

Towards strategic Intellectual Property Management – Events during the Development. Evidence from Biotech SMEs.

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Abstract

In the emergence of a pro-patent and intellectual capital era the management of Intellectual Property (IP) is currently undergoing major changes. IP management systems are becoming increasingly complex and strategic in handling an integrated portfolio of IPRs and intellectual assets rather than just “administrating” patents, trademarks and copyrights as single, independent assets in an operational management way.

Our paper analyses the development of IP management in a sample of German and Swedish Dedicated Biotechnology Firms (DBFs) with the main focus on the following two research questions: (1) Which events trigger the development towards a more strategically oriented IP management? (2) Can distinctive stages be identified and characterised in the development of IP management systems? The empirical part of our study draws primarily on 12 personal interviews with leading managers from six larger German and Swedish dedicated biotechnology firms (DBFs) with ‘rich experience’ in IP management that were founded between 1984 and 1997.

During our study we found that shifts towards an advanced IP management were triggered by single crucial events (e.g. litigation) or an accumulated sum of incremental events, of either internal or external nature. Up to four different stages of IP management were found throughout the development of the case companies, while six criteria were identified that can be applied to characterize an IP management stage.

Keywords: Intellectual Property Management; Dedicated Biotechnology Firm; Germany; Sweden

Introduction - Recent developments towards IP dependent businesses

Since the 1980s there a significant shift in the business and economic environment of many industries has occurred. Today, as Teece [48] notes “traditional sources of competitive advantage have been stripped away.” Accompanying this or in some cases anticipating it many ‘new’ theoretical concepts have emerged, “knowledge economy” (e.g. information economy, new economy) [31], and “knowledge strategy” [24] or “knowledge creating company” [4, 33]. Intellectual capitalisation at macro level and “IP strategy” at micro level, often concepts that extend the traditional technology management concepts.

One major reason behind this development has been the emergence of new generic technologies (e.g. electronics, ICT, and biotechnology), which resulted in the foundation of many new technology based firms (NTBF) as well as in an increasing pace of technological change [14, 21] and cumulation of intellectual capital.

Accompanying this shift a ‘pro-patent era’ emerged with a strengthening of the intellectual property regime originating in the U.S.A. In this new era, for a growing number of companies and industries IP is coming to the ‘forefront’ of competitive concerns with intensified international competition, global activism of IPRs from industrialized countries, increased international patenting, almost worldwide strengthening of the patent system, and, finally, the fact that in many companies the value of IP and intellectual capital increasingly surpassed the value of physical capital [15] [48].

Owing to this shift in economic environments, accelerated by further emergence of new technologies, the management of IP on the whole has changed and recognition in industry has risen that there is a need to integrate IP into strategic management. Companies have started to manage their knowledge and IP assets more carefully and “patenting and licensing have become more strategically managed” [14]. A succinct conclusion of all these developments was given by Grindley and Teece [21] when they stated: “the most significant emerging business

development [...] in the last decade [...] has] been the proactive management of intellectual capital.”

Although intellectual capital has gained major importance for many companies in several industries, the importance of IP has been recognized mainly in particular industries: pharmaceutical, biotechnology, electronics, semi-conductors, chemicals, and ITC [1, 21, 28]. But its these generic technologies that are often seen as the “key technologies for the next millennium” [49] and patents, trademarks, and IPRs “have become a key element of competition” for them [21].

Already in the early 1980s, Mansfield et.al. [29] showed that “practically none of the drug innovations would have been introduced without patent protection” and “patents are regarded as more important in drugs than elsewhere”. Other studies, e.g. Scherer [40], have proved this importance.

Today, many companies understand IP management as part of their business strategy and started to generate revenues through out-licensing¹, enable freedom-to-operate by cross-licensing [48] and use strategic patents as a ‘flexible entry barrier’ for potential competitors or partners [36, 44] and as a result, IP became critical to companies’ competitive advantage [2]. Today’s companies must either invest in R&D to develop their own technologies or pay license fees for accessing technologies, respectively patent portfolios of others [21].

Purpose

IP management and its strategies and organisational structure have been analysed yet mainly in large multi-technology corporations [14, 33]. One of the very few early studies analysing the development of IP or patent organisations in the UK was undertaken by Taylor and

¹ IBM gained licensing revenues, which accounted to about 20% of their total profits in 1999 [27]

Silberston [46], describing four developmental stages of patent organizations. Their typology of stages was then elaborated upon and extended for large Japanese corporations in [14].

The purpose of this paper is to explore and describe the development of IP management in selected large German and Swedish companies operating in the biotech sector. Many different models have been developed in the past which claim that throughout a company's history its organization evolves through different stages see e.g. [17] for more recent ones see Sae-mundsson, R. J. [39], Churchill, N. C. and V. L. Lewis [3], and Rothwell, R. [38].

Method

This study was undertaken in the second half of 2003 and was designed to focus on two main research questions: (1) Which type of events (radical/incremental, internal/external) trigger the development towards strategic IP management? (2) Can distinctive stages be identified in the development of IP management and if yes, how are they characterised?

The development of IP management from six established DBFs with 80 to 500 employees in Germany and Sweden was analyzed conducting case analysis applying the 'technology base' concept as our key research tool.² Therefore, we assumed a relation between the development of the company's IP management as a consequence of the growing complexity of a company's technology base over time.

The methodological approach was mainly exploratory and descriptive. Leaving efforts to explain, predict or prescribe any aspects merely related to the topics to further research, possibly using a broader survey approach[16]. Further, no cross country comparison was the aim of this study. We have rather chosen two countries to mainly broaden the explorative nature.

² For further information regarding this concept see [18].

In addition, this paper is limited to the description of developments in biotechnology. Other industries (e.g. nanotechnology, ICT, electronics, etc.) are not compared although they might be similar in several characteristics. In particular, this paper focuses on pharmaceutical biotechnology³ excluding other areas of application (e.g. industrial, maritime, and agricultural usage) as well as traditional biotechnology and medical fields.

The exploratory nature of the research questions limited the choice of possible research strategies, so case studies were most appropriate [16]. Due to the explorative nature, we decided to conduct multiple case studies - instead of trying to identify one single unique case - thereby covering a larger set of situations. Further, different perspectives through multiple interviews in each case is necessary to achieve some reasonable reliability and validity [50] [12].

Biotechnology companies in Germany, the UK, France, and Sweden represent almost 73% of all European biotech companies. In 2003, out of these four countries Germany ranked first concerning the number of biotechnology companies (Sweden was number four), while Sweden had the highest number of biotech companies as well as bio-technology patents per capita [1].

In order to get significant results, appropriate case study objects needed to be identified and chosen. Two sets of sampling criteria were defined to identify ‘rich-experience’ companies⁴ concerning IP management in the biotech sector in a two step process⁵.

³ Often different terms are used e.g. pharma, health care biotechnology, etc. This paper uses the term biotechnology synonymously.

⁴ ‘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.A.

⁵ Similar to a two-step sequential process, wherein the first step determined the sampling frame [37].

In order to define sampling criteria a literature review was complemented by interviews held with industry experts from the Swedish Governmental Agency for Innovation Systems (VINNOVA), AWA Patent (one of Europe's leading specialists in IP), the Ernst&Young life science group, the Swedish, German and European Patent Offices (PRV, DPMA, EPO) and representatives from several Swedish and German industry associations (e.g. VBU, BioTop⁶, BIOSWEDEN, etc.) as well as with researchers in the fields of biotechnology and management from three different universities.

As an outcome of this process, six 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 worldwide⁷, headquarters based in Germany or Sweden, operating in the pharmaceutical biotechnology industry, product based company or technology provider or both, feasibility to reach, and founded before 1998. These criteria allowed identifying 16 companies in Sweden and 25 in Germany.

In a second stage, seven criteria were applied to these 41 companies. These criteria were defined as directly linked to the company's IP management experience. Companies did not have to fulfil all of these criteria, but at least two of them: a large number of patents granted or pending at the EPO, DPMA, or PRV, by strong licensing activity (reported in industry reports, public press, or by industry experts), alliances with BigPharma (reported in industry reports or public press), companies are known as 'success stories', presence of an IP strategy, sophisticated/strong IP department. Further, recommendations of industry experts interviewed (venture capitalists, patent attorneys, science park and incubator managers) or by researchers from biotechnology or IP related fields were taken into account. As a result of the second

⁶ A biotech association for the region Berlin-Brandenburg in Germany

⁷ However, it appeared that one very valuable case company had significantly more than 500 employees. This company was included anyway as the company was recommended by several industry experts as having rich experience in IP management and valuable interviewees were available.

stage evaluation, eleven possible case study objects (six in Sweden and five in Germany) could be identified.⁸

For the first sampling step of online and offline industry reports were investigated as well as personal suggestions of industry experts and researchers were taken into account. For the ‘second step’ the companies’ websites and at least the two latest annual reports of almost all 41 companies, which fulfilled the first set of criteria, were investigated. If no satisfactory information could be obtained, the companies were contacted personally with detailed requests.

Having identified possible case study objects, a semi-structured interview guide was designed, while these companies were contacted. To validate and improve the interview guide three pilot studies were carried out in mid September 2003 with (1) the CEO of a small company (16 employees) operating in the drug development business, (2) a patent attorney of a larger biopharmaceutical company (99 employees), and (3) with the responsible person for technology trade of a fairly small university start-up (around ten employees).

The interviews with diverse pilot objects proved to be very helpful, since all interviews delivered insight into different phases of a company’s ‘life cycle’ and thereby illustrated different needs, requirements, and challenges of IP management. As a result of these pilot interviews the draft for the interview guideline was modified. It proved to be very robust throughout all six case studies.

Parallel to the pilot studies, the ‘selected’ case companies were contacted by phone throughout the summer 2003. Since the number of possible companies was quite small, there was a risk of finding a too small number of companies willing to participate in our study,

⁸ The particular industry itself in which the companies were operating (e.g. diagnostics, therapeutics, bioinformatics), was not a sampling criteria, as the approach was to identify biotech companies with expertise in IP management. Finally, it turned out 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.

wherefore all phone-requests were thoroughly prepared. Finally, three Swedish and three German companies agreed to participate in our study.

Before visiting the companies the case studies were prepared by studying secondary literature (incl. at least last three annual reports, industry reports, PhD and master thesis). Additionally, the companies were asked to provide extra material on particular IP issues in advance to the interview sessions (although only three companies complied).

From end of September to mid November 12, semi-structured interviews (26.5 hours in total) were conducted. Each case study is based on a total of 4-5 hour's interview time with one to three interviews, with interviewees who had spent at least three years (except one interview partner) within the company, and held key-positions, e.g. founder, CEO, head of patent department, or head of R&D.

	Swedish			German		
	BO	NB	PS	EO	MG	MS
City of headquarters	Malmö	Göteborg	Upsalla	Hamburg	Munich	Munich
Age of company end in 2003 (years)	15	19	6	10	9	11
degree of biotechnology *	low/medium	low	medium	medium/high	high	high
Business model **	product development/technology utilization	product development/technology utilization	Service & Product development/technology development & utilization	Service & Product development/technology development & utilization	product development/technology utilization	product development/technology utilization
# of employees ***	78	1330	145	635	185	110
employees in IP department	0,5+0,5	1,5	1	4,5	2,5	3
# of patent family applications ***	~ 10	110	35	179	72	19
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 (6)	Assistant Director IP (5); CEO and co-founder (9)	Senior Director Intellectual Property (10)
Total length of interviews	4.5 hours	4.5 hours	4 hours	5 hours	4.25 hours	4 hours

* pure drug development company=high, pure technology provider=low

** according to definition of business models in biotechnology industries from Crocker (2003) that differentiates

*** as of 31.12.2002

among the technology (utilization or development) and economic (product, service, both) dimension

^ counted including 2003

Table 1: Overview of case studies

The interviews were constructed along the development of the companies' technology base since their foundation until today.

Before the case interviews were analyzed, case reports were transcribed from the interview protocols that were sent to the companies for review and corrections. All but one company complied with this procedure.

The case reports were analysed in a two-step process; first separately and then in a 'second order analysis' comparing the results from each case on an aggregated basis. However, due to the exploratory nature of this paper 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. The analysis of the cases is thus mainly of qualitative nature, and does not allow for statistical analysis.

IP management – Introduction and review

In recent years, the number of patent applications has increased enormously, as reported by almost all large 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 [20, 34].

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 structures, deploy a patent or IP culture, and exploit value from patents, IP, and in general their knowledge assets e.g. knowledge-worker [10], knowledge society, and knowledge-based economy [35], knowledge assets [47].

To comply with these broader developments companies of all sizes have started to establish organisational structures to actively manage their IP instead of just 'administrating' pat-

ents and trademarks. Some studies even indicate that quite often IP is even more crucial in smaller firms than in larger ones [29].

Managing IP (including registered, unregistered IPRs, know-how, technologies, licensing, etc.) in an integrated manner in the short-, mid-, and long-term has become the primary task and challenge of the IP management in many companies. Besides dealing only with IPRs developed in-house the IP management is further concerned with the company's technology management, including external technology acquisition and exploitation. Depending on the individual company situation, IP management includes a quite extensive set of tasks; just to name a few important ones to illustrate their breadth: obtaining patent protection and patent (fee) administration, developing a patent- respectively IP-strategy, in- and out-licensing activities, technical due diligence during M&As, patent exploitation and enforcement, litigation management, etc.

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" [22]. 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 IP management competence. As reported and suggested by many authors (e.g. Davis and Harrison [9], Sullivan [44], Edvinsson and Sullivan [11]) companies are likely to move towards a sophisticated and even strategic IP management.

However, for different companies due to several reasons e.g. a different sequence of different events - various 'paths' of IP management developments - are possible. How sophisticated IP management has developed and why and how it has developed to this status quo in our case companies is further subject of this paper with particular focus on DBFs. The following paragraph tries to give a short, introductory overview of two models that try to describe the development of IP, respectively patent management.

Davis, J. L. and S. S. Harrison [9] introduced the concept of the “value hierarchy” and defined five stages until a company has reached a sophisticated IP management (defensive, cost control, profit centre, integrated, visionary). 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.

Entering the ‘Profit Centre’ 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 [9] 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 [9].

In contrast to this model Taylor, C. T. and A. Silberston [46] 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 our study. However, characterizing IP management stages according to the number of employees seems to be obviously a possible criterion.

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 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 [46]. These four stages have been expanded through findings during studies of 25 large Japanese companies from the chemical, electrical and mechanical engineering industries by Granstrand, O. [14] with two additional stages. 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.

Towards strategic IP management

Although, recent studies by e.g. Sullivan [44] 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 advantage⁹, 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 [13, 43]. 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 venture capital is limited. Licensing offers an important tool for generating revenues through royalty incomes since royalty incomes contribute directly to the company’s bottom line profits [48].

Handling IP strategically leads an increasing number of companies to shift from a defensive towards an offensive IP management, as Granstrand, O. [14], Sullivan [44], and several other authors indicate. Cohen, et al. [7] define 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.

In order to accomplish a strategic IP management companies apply different tools (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 develop-

⁹ In a survey conducted by Schwieger, A. [42] it appeared that almost 94% of the investigated companies “use their IP only defensively”.

ing a patent or IP culture¹⁰ - as many (large) Japanese companies did in the past as surveyed by Granstrand, O. [14] - in order to support their ‘total’ IP management with the aims of cost control, pursuit of profits, the integration of IP into corporate ‘fabric’, and the creation of a lasting vision for IP [9].

Dedicated biotechnology firms – Importance of IP management

SMEs, which are solely founded to “explicitly explore and develop new biotechnology products and services” [32], are frequently labelled as Core Biotech Companies [41], Entrepreneurial Life Science Companies (ELISCO) [8], or Dedicated Biotechnology Firms (DBF) [32]. All definitions are quite similar and in this paper the term ‘Dedicated Biotechnology Firm’ is used, as applied by in several studies e.g. Allansdottir, Bonaccorsi et al. [1], McKelvey [30]. Typical DBFs are founded by scientists as spin-offs from universities as technology-based firms in order to further develop and commercialise upon proprietary technologies.

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) [21, 28, 32] or even service industries [25]. Patents were judged “essential to the development of commercially important inventions” in 65% of pharmaceutical inventions. This rate was the highest of 12 industries [19]. Further, industry reports for biotechnology by Ernsy&Young stress the importance of IP management in the life science industries that emerged during the 1980s and 1990s and in particular for SMEs. In the 2003 year global life science report, IP matters are top ranking on

¹⁰ 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 [14].

page one in a list of key-factors to enable biotech growth: “patent laws that encourage and reward innovation” [45].

Further, analyzing the market value of DBFs Nesta and Saviotti [32] showed that it 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. As main components of companies’ intangible capital the authors and other studies found “R&D stocks, patent stocks and advertising” [5, 23, 32].

As IP is strongly linked to all of these three components, 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 [49].

Additionally, there is an enormous importance of technology trade throughout all biotechnology related sectors as many DBFs 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. 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 [6, 26].

Results

1. Events in the development of IP management

In all case companies the companies' IP management had evolved and became more advanced over time. Events that caused the companies to adjust their IP management are shown in Table 2. In general we found that events which triggered the development of the IP management were of internal as well as of external nature throughout all case studies.

Table 2: Events causing companies to adjust their IP management

Case companies	BO	Swedish NB	PS	EO	German MG	MS
events for 1st shift	lack of financial resources	foundation of patent department, due to critical workload	change in business strategy to diversify	critical workload	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 biotech company	%	%	%

Looking more detailed on the list of events that led to changes in a company's IP management, we found that some events caused companies to make a decision to establish an IP management and some events triggered a further development of the company's IP management system.

Founding an internal IP department rather than outsourcing patent services is quite a step especially for newly founded, young enterprises e.g. DBFs, requiring the top management to make available some of the limited resources. We found two different events that initiated an IP management in our case companies: litigation and critical workload.

In two case companies litigation - as a rather critical event - caught top managements attention regarding the necessity to build up in-house IP competence and led to the foundation of an IP department respectively a patent department.

In one company IP workload became critical from a certain point - although this point might be 'flabby' and prolongable – and led to the foundation of an IP department. When a company produced 'too' many ideas and inventions to take care of, sooner or later it needs to hire an employee to cope with this IP work although extensive outsourcing could delay this decision. Even small companies realized that hiring a full time employee becomes cheaper than outsourcing all IP work to external patent agents. However, with this merely 'passive' event the in-house IP competence of this company and the IP awareness of the top management increased only incrementally focussing primarily only on operational patent work. This suggests that insourcing may be necessary but not sufficient for linking IP strategies to business strategies.

After companies had installed a basis of strategic IP management for certain reasons, the IP management in all our case companies developed further. The following six events could be identified during the case studies¹¹ leading companies to make changes concerning their IP management: business diversification, litigation, new staff, listing at stock exchange (IPO), conscious decision, and merger. 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.

One critical event to cause a development towards an strategic IP management appeared in two cases 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-

¹¹ 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.

knowledge¹² became important e.g. when signing collaborative licensing contracts. When making this strategic decision both companies realized the need for licensing competences by either founding an independent licensing department, expanding their existing department, or assigning the tasks to the patent department.

As we have argued above, a critical event to install an IP management is the involvement into litigation. However, if an IP management is already installed, litigation can as well serve as an event to enter a more advanced IP management stage. The two case companies that were involved in litigation, 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 which they then started to establish. The second company was running already a small IP department and sued another company. This company realized that it better avoids being involved in a litigation in the future, therefore strengthening their IP competence in order to either carefully ensure freedom-to-operate, to proactively protect future and existing businesses or enforce their IP.

Another critical event that ‘cooked’ up the IP management of one case company took place 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 since their founders were used to the importance of IPRs in biotechnology already from the beginning.

Finally, in one case the company was trapped in 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.

¹² Foreground knowledge means the technology competence brought in by companies in collaborations and JVs. Background knowledge is the technological competences, which are the outcome of collaborations and JVs.

The availability of financial resources is often seen to be an enabling factor for a company's growth. Especially for DBFs or SMEs in general financial constraints often hinder their growth. But only in one of our 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 an advanced 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 management.

When two companies merged both partners needed 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.

2. Stages in the development of IP management

During our research we found indications that the development of a company's IP management system can be split up into distinctive stages. Comparing these findings to the two major studies undertaken on IP management development before (see Taylor and Silberston [46] and Davis and Harrison [9]) we found that these two taxonomies introduced are not ex-

tensive enough to fully describe an IP management stage, although they are basically included in our findings.

During our study, we found that an IP management stage can be characterised quite well by relatively constant capacity, competences and responsibilities of the IP department. As well the tools applied by the IP department are more or less alike during one stage; as well the top management awareness and the financial commitments for IP management are almost constant. Thus we found that the following six determinants can be applied to describe an IP management stage quite exactly: capacity, competence, responsibilities, applied tools, top management awareness, and financial commitments. However, besides these six determinants other determinants might exist.

Thus, a shift towards an advanced IP management stage can be characterised by a major variation in one or more of these six determinants through a single ‘crucial’ event or an accumulated sum of events that achieve a particular level of impact for this shift to happen.

Analysing the six cases on an aggregated level, based on these six determinants we found that each case company went through at least two stages of IP management until November 2003. One case company already finished its third stage and was about to move towards the fourth. Three cases had three stages and two cases can be characterised having gone through two stages.

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 companies¹³. The other companies still vary in the number of employees in the IP department.

Although stages could be identified in the histories of all case companies we found that the length of the stages differed across the case companies and that the role of IPRs in the stages changed during the path of the IP management.

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 (compared to five years' length of first stage) and in the third case after seven years (nine years). Based on our research it seems to be difficult to conclude a general length of the different stages, so that further research is needed.

Besides the length of the IP management stages, the roles of certain IPRs varied across these stages in the different case companies (see table 3). 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.

¹³ However, one case company had five employees working in its IP department, but reduced the staff down to three.

Table 3: Number of stages and roles of IPRs throughout stages

	Swedish			German		
	BO	NB	PS	EO	MG	MS
# of IP management stages	3 (4*/5/...)	3 (9/7/...)	3,5 (3.5/1/1.5/...)	2 (7/...)	2 (4/...)	3 (5/4/...)
Roles of IPRs in 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,
Roles of IPRs in 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
Roles of IPRs in 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
Roles of IPRs in 4th stage	%	%	two patent portfolios merged, integrated IP approach	%	%	%

* years of stage duration

Investigating the first IP management stage from each case study it appeared that all cases companies handled 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 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 products. 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 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 company'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 had run into litigation during this second stage.

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. 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. [14].

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 faced a need to diversify in several biotechnology fields to stay competitive in the future. The management was aware of the possibilities a sophisticated IP management offers.

When one case company announced to merge during the end of our study, it was forced to integrate two different patent portfolios, wherefore the IP awareness increased and the newly formed company was 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 had 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 implement a focused management of IPRs as stated by some interviewees.

Conclusions

During the study the historic development of IP management in six case companies was analyzed regarding (1) events that triggered the development of the companies' IP management and (2) stages in this development. Our key findings can be summarized as follows:

A development towards an advanced IP management is 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. A general pattern throughout our study could not be identified or proved.

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

phenomenon 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 six criteria: capacity, competence, responsibilities, applied tools, top management awareness, and financial commitments of the IP department.

We found further that throughout the development of the IP management 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.

Managerial Implications and further research

The main important managerial implications from this study relate to the managerial aspect of the development process of IP management. Especially in small firms, 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. One example might be the focus on patenting early on in the product development process in contrast to the increasing importance of trademarks and licensing when the technology or product/service gets close to the market launch. Our study showed that top management should be prepared to make adjustments in a company's IP management when certain events appear. Events that we found during this

study were 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.

From a research point of view, a more quantitative analysis of the results is needed to validate our findings and especially the criteria to distinguish the IP management stages. As this paper is of 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. Upcoming research studies would have to take into account companies' competitive environment. As our 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.

Finally, one might highlight that all findings derived from this study strengthen recent developments found in literature that IP management became increasingly important, while the study showed no evidence that this increase will slow down in the short term.

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