure freedom-to-operate in its businesses. The focus was mainly on its core FCS technology as well as on related ones for the EvoScreen® technology.

When the company experienced major breakthroughs in the development of its EvoScreen® technology and two generations of its EvoScreen® Systems were ready at the end of 2000 the IP management focus shifted. The company began to attract customers for its service business, operating as a service provider (Service Offering Stage) and the IP department became responsible for formulating the contracts with its customers. It appeared to be of extraordinary importance to clearly regulate the ownership of background and foreground IP. At the beginning of this Service Offering Stage Evotec OAI worked with external law firms in Germany, the U.S. and England and did not hire a legal specialist in-house. To improve the working processes and decrease costs an internal lawyer was hired in 2002. Nevertheless, the IP department continued to be involved in processing the service contracts. Today, the IP department is therefore sometime called "legal IP".

The role of different IPRs changed when the company diversified and founded Evotec Technologies in early 2002. The focus was first on process patents protecting certain technologies later the company started to secure parts of its instruments by product patents. Further, trademarks became increasingly important to protect the brands of its more compact instruments the company began to build. Now, the IP management too, was more concerned with actively building up an IP portfolio for this affiliate as well as the one of Evotec Neurosciences, which already happened in parallel.

5 Summary of case results and second order analysis

This chapter analyses first the findings from each single case described in the previous part of the thesis on an aggregated level, thereby aiming to answer the first and second research question. In the later part the third research question is targeted when trying to describe problems associated with the measurement of IP management performance and the trial to derive possible measures for it.

5.1 Different stages and events in the development of IP management

Analysing the six cases on an aggregated level one could find that each case company went through at least two stages of IP management so far. One case company already finished its third stage and is about to move towards the fourth. Three cases had three stages and two cases can be characterised having gone through two stages (see Table 2).

	Swedish Case Companies			German Case Companies		
	Biora AB (1988*)	**Nobel Biocare AB (1984)**	**Pyrosequencing AB (1997)**	**Evotec OAI AG (1993)**	**MediGene AG (1994)**	**Morphosys AG (1992)**
# of IP management stages	3 (4**/5/…)	3 (9/7/…)	3,5 (3.5/1/1.5/…)	2 (7/…)	2 (4/…)	3 (5/4/…)
Age of company (years)	15	19	6	10	9	11
degree of biotechnology	low/medium	low	medium	medium/high	high	high
today's # of patents	~ 10	110	35	179	72	19

* year of foundation

** years of stage duration

Table 2: Stages of IP management in case companies

During the research it was found that an IP management stage can be characterised by relatively constant capacity, competences and responsibilities of the IP department than just the two taxonomies introduced in chapter 2.4.3. However, both are implicitly reflected in the characteristics found in this study. As well the tools applied by the IP department are more or less alike during one stages; as well the top management awareness and the financial commitments for IP management are almost constant. It was found that a shift towards another stage can be characterised by a major variance in one ore more of these six determinants: capacity, competence, responsibilities, applied tools, top management awareness, and financial commitments. However, there might exist other determinants besides the ones found in the six case studies.

Although stages could be identified in the histories of all case companies, these stages differed in their lengths. A first shift to the second stage happened in two cases after around four years after the company's foundation, in one case already after 3.5 years, in one case after five years, and in two cases after either seven or nine years.

A second shift into a third IP management stage happened only in four of the six case companies. However, in three of the four cases the period of the second stage was shorter than of the first stage. In one company the second shift appeared already after one year compared to the 3.5 years-long first stage. In one case the second shift happened after four years (five years) and in the third case after seven years (nine years). Therefore it seems to be difficult to conclude a general length of a stage. Nevertheless, one might question why it took one company still seven years to transform into another stage while one company managed to do this already after one year[182]. However, both companies shifted to an 'advanced' IP management between early 2000 and mid 2001[183].

A third shift to an even more advanced IP management happened already only at one case company. In the end of 2001, this company installed an explicit IP strategy together with an IP council, as a steering committee meeting regularly once a month on IP issues with top management participation, although this company has the smallest IP department employing only 1.5 employees compared to 4.5 in one case company with the maximum of employees of all case companies[184]. The other companies still vary in the number of employees in the IP department. One company still has no formal IP department. The IP tasks are handled by the R&D manager in cooperation with a secretary. The other companies employ 1.5, two, or three employees. However, the company with the largest amount of patent families could be identified as having the highest number of employees working in the IP department. Although the company with the second largest patent portfolio has just 1.5 employees working in the IP department compared to 2.5 employees working in the company with the third largest portfolio. Still, taking into account only the number of patents does not reflect all the related tasks and responsibilities of an IP department. Some IP departments are as well responsible for licensing issues and some only handle patent and maybe

[182] A deeper analysis and search for the reason would very helpful, but out of range of this study.
[183] Maybe due to an increased discussion of IP management in the public during these years.
[184] However, one case company had five employees working in its IP department, but reduced the staff down to three.

trademark issues. At this point a more sophisticated analysis of the responsibilities of the single departments would be necessary to draw any further conclusions.

Although this thesis does not aim on explaining the phenomenon of the path through different IP management stages, some possible events could be identified, which caused the companies to make a transition into another IP management stage (see Table 3).

Driving forces behind a shift into another stage were internal as well as external events throughout all case studies. These events can be said to be either a result of many small accumulated events or of one event with large impact, a so called 'critical event'.

A shift into another stage can be seen as a result of the internal accumulation of work. When the company produced 'too' many ideas and inventions to be patented, sooner or later the IP department needed to hire an additional employee to cope with this patent work. However, with this merely passive event the IP competence accumulated in the company and the IP awareness of the top management increased only incrementally with focus on operational patent work and thereby only incremental IP competence gains. This pure 'event of accumulated work' was a driving force for companies to shift into another IP management stage in two cases, but only for the first shift, when the company founded their patent departments.

	Swedish Case Companies			German Case Companies		
	Biora AB (1988*)	**Nobel Biocare AB (1984)**	**Pyrosequencing AB (1997)**	**Evotec OAI AG (1993)**	**MediGene AG (1994)**	**Morphosys AG (1992)**
# of IP management stages	3 (4**/5/…)	3 (9/7/…)	3,5 (3.5/1/1.5/…)	2 (7/…)	2 (4/…)	3 (5/4/…)
Events for 1st shift	lack of financial resources	foundation of patent department, due to too much work	change in business strategy to diversify	too much work pilled up	litigation case	litigation + change in business strategy
Events for 2nd shift	IPO brought in new financial resources, formal management team	new head R&D and VP legal affairs	decision on IP strategy and foundation of IP council	%	%	Business diversification, more work
Events for 3rd shift	%	%	merger with other biotechnology company	%	%	%

* year of foundation

** years of stage duration

Table 3: Events causing companies to shift into another IP management stage

Further, it seems as there are different reasons to 'install' an IP department the first time (entering the first stage) than reasons for enlarging the department (entering further stages). Founding an internal IP department rather than buying-in external patent services is a 'huge' step especially for newly founded, young enterprises e.g. DBFs, requiring the top management to make available some of the anyway limited

(financial) resources. Therefore, it is more likely that a more critical event is the trigger to catch top managements awareness and make the decision to found an own IP department. This appeared even in two case companies when they became involved in very costly litigation. However, even accumulated work becomes critical from a certain point, although this point might be 'flabby' and prolong able, as it was the case in one company.

One critical event to cause a shift into another IP management stage appeared in two cases each when the companies' executive board made internal decisions to change its business strategy and to diversify into a business in which the regulation of fore- and background-knowledge[185] became important e.g. when signing collaborative licensing contracts. When making this strategic decision both companies realized the need licensing competences by either founding an independent licensing department, expanding their existing department, or assigning the tasks to the IP department.

Further, a critical event seems to be the involvement in litigation for founding an IP department (as mentioned above) or rather entering a more advanced IP management stage. Two case companies were involved in litigation, but both companies interpreted the initiation of the litigation differently. While one case company was sued, the top management immediately realized that this was due to the lack of IP competence. The second company rather sued another company. In this second case the top management did not blame the own IP department. However, in the midterm as well this company realized that it better avoids being involved in a litigation in the future, therefore building up/strengthening their IP competence in order to either carefully ensure freedom-to-operate or to proactively protect future and existing businesses. Reasons to avoid litigation are on the one side the immense costs for court, lawyer etc. and on the other hand possibly resulting bad reputation.

Another critical event for shifting into a higher IP management stage appeared in one case company, when the members of the executive board changed and managers came in with experience and IP awareness from their previous jobs. As in this case two other case companies had an above average awareness of the importance of IP

[185] With foreground knowledge I mean the technology competence brought in by companies in collaborations and JVs and as background knowledge I understand the technological competences, which are the outcome of collaborations and JVs. See as well: (Granstrand 2000)

since their founders were used to the importance of IPRs in biotechnology already from the beginning.

Finally, in one case company the company was trap into a stage, where it was very short of monetary resources. However, when the company went public the company did not face so strong financial constraints any more, so that it constantly built up IP competence, as the awareness of the top management increased continuously.

The availability of monetary resources is often seen to be an enabling factor for a company's growth as stated by Churchill, N. C. and V. L. Lewis (1983), Stanworth, J. and J. Curran (1986), and many others. Especially for DBFs or SMEs in general financial constraints often hinder their growth. But only in one of the case companies financial constraints were so crucial during an early stage that it was critical for investing in IP related resources. However, if the company would have had monetary resources available to build up a sophisticated IP management, one might doubt whether the awareness of the company's top management was high enough to make an investment decision for IP management and not have chosen alternative investment options during this early stage. Therefore, one can rather state that the question is fairly to which investments companies commit their constrained resources, what is obviously even more difficult with a tighter budget respectively during early years.

Still, two other major events caused companies to expand their IP management. A conscious decision of a company's top management to define an explicit strategy and found a steering group for IP decision is a major internal progress towards a sophisticated IP handling.

When two companies merge both partners need to be evaluated concerning their assets often including companies' IP portfolios. When the companies actually get together, both' portfolios need to be merged as well as both IP competences. This leads most probably, as it was just in progress in one case company, to a more advanced IP management.

Summarizing; seven major events could be identified during the case studies[186] (too much work, business diversification, litigation, new staff, IPO, conscious decision,

[186] However, another event appeared to be crucial, although it did not seem to cause a company to move towards and advanced IP management stage. When a company had spin off one of their business units into an own affiliate the mother company needed to transfer some assets, which include intellectual property rights.

and merger) leading companies to make changes concerning their IP management. Whether this list is complete might be doubted, however, as a result of one or more of these events simultaneously companies' IP management most likely needs to be adjusted. Still, the different events are of different nature and different weight and the development of the IP management depends on enabling factors as well which appeared to be in the six case companies the top management IP awareness as well as the availability of (financial) resources. Still, the events, the enabling factors as well as the relationship between them need to be investigated more deeply.

If one would want to judge the current IP management competence of companies, one might investigate several characteristics, e.g. how many employees actually work in the IP department, through how many stages the company went, and the intensity of IP importance due to the business environment. One could even apply the 'data' given in Table 2 to calculate a weighted average IP competence of each company, when assigning numbers to parameter like "degree of biotechnology" from one to five, etc. But as this is out of range of this study it might be subject of further research.

5.2 Roles of different IPRs in different IP management stages

The roles of different IPRs were identified through a means of analysing the development of the companies' technology bases as described in chapter 2.4.1 and shown in each case study. From the results (see Table 4) some findings concerning the different roles in the different IP management stages could be derived.

In all case studies a clear tendency from a merely passive approach on IPRs and especially patents to a more active and integrated 'IP-mix' approach could be identified throughout the history of the companies, although with a different extent throughout the different case companies.

		Swedish Case Companies			German Case Companies		
		Biora AB (1988*)	**Nobel Biocare AB (1984)**	**Pyrosequencing AB (1997)**	**Evotec OAI AG (1993)**	**MediGene AG (1994)**	**Morphosys AG (1992)**
Technology Acquisition	internal R&D	9	several	several	several	few	several
	Acquisition of innovative firms	0	2	0	2	0	0
	Joint Ventures	0	1	0	0	0	0
	Technology purchasing	3	several	4	few	4	5
	Technology scanning	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Technology Exploitation	Internal exploitation	yes	yes	yes	yes	yes	yes
	Creation of innovative firms	1	1	0	3	2	1
	Joint Ventures	0	0	0	0	0	0
	Technology Selling	2	n.a.	2	3	2	1 (+11)
	Divestment	several	several	several	0	few	0
	Storage and leakage	few	n.a.	n.a.	n.a.	n.a.	n.a.

Table 4: Overview - development of companies' technology bases

Investigating the first IP management stage (see Table 5) from each case study it appeared that all cases companies handed IP matters mainly to protect their core technologies by filing patents on in-house developed technologies or their first initial technologies acquired from third parties as a basis for their business. However, often when a company acquired a technology, which later became one of its core technologies, the technology was already protected by (a) patent(s). As the main businesses of all case companies were/are technology based and research intensive during their early stages in-house R&D was focused on the company's core technologies to get this technology ready for offering services or selling a product. In addition, technology acquisition took place, when necessary in order to complement these core technologies. However, during this early stage the company's core technologies mainly were just 'one' core technology merely passively protected by process patents.

In four cases, during the earlier years, the companies needed to be able to present patents or even patent applications as a prove of their reliability to potential investors. The companies' technology bases mainly consisted of a few patents on the companies' core technologies which were mainly process patents, one or a few trademarks on the companies' names and of a few product patents related to applications of the core technologies, as well as not legally protected knowledge of key scientists.

When the case companies grew, their in-house R&D resulted in first patent applications which needed to be filed. In addition, the acquisition of technologies from third parties became increasingly important, wherefore patent searches needed to be carried out. To ensure freedom-to-operate became increasingly important as the com-

pany's business faced increased competition as the biotechnology landscape in Europe became increasingly 'crowded'. As a second means of IP management the filing of trademarks became increasingly important either on the company's name (when not done earlier) or on their lead products. However, the two drug development companies among the six case companies showed a distinctive characteristic. Since their customer group is much focused on a few BigPharma companies creating a brand was not that important as it was for the technology providers and especially for the two least biotechnology integrated companies, since they needed to approach and convince a much broader customer segment. One might highlight that already both drug development companies of the sample companies ran into litigation during this second stage.

		Swedish Case Companies			German Case Companies		
		Biora AB (1988*)	**Nobel Biocare AB (1984)**	**Pyrosequencing AB (1997)**	**Evotec OAI AG (1993)**	**MediGene AG (1994)**	**Morphosys AG (1992)**
# of IP management stages		3 (4**/5/…)	3 (9/7/…)	3,5 (3.5/1/1.5/…)	2 (7/…)	2 (4/…)	3 (5/4/…)
Role of IPRs	1st stage	secure core technology	patents just to protect core technology and few product parts	secure freedom-to-operate by protecting core technologies, surrounding not long lasting patents by new applications	secure core technology, acquire technology to ensure freedom-to-operate	acquire complementary technologies, secure core-technologies	secure developed core technologies and complement with external ones,
	2nd stage	almost no, but trademark needed for FDA approval	patents and trademarks to protect against competitors	increased importance of trademarks	build up brand, although only few customers, handle service contracts	handle litigation, secure future projects in advance by IPRs, build trademarks, secure future businesses	ensure freedom-to-operate, build brand, handle license negotiations
	3rd stage	protect core technologies, build brand, secure freedom-to-operate	IP mix to secure today's and future businesses	using several IPRs to secure future businesses and protect core technologies	%	%	secure lead products by several IPRs
	4th stage	%	%	two patent portfolios merged, integrated IP approach	%	%	%

Table 5: Roles of IPRs in different IP management stages

A further development into a third IP management stage could be seen in the three Swedish case companies but only in one German case company, although during the case interviews it seems to be likely that the other two German companies are likely to make a transition in the near future. During this stage two of the three Swedish companies already started to handle licensing, copyrights, designs, and (product, process and MDB) patents in an integrated manner together with trademarks what one of these company calls 'IP mix'. This tendency towards more integration between different functions/departments is in accordance with literature (e.g. (Granstrand 2000)). In earlier stages of a company's life cycle different IP related tasks are handled by separate departments (e.g. trademarks by the marketing depart-

ment, patents by the R&D department, etc.) while throughout later stages these tasks are centralized in one 'IP department' which works closely together with the top management when developing new technology or business strategies. This phenomenon was observed in three case companies during the study, but being especially obvious at one company.

Further, two companies formulated an explicit IP strategy in the third IP management stage, respectively an IP policy with explicit 'objectives' for the IP departments. However, both companies had trouble formulating explicit goals, so that both decided to determine a certain number of patents to be filed per year together with a few less accurate goals. However, these companies at least tried to find a solution to this problem. Further, these two Swedish companies started to interpret their IP portfolio as a means to protect today's and future businesses. Especially one company faces a need to diversify in several biotechnology fields to stay competitive in the future. The management is aware of the possibilities a sophisticated IP management offers.

Recently, when one case company announced to merge, it was forced to integrate two different patent portfolios, wherefore the IP awareness increased and the newly formed company is about to move towards the fourth stage of IP management handling licensing contracts and an extensive patent portfolio together with trademarks and other IPRs in an integrated manner. It might prove to be valid that this company has installed an explicit IP strategy since 2002. Especially, when new employees take over distinct tasks without intensive know-how about a company's history a codified strategy supports to implements a focused management of IPRs as stated by some interviewees.

5.3 Assessing IP management

Due to the complexity of the third RQ this chapter is subdivided in three parts. First, highlighting three major problems associated with the measurement of the IP management performance from a practical point of view. In a second part the characteristics of the IP performance are characterised, while the third section gives suggestions on how to assess the IP management performance anyway. Still the aim of this RQ was not to develop a distinctive model for assessing IP management performance rather to explore this topic and derive some possible ideas.

5.3.1 Problems with assessing IP management performance

1) During the interviews it appeared to be of importance to clearly know how the IP department contributes to the overall company performance. To assess this link is still a major problem for most of the case companies, due to the fact of the absence of an external measure that reflects the performance of the IP department. On company level the market value is reflected in the stock price, that can be used to judge the top management performance, but in this case the aim is to measure the performance of IP management on department level. The same problem is still present for several other departments (e.g. marketing, accounting, etc.), although in recent years some approaches have been suggested e.g. the balance score card or the classification numbers approach. Even five of the six case companies do not monitor patenting costs individually for each single patent, which is a minimum prerequisite for assessing the IP management performance.

2) After a company is able to overcome the first problem and it really understands how the IP department contributes to its overall performance the company is enabled to define objectives against which the performance of the IP department can be judged. However, defining reasonable and appropriate objectives and responsibilities appeared to be the problem for the top management, as no exogenous indicator is available which directly reflects the IP management performance in context of the overall goals and performance of the company. A measure, or rather a set of measures needs to be defined that is linked to the overall company performance and can be broken down to operational indicators.

3) Another problem appeared when trying to assess the IP management performance is hidden in the nature of IPRs. IPRs are designed to gain an inventor a monopoly on inventions for a certain period of time in order to stimulate investments in R&D to ensure progress and wealth of societies. Grounded in this long period and in the aim of a patent system is a long-time utility. This is what makes the IP management difficult to judge upon as many companies use IPRs as means to protect current (and futures businesses), thereby receiving their main return on investments with a large time delay. Therefore, it appeared to be extremely difficult to assign future profits from sales of a certain product to past investments in several IPRs which are embedded in it or the manufacturing process when running the IP department as a profit centre.

5.3.2 Characteristics of IP performance

The IP management is mainly concerned with managing and ensuring the 'future' of the company. At least this is reflected by the fact that for many companies IP management has become of strategic importance in recent years, but it reflects as well the core characteristic of the IP management performance. On the one hand the IP department has to deal with strategic components to secure future (and today's businesses), while on the other hand investments appear today. In some way managing IP is comparable with managing long term investments, which are essential for the company's future success, but as well difficult to judge. Derived from this characteristic a simple quantitative aim appears to be difficult to define and it seems to be likely that one has to think of a set of objectives or measures[187] which assesses current IP management performance and – very important – the future strategic objectives.

However, during the case studies it became clear and possible to define at least a general but overall objective for the IP department. The IP department must contribute to bottom line profits in the short and long run. This means (1) maximizing the current company performance, (2) maximizing future strategic fit, (3) while minimizing needed resources. How can these three levels be assessed with quantifiable measures?

1) Revenues are generated through sales of products, but as well out-license agreements. Several alternative licensing contracts are possible, e.g. signing exclusive or nonexclusive out-licensing agreements, in some cases even collaborative service contracts, drug candidates and technologies have been out-licensed with the potential to generate revenues. However, the problem remains identifying the right partners and technologies to out-license in order to maximize revenues of today's and future businesses.

2) A prerequisite for this task is to work closely together with a committed top management, although it is extremely difficult in competitive environments where uncertainty about future business and technology developments is high as it is especially for many emerging companies operating in emerging technologies e.g. biotechnology.

[187] A well known tool offering a set of measures is the BSC invented by Norton and Kaplan; (Kaplan and Norton 1992)

3) The department needs to split up their costs and at least monitor the components accounting for the major share of it. This might be even only a few cost components besides the salaries (e.g. negotiation costs, training, fees (filing, maintenance), to external patent firm, freedom-to-operate, administrative etc.). As this study proved only one of the case companies monitors costs individually for each single patent.

5.3.3 Suggestions for measures of IP management performance

Although the problems described above still remain, this study tried to explore some possible measures anyway. During the study, many interviewees highlighted that reasonable objectives for the IP department should included measures for the efficiency (doing things right) and effectiveness (doing the right things) of the IP management. As seen from the argumentation above the effectiveness would be in line with the strategic nature of IP investments (objective 3) and the efficiency would be related to the current daily business of the IP department (objective 1 and 2).

A list of suggestions from the interviewees includes[188]: the number of patent applications per year and per employee, number of litigation cases, percentage of non-compliance with deadlines (e.g. for paying annual patent fees etc.), patent fees paid to patent firms, costs for patenting, number of claims per patent, number of competitors, number of claims against competitors, necessary readjustments of IP strategy, number of IP seminars given by the IP department per year and number of participants in the seminars, revenues generated by licensing, patents younger than two years, patents older than twelve years[189]. Most of these measures relate to the technology base of the company, wherefore it seems to be obvious that the consistency of the technology base should be a major element when assessing the IP management performance. Investigating the technology base provides information about current businesses as well as future businesses of the company[190]. E.g. patents younger than 'two' years are probably filed with the purpose to protect future businesses, while it

[188] Each of this 'measures' could be a starting point for an extensive discussion as each has certain advantages as well as disadvantages. However, this is not the focus of the third RQ, neither of the thesis. As in Nobel Biocare a goal for the IP department is to file around 20 patents p.a. However, this aim bears the risk that 20 patent applications are filed, but not with reasonable strategic value, etc.

[189] A characteristic of the development of patent fees is that these fees increase over time and can become considerable high during the end of the patent duration.

[190] Often competitors try to apply their intelligence to analyse rivals technology bases.

might be questionable if patents older than 'twelve' years should be held further, as the maintenance costs climb up through the end of the patents 'lifetime'.

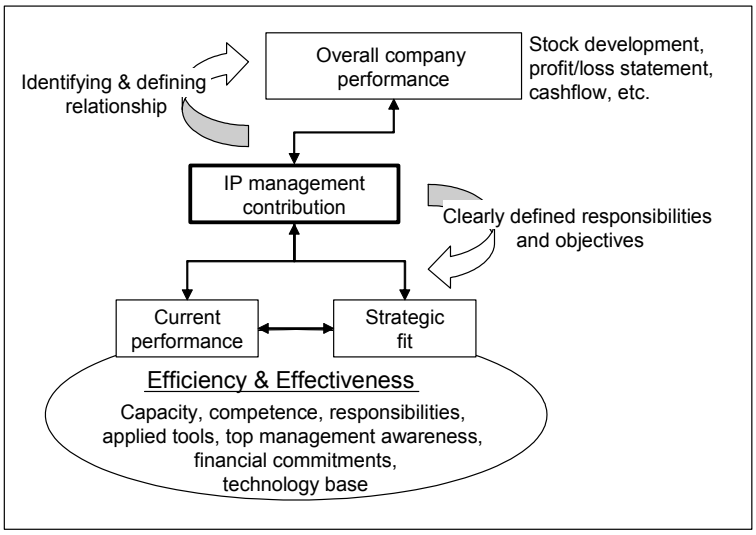


Figure 42: Assessing IP management performance

In addition, to the technology base the IP management performance is indirectly linked to supplementary factors. As it was found from the first RQ, the IP management performance of one stage can be characterised according to six determinants: capacity (number of employees, approximately twelve patent applications/patent attorney/ p.a.), competence (education of employees, (management / scientific) background), responsibilities (just patent or as well licensing issues[191]), applied tools (strategy, policy, databases, portfolio management), top management awareness (where is the IP department reporting to, IP council), and financial commitments (budget, budget/person). As these criteria do not directly reflect measures to assess the IP management performance, they need to be broken down further into indicators - as some examples given in brackets – which have to be weighted against their importance and aggregated into a few performance measures.

As shown, it appeared to be very unlikely that a single measure fits to assess the IP management performance; rather a set of quantitative and qualitative measures needs to be developed. The findings from this RQ are summarized in Figure 42. The set of measures might even reflect different dimensions as it is the case in the BSC approach.

[191] The responsibilities appeared to be different throughout the case companies. In three case companies the IP department handled only patents and trademarks; however, the IP departments in the other case companies handle as well licensing tasks.

6 Conclusions

At this part of the thesis its purpose should be fulfilled, as it was to describe and explore the history of IP management in selected larger German and Swedish companies operating in biotechnology related fields, while trying to identify measures for IP management performance. During the study six case companies were selected and it appeared that the number of cases was feasible and delivered valuable results as shown in the previous part. Referring to the three research questions defined in chapter 1.2, the key findings can be summarized as follows:

RQ1: How can different stages in a company's IP management be characterised?

Different stages of IP management could be found in all case companies. The stages differed in their length throughout the companies, but also throughout the stages. However, as a phenomena appearing throughout all cases, the first IP management stage was longer than the second stage, which was longer than the third stage. It was found that an IP management stage can be best characterised by capacity, competence, responsibilities, applied tools, top management awareness, and financial commitments of the IP department.

Shifts towards another IP management stage were caused either by internal or external events which were single crucial events (litigation, change in business strategy, IPO, merger, conscious decision, new top management members) or an accumulated sum of events, most probably the amount of work of the IP department reaching a critical level. Still these events are linked although a general pattern could not be identified or proved.

RQ2: What has been the role of different IPRs in different IP management stages?

It was clearly found that throughout different IP management stages the roles of different IPRs evolved from a merely passive role of patents towards an active role of handling the 'IP mix'. In four of the six case companies it appeared that during early years IPRs were mainly restricted to patents on core technologies/ processes and in some cases trademarks on the companies' names. In more advanced IP management stages, product and process patents became increasingly important in all case companies as they became oriented towards a final product. Thereby, it appeared that a central IP department was founded handling integrated tasks and IPRs, which were

done before by separate departments. Further, the importance of technology trade/transfer from/to third parties grew. Almost all case companies became increasingly outward oriented and the need to ensure freedom-to-operate increased.

RQ3: How to assess the economic performance of IP management?

The third RQ appeared to be the most difficult to answer, although its aim was not to deliver a comprehensively validated set of measures for IP management performance. Its aim was to come up with a description of the problems and some reasonable suggestions to assess IP management performance. Three problems appeared to be important when judging the IP management performance: (i) There is a 'huge' time delay between investments and return of these investments in the IP management, (ii) as well as that there is a lack to define clear objectives for the IP department, and (iii) the relationship to the company's overall performance was not clearly defined yet. However, during this study it was found that IP management performance can be characterised quite well by applying the following seven criteria: capacity, competence, responsibilities, applied tools, top management awareness, and financial commitments as well as the consistence of the company's technology base. These criteria either aim on the effectiveness or efficiency of the IP department thereby being directly linked to the current IP management performance (minimizing costs and maximizing profits) and the future strategic importance. However, before starting to measure the IP management performance, companies might be aware of the need of internal processes for the valuation and flow of IPRs.

7 Management implications and suggestions for further research

On the one hand the results of this study are helpful for managers - either top management or IP managers - and on the other hand this thesis proposes topics for further.

The most important managerial implications from this study relate to the managerial aspect of the development process of IP management. IP management is not a static 'tool' implemented once, but rather an evolutionary process. During its development, IP management evolves throughout different stages in some way correlating with the different stages of companies' development. Although this correlation not investigated in detail during this study, in all case studies different IP management stages were identified. This should make managers aware of the need to make certain adjustments in a company's IP management when certain events appear. Events in the investigated case studies (either of internal or external nature) were single crucial events (litigation, change in business strategy, IPO, merger, conscious decision, new top management members) or an accumulated sum of events, most probably the amount of work of the IP department reaching a critical level.

Managers might be able to be prepared in advance for upcoming changes in the IP management. As it was shown in this study, IP management becomes more complex and shifts from a merely passive view on patents to an active and strategically handling of the 'IP mix'. Managers might be able to adjust the development of their IP department by being aware of associated challenges in different IP management stages.

In addition, managers might derive ideas – although to be further developed - how to formulate reasonable goals for their IP department and assess the department's performance. As it was shown throughout chapter 5.3.3, there are still many difficulties to overcome when setting clear and strategically relevant objectives for IP departments, even in companies with an advanced IP management.

From a research point of view, a more quantitative analysis of the results is needed to validate the findings. Some further research can be derived especially and directly from the findings of the third RQ as illustrated in Figure 42. To identify the relationship between IP management and the overall company performance with the purpose to define quantifiable goals for the IP department could not be accomplished yet in

an appropriate manner[192]. Additionally, the relationships between the suggested indicators for IP management performance need to be investigated further. As a set of measures was suggested, their dimensions need to be consolidated in order to define an aggregated measure. Further, as this thesis is of mainly descriptive and exploratory nature, a more extensive study might help to explain the findings or rather predict some findings for emerging DBFs or just recently emerging industries as e.g. nano-technology. Since a current research project on this topic is ongoing at the Copenhagen Business School with a large sampling frame, I would rather suggest to accomplish one in-depth case study with a company that is running their IP department already on a profit centre' basis (see 2.4.3). This company does not have to be necessarily a biotechnology company, an equally possible case companies could be larger companies operating in the electronic business having a sophisticated IP department e.g. IBM, Canon, etc. The results of such research need to be transferred to a DBF.

Concerning the second RQ another to be further investigated phenomena is the influence of the different competitive environments of young but as well as older DBFs on IP management. As all case companies did not face much competition during their early years, today's changed environment might force recently founded DBFs to become earlier aware of the importance of IP in order to ensure freedom-to-operate. This presumption might be further investigated as well as further research might investigate the distinctive roles of IPRs in the different IP management stages and derive a general 'dynamic model' as compared to e.g. the product life cycle.

As the first RQ aimed to identify different stages of IP management in six case companies, further research might be necessary to validate these findings especially regarding the lengths of the different stages, as well as the criteria upon which a stage can be characterised. Furthermore, an in-depth study of a very mature DBF – maybe in the U.S. – might be of great help.

Finally, one might highlight that all findings derived from this study strengthen recent developments found in literature that IP management became increasingly im-

[192] Roos, J., G. Edvinsson, et al. (1997) made some suggestions on how to connect IC to shareholder value. However, they defined IC as an even more encompassing term, so that it can not be compared to IP at this point.

portant, while the study showed no evidence that this increase will slow down in the short term.

Appendix A –Requested information material from case companies

- Description of the company's history (including reasons for its foundation)
- Description of your current and former business model(s)
- Number and date of in-, out- and cross-licensing deals
- Number and date of registration of IPRs in company (trademarks, copyrights, patents)
- Number of product and process patents filed, granted, pending, dropped
- If possible: Licensing, patenting policies/strategies
- Founder and patent attorneys: background, when hired, etc.
- Current IP organizational structure and responsibilities
- Information concerning the company's IPO
- Product portfolio and technology overview
- Where does the initial technology bases (patents) came from
- Usage of technology trading exchanges (e.g. yet2, PLX)
- M&A, litigation cases, cooperation agreements and other critical events with major influence on the company's historical development and in particular the IP management

Appendix B – 'Structure' of semi structured case interviews

As a visual guideline throughout the interviews the interviewees were confronted with the following two figures. These were used to introduce the topic and explain the purpose. Further, the interview mainly followed the right figure.

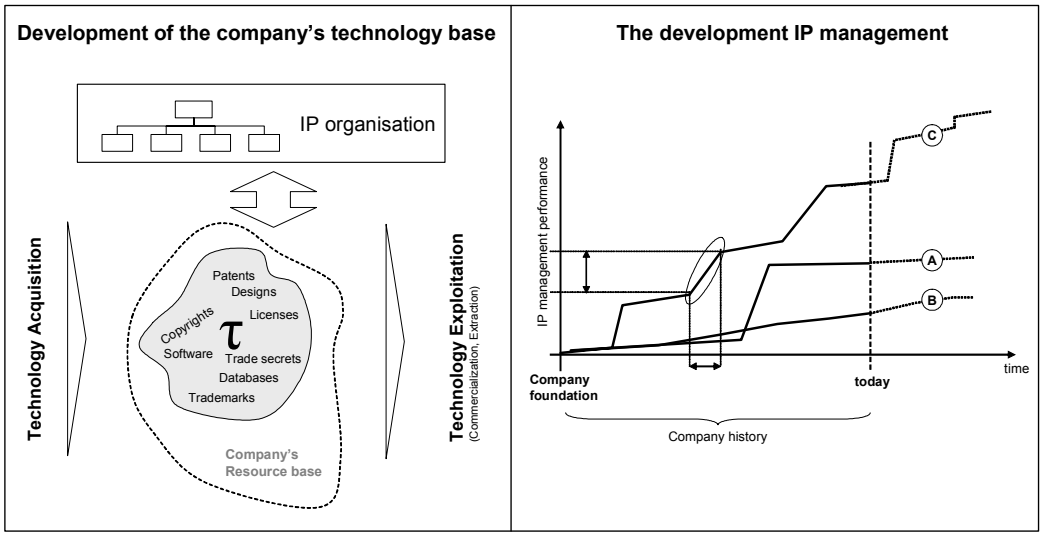


Figure 43: Slides for interview introduction

In general the interviews were divided into four major parts:

1) During the first part of the interview, the interviewees were asked to explain the current situation, organisational structure and responsibilities concerning IPRs in the company.

2) Secondly, the interviewees were asked to describe the circumstances under which the company was founded. This was not of primarily interest, but after the pilot interviews and as well from literature e.g. (Beaver and Prince 2002), (Pena 2002) it turned out that the background of the founders and the motives behind the company's foundation can influence the further development of it.

3) In the following third part of the interviews, the interview partners were asked to describe the development of the company's IP 'management' until today. This major part of the interviews was highly interactive. In this part mainly the research question one and two were included.

4) In the final part of the interviews the interviewees were asked of their opinion how it might be possible to measure the efficiency and effectiveness of the IP departments work[193]. Which aims and objectives they are given by the top management and how the measurement of the achievement of these goals is done in the company.

[193] This question was highly difficult to address. Sometimes this question was only discussed when top management was interviewed separately.

Appendix C - Interview guide used for semi-structured interviews

General Question directed towards IP manager/scientists

1. Please describe the current organizational structure of the company's IP management (responsibilities, background of patent attorneys, organizational position) as well its today's technologies and applications.

2. Describe the company's heritage, foundation, founders, initial business strategy, and where its initial technologies came from.

3. How did the company's technology base, IP management, and 'business model' develop? What have been major events?

Additional question directed towards executive managers, R&D (and sometimes IP managers)

What parameters are given the IP department for defining its goals? How are these goals measured? What problems appear when defining and measuring these goals? Why do these problems appear?

Appendix D – The drug development 'pipeline'

A core element in the pharmaceutical sector is the drug development process that is often illustrated as a 'pipeline' (see Figure 44). This 'pipeline' consists of five phases, whereas new drugs have to go through the first three prior to approval for sales. Throughout this process each phase becomes more costly than the previous one, while the probability of having to drop drug candidates increases.

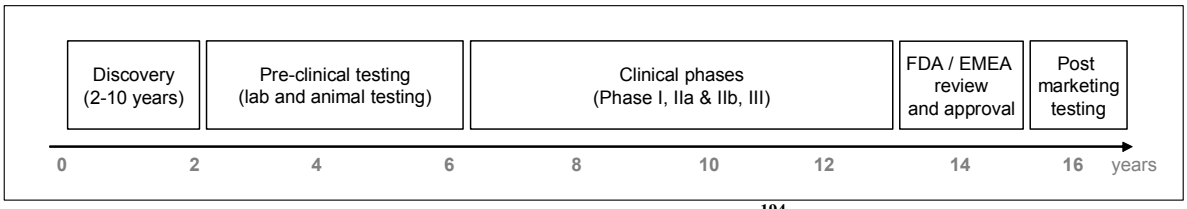


Figure 44: The biopharmaceutical pipeline[194]

The first phase (discovery) aims at identifying potential drug candidates, so called lead candidates, out of 5,000 to 10,000 components. These lead candidates cause a certain reaction with a so called target molecule. This target molecule is responsible for causing a certain disease and needed to be given (meaning identified and isolated before). As an outcome of the discovery phase about 250 lead candidates are taken into the pre-clinical phase for lab and animal testing. Out of the 250 lead candidates about five drug candidates enter the clinical phase for testing with humans, which is subdivided into three sub-phases (I, IIa & IIb, III). With a probability of 80% these five drug candidates pass the first clinical testing phase. 30% of these 80% pass through the second phase and only 30% of these 30% the third phase (Giovanetti and Morrison 2001).

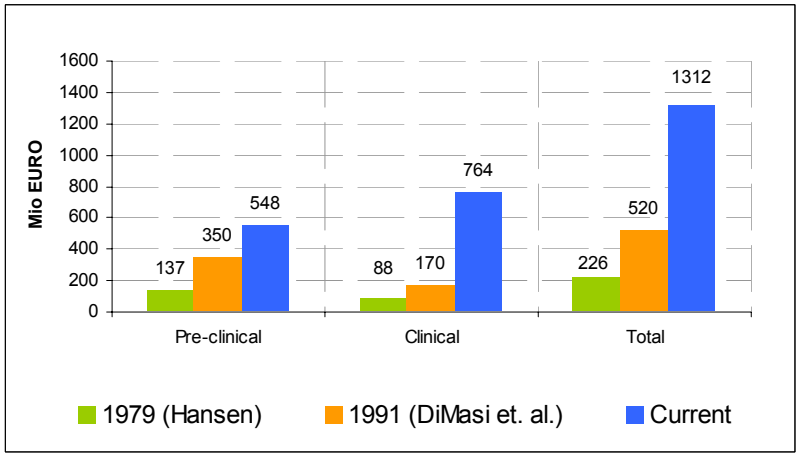


Figure 45: Drug development costs (1979, 1991, and 2002)[195]

[194] Adopted from: (Crocker 2003)

Developing a new drug can take up to 16 years with associated costs up to 1,312 M€. The drug development process has become more sophisticated during recent years and it has been more difficult to develop drugs for more sophisticated diseases (e.g. viral diseases as AIDS). In addition, regulations became tighter, so that costs increased steadily by 250% (580%) compared to 1991 (1979) as shown in Figure 45 (DiMasi et al. 2003).

[195] Capitalizing costs to the point of marketing approval at a real discount rate of 11% excluding approval cost. Adopted from: (DiMasi et al. 2003)

Appendix E - Description of case sources and interview partners

This section lists the case sources for all six cases including information on when the interviews were conducted, and gives background information of the interview partners. The companies are listed in alphabetical order.

Biora AB, Malmö, Sweden

a) Case Sources:

The case was prepared based on a four hour interview with Stina Gestrelius, the Director R&D at the company's headquarters in Malmö, Sweden on October 3rd, 2003. Additional information was obtained from secondary literature, mainly the company's annual reports from 1997 to 2002.

b) Interview partner(s):

1. Director, R&D and Regulatory Affairs: Stina Gestrelius, Biora's Director, R&D and Regulatory Affairs until December 2003. Stina Gestrelius left Biora as a consequence from the merger with Straumann Pharmaceutics, but is still working as a consultant with Biora. Since 2004, Biora is a business division of Straumann Pharmaceutics. Stina joined the company in 1987 from the pharmaceutical company Ferring, where she had worked as Director of peptide synthesis development. Ferring worked with Biora for half a year on a collaborative R&D project. When the project was about to finish Stina went over to Biora pulling over additional five employees as well as one external including researchers, production personnel, and an administrative assistant. They are still working with Biora. Stina holds a PhD in biochemistry, and worked as Director of enzyme immobilization/ R&D for Novo Nordisk (Copenhagen) as well as in an R&D position at Astra (Lund) previous to Ferring. From 1989 to 1997, she was Vice President – Research and Development and Regulatory Affairs. Stina was also responsible for manufacturing until 1998. Stina is also a member of the Boards of the Medicon Valley Academy and the Medical Faculty of the University of Lund.

Evotec OAI AG, Hamburg, Germany

a) Case Sources:

This case study was designed as an outcome of a four hours interview session with Evotec's CSO, one IP manager as well as with the Vice President Core Technologies of Evotec Technologies, a subsidiary of Evotec OAI on November 18th, 2003. In addition the case is based on the company's annual reports (1999-2002) as well as the company's IPO brochure.

b) Interview partners:

1. CSO: Dr. Timm-H. Jessen holds a Dr. degree in biochemistry from the University of Munich, Germany. He worked with Hoechst (today Aventis) and studied for one year at the Harvard Medical School genetical methods for target identification and validation. He started with Evotec in November 1997.

2. IP manager: Dr. Frank Sauer joint Evotec in April 2000 and has its background in chemistry.

3. VP Core Technologies of Evotec Technologies: Dr. Jürgen Müller holds a Dr. degree in physics.

MediGene AG, München

a) Case Sources:

This case report is based on two interviews carried out with the company's Assistant Director IP (3.5-hour interview) and the company's CEO and co-founder (45-min interview) on November 3rd, 2003.

The data collected during the interviews was complemented with information from the company's annual reports 2000 to 2002 as well as by press-releases from the company's website from November 17th, 1997, to September 15th, 2003.

b) Interview partners:

1. Assistant Director IP: Dr. Rehfueß holds a PhD in Molecular Biology from the Ludwig-Maximilians-University of Munich. After finishing his PhD, he started di rectly working with MediGene.

2. CEO and co-founder: Dr. Heinrich holds a PhD in biochemistry from the Ludwig-Maximilians-University of Munich. Afterwards he worked as a scientist at Harvard University. Prior to his work at MediGene he was in charge of developing a biotech division at Wacker Chemie, a subsidiary of former Hoechst AG, where he gained considerable management experience. He filed several patents by himself and is president of EBE (Emerging Biopharmaceuticals Enterprises), Brussels, co-founder and vice-chairman of the VBU (Association of German Biotechnology Corporations), and a board member of the DECHEMA (Society for Chemical Engineering and Biotechnology).

Mophosys AG, Munich, Germany

a) Case Sources:

This case report is based on a four hour interview session with the Morphosys's Senior Director Intellectual Property on November 4th, 2003 at the company's headquarters in Martinsried close to Munich, Germany. As additional sources the company's annual reports from 1999 to 2002 were used.

b) Interview partners:

1. Senior Director Intellectual Property: Bernhard Virnekäs holds a Dr. degree in chemistry from the Ludwig-Maximilians-University of Munich, Germany. He joined MorphoSys in end 1992 working as a scientist until his project was finished in 1995. In the following months he joined an annual seminar from the patent firm 'Vossius & Partner'. In early 1996, he became the company's Manager of Intellectual Property and received training as a European patent attorney, what he became in end of 1998.

Nobel Biocare AB, Göteborg, Sweden

a) Case Sources:

This case study was prepared on a four hour interview session simultaneously with the company's VP, General Counsel, the Head of R&D and the head of the patent department on October 13th, 2003 at the company's headquarters in Göteborg, Sweden. Additionally, the case study is partly based on secondary literature, mainly the company's annual reports from 1998 to 2002 as well as on (Rickne 2000).

b) Interview partners:

1. VP, General Counsel: Michaela Ahlberg joint Nobel Biocare as Head of Legal Affairs in April 2002. Prior, she worked at a similar position in a joint venture company between Ericsson and HP. She holds a master of law from the University of Lund, Sweden, and has previous work experience with one of the largest law firms in Sweden.

2. Head of R&D: Jeppe Magnusson joined Nobel Biocare in 2000 as Head of R&D. Previously he worked with Nobel Industries, Union Carbide, Mölnlycke and SCA Hygien Products. He holds a PhD in Chemical Reaction Engineering from CTH, Göteborg and gained some management experience during his previous work experience.

3. Head of the patent department: Gunnar Olsson studied electrical engineering at CTH and worked four years with the PRV, where he received training as a patent engineer. Later he moved to the patent department of Bofors and founded the patent department at Nobel Biocare in 1993.

Pyrosequencing AB, Upsalla, Sweden

a) Case Sources:

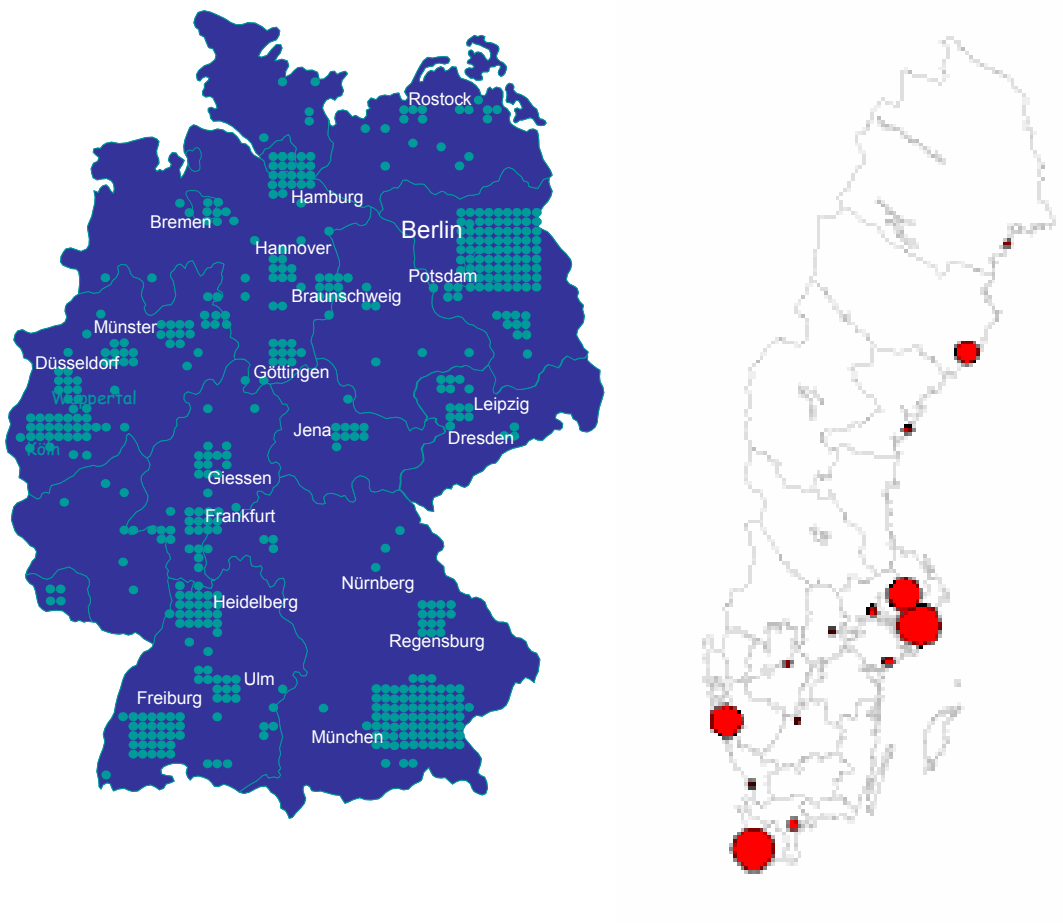
This case is based on a four-hour interview with the Director IP of Pyrosequencing AB. The interview was carried out on October 16th, 2003, at the company's headquarters in Upsalla, Sweden. Additionally, the company's annual reports from 2000

to 2002 were used as a secondary source, as well as (Savage 1999), the company's IPO brochure, several press releases, and internal documents.

b) Interview partners:

1. Director IP: Per Johan Ulfendahl holds a PhD in Medical Genetics and worked 12 years with Amersham Biosciences prior to his job at Pyrosequencing. Ten years of his work with Amersham Per Johan worked for the R&D department and filed several patents himself. He started explicitly working with patents about 1992.

Appendix F – Biotech clusters in Germany and Sweden



Germany (left): number of companies in 2001. Not each dot shows one company, but the size is proportional to the number of companies.

Source: Secretary for biotechnology information, 08/2001, http://www.i-s-b.org/firmen/graphics.ppt

Sweden (right): number of companies in 1999. The sizes of the circles are proportional to the number of employees/companies. Only micro-, and small-sized companies (<200 employees) are included.

Source: Sandström, A. and Verket för innovationssystem (2001). The Swedish biotechnology innovation system. Stockholm, VINNOVA.

Appendix G - Deutsche Zusammenfassung

Diese Arbeit untersucht die Entwicklung des Management von Geistigem Eigentum (sog. Intellectual Property Management) in bereits etablierten Deutschen und Schwedischen Biotechnologie Unternehmen, sog. Dedicated Biotechnology Firms (DBFs). Das übergeordnete Ziel war es die historische Entwicklung des IP Managements in sorgfältig ausgewählten Deutschen und Schwedischen Biotechnologie Unternehmen zu analysieren und zu beschreiben, während Kriterien für die Beurteilung der IP Management Leistung identifiziert werden sollten. Um dieses Ziel zu erreichen wurden drei Forschungsfragen definiert: (i) Wie können verschiedene IP Management Phasen während der Entwicklung eines Unternehmens charakterisiert werden, (ii) Welche Rolle spielen verschiedene Typen von Intellectual Property Rights (IPRs) in diesen Phasen und (iii) wie kann die Leistung des IP Managements bzw. der IP Abteilung in einem Unternehmen gemessen werden?

Um diese Forschungsfragen zu beantworten wurden im Rahmen dieser Studie sechs Fallstudien (jeweils drei in beiden Ländern) durchgeführt. Die daran beteiligten Unternehmen sollten mindestens „reich“ an IP Management Erfahrung sein und wurden anhand eines zweistufigen Auswahlprozesses identifiziert. Für beide Stufen wurden basierend auf Interviews mit Personen aus Wirtschaft und Wissenschaft Auswahlkriterien definiert (im ersten Schritt sechs und im zweiten Schritt sieben). Ergänzt um eine eigene Literaturrecherche sowie drei Pilotstudien wurden diese Kriterien validiert. Es konnten sechs Unternehmen für die Fallstudien gewonnen werden, die im Oktober und November in insgesamt 12 persönlichen Interviews untersucht wurden. Die Interviewpartner waren Personen, die mindestens seit drei Jahre für die entsprechende Firma tätig sind und Schlüsselpositionen für das IP Management besetzen (z.B. Geschäftsführen, Patent Anwalt, IP Direktor, Forschungsvorstand etc.).

Um die oben angeführten Fragestellungen zufrieden stellend beantworten zu können wurde als Forschungstool das Konzept der so genannten „Technology Base“ verwendet. Da das Ziel dieser Studie explorativer und deskriptiver Natur war, lieferte die Durchführung der Fallstudien keine statistisch signifikanten Ergebnisse. Dennoch konnten die Forschungsfragen zufrieden stellend beantwortet werden.

In allen untersuchten Unternehmen wurden zwei bis vier IP Management Phasen identifiziert, obwohl die Phasen signifikant in ihrer Länge variierten. Sechs Kriterien konnten gefunden werden, die eine IP Management Phase beschreiben: Kapazität,

Kompetenz, Verantwortlichkeiten, Verwendete Tools, Bewusstsein des Top Managements sowie das finanzielles Budget der IP Abteilung.

In diesem Zusammenhang konnte die Transition zu einer fortgeschrittenen IP Management Stufe beobachtet werden. Grundsätzlich waren die dazu führenden Ereignisse entweder einzelne kritische Ereignisse oder viele aufeinander folgende Ereignisse von inkrementaler Bedeutung, von externer oder interner Natur. Weiterhin wurden unterschiedlich Rollen von verschiedenen IPRs in verschiedenen IP Management Phasen identifiziert. Ein eindeutiger Trend konnte hierbei beobachtet werden. Das IP Management veränderte sich von einem passiven Prozess, der sich hauptsächlich mit Prozesspatenten beschäftigt und diese hauptsächlich als rechtliche Schutzrechte begreift hin zu einem aktiven Management von einem so genannten IP Mix (inklusive Marken, Copyrights, Database Rights, Produktpatenten etc.). Während dieses Prozesses behalten IPRs zwar ihren rechtlichen Charakter, welchem aber mehr und mehr wirtschaftliche Aspekte zu Teil werden.

Im Rahmen dieser Studie stellte sich die dritte Forschungsfrage als die aufwendigste und komplexeste dar. Auch wenn es nicht das Ziel war ein konkretes Bewertungssystem für die IP Management Leistung zu entwerfen, so konnten doch immerhin drei dabei auftretende Probleme herausgearbeitet werden. Im Rahmen dieser Studie wurde gezeigt, dass ein einziges Kriterium für dessen Bewertung nicht ausreichen wird und vielmehr mehrere aufeinander abgestimmte Kriterien dazu herangezogen werden sollten. Als mögliche Kriterien schlägt diese Studie vor die sechs Kriterien für die Beschreibung einer IP Management Phase um die Zusammensetzung bzw. Veränderung der Technology Base eines Unternehmens zu ergänzen. Für diese Kriterien müssen im Weiteren Messgrößen definiert und in zwei bis vier Kenngrößen konsolidieren werden.

Weiterer Forschungsbedarf aufbauend auf die Arbeit bezieht sich überwiegend auf das Verständnis von IP Management. Hierbei handelt es sich um einen evolutionären Prozess. Dieser Prozess wird kontinuierlich weiterentwickelt aufgrund eintretender Ereignisse. Die nähere Beschreibung der IP Management Phasen und die unterschiedlichen Rollen von verschiedenen IPRs in den Stufen müssen sollten durch weiterführende Studien näher klassifiziert werden.

Appendix H - Deutsche Gliederung

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