CHAPTER 5

SUMMARY, CONCLUSIONS AND SUGGESTIONS

This final chapter summarizes the previous ones and concludes this study in light of the research questions. Since this research product is of a theoretical nature, these conclusions refer to the academic discussions as they have been highlighted before. On the basis of these conclusions, further research is suggested in order to build on the management model as described and proposed. This study hopefully contributes to the development of theory on IP management and will hopefully provide a basis for discussion about improved practices in this field.

5.1 SUMMARY

This study focused on IP management in the context of pharmaceutical innovation. The pharmaceutical industry was chosen because, in an early stage of the project, several indications were found that intellectual property is of particular concern to management in this industry. The theoretical contribution of this study lies in focusing on the creation of technical knowledge starting from the problem of attaining exclusive rights to it. How IP management has been conceptualized and modeled is explained in the previous chapters which are summarized in this section.

Chapter 1 answers the question why this scholarly attention should be of importance to both public and private research organizations. First of all, there is a growing interest in knowledge management and competence theory, both within the management practice and the academic world of business studies. More in particular, increasing average costs per market introduction cause pressure on the ability to exploit research results, making the patent a 'conditio-sine-qua-non' in pharmaceutical product competition. Therefore, a managerial perspective and its concerns about the business environment, the technological regime, corporate strategy, and the patent's underlying knowledge have been subject of theorization. In such a strategic context, knowledge and competence are the innovative pharmaceutical company's most important resources which are still underconceptualized when taking the proprietary conditions made to pharmaceutical

R&D into account. Secondly, innovation has become more and more the result of interorganizational research activity, making the appropriability of such collaborate effort a managerial issue. However, despite the − often decisive − influence of proprietary conditions on decision-making, hardly any attention has been paid to them in academic studies on business and management. The review of previous studies has been based on three initial elements to be identified in the literature: the pharmaceutical industry, intellectual property rights, and strategic behavior. The first element appeared to have been subject to a lot of research, but only few related to any of the other two elements, let alone both of them. Contrary to many studies on the second element, prior research on IPRs is in this study focused on the historical arguments underlying the patent system and not on current legal issues and/or technicalities. Contemporary controversy amongst policy makers can be described in terms of these arguments. The third element, strategic behavior, is conceived of in terms of the resource-based approach in strategic management. This review led to a focus on the roles of patents in creating corporate, proprietary knowledge, taking the particular characteristics of (the science-based nature of) pharmaceutical innovation into account. Managerial problems in controlling this process are considered from the perspective of strategic planning and knowledge management. The basic proposition of this study is based on the, often heard, claim that information technological and bio-technological developments in pharmaceutical innovation would make research a better controllable activity. If so, corporate strategic planning on the basis of proprietary positions would become possible, offering better steering possibilities of technological trajectories and providing a pro-active approach to IP in business. This position links up to the third generation R&D approach of Roussel et al. (1991). If not so, corporate strategic planning would be restricted to the provision of guidelines for patenting policy, remaining facilitative and reactive in its approach to IPR in business and R&D strategy. This position links up to the first generation R&D approach Roussel et al. (1991) describe.

Chapter 2 synthesizes relevant ideas from a pilot project and the advanced study of literature at several levels of analysis concerning the roles of patents. First of all, the context of pharmaceutical innovation as a science-based activity is related to the concept of the technology life cycle in order to explain the different roles of patents. The science-based nature of pharmaceutical innovation explains the increasing interaction between academic and corporate research in a period characterized by a decreasing number of 'traditional, chemistry-based pharmaceutical technologies' on the one hand, and an increasing number of breakthrough technologies going off-patent and an expanding influence of university-based biotechnological research on the other. As an incentive, the patent not only stimulates companies to invest in R&D and individual researchers to articulate and codify their

ideas and research results – thereby enhancing knowledge dissemination and transfer – but, in a negative sense, also induces divestment. The protection a patent provides to a firm's market position is especially of importance to the exploitation of the invention to which the patent pertains. In earlier stages of the pipeline, the patent serves as a means of dissemination and can be a useful source of ideas. Therefore, competitors' patents have to be scrutinized for their effects on the firm's on-going research projects, programming and proprietary positions. These positions are built by appropriating results from research, either from public information sources – through the interpreting researcher's creativity to translate them in a patentable invention – or from in-house research. Appropriability problems often rise in cooperative efforts. And in corporate research management, patents are suggested as performance indicators for which purpose they are more suitable than for the analysis of highly aggregate variables like the national technological performance. At the corporate level of analysis, the quality of patents can be assessed and inventive leaps and portfolio improvements can be better interpreted relating such data to other pipeline data. Objectives and criteria are then formulated as a first conceptualization of IP management. Reviewing the issues and dilemmas concerning the roles of patents, the different stages of creation and exploitation in IP management have been related to activities management conduct in light of such objectives and criteria. A typological distinction between IP management and IPR management has been made defining two basically different sets of issues and activities, whereby the second relates to the exploitation stage only.

Chapter 3 is also based on a synthesis of ideas from the pilot project and a consequent, advanced study of literature, answering the second research question on the strategic relationship between the creation and exploitation of proprietary knowledge. Technological expectations are decisive in appropriability questions at two strategically important moments in the research process; the allocation of resources to selected project proposals in the first stage and the patenting of inventions in a latter stage. The degree to which corporate management influences R&D activity and strategy depends on the technological regime. The strategic relationship between managing the input to R&D activity and exploiting the output from it in a latter stage are found to be highly dependent on the managers' perceptions of technological opportunities on the one hand and of technological and marketing capabilities on the other. The allocation of resources to the firm's R&D should be considered as an expression that weights all the relevant factors constituting technological expectations and technological capabilities. Competitive advantage results from the effective management of knowledge under proprietary conditions, that is actualized in the firm's capabilities and competences and expressed in its proprietary positions. Companies will differ in the degree to which they

analyze technological trajectories in terms of proprietary positions. Retrospectively, if an intended strong patent position results in a strong market position, a company apparently is capable of managing IP effectively; characterized as having a strong strategic relationship. Otherwise, it can be characterized as having a weak relationship, i.e. ineffective IP management. This relationship is conceptualized as consisting of three organizational levels of strategy formation; corporate, business and functional management. The fundamental elements of IP managerial activity will more or less be used to the benefit of technology strategy, depending on management's perception of the controllability of the research process. Furthermore, appreciation and appropriation are considered the building blocks in my conceptualization of IP management.

Finally, chapter 4 is based on the analyses of chapters 2 and 3. Focusing on the first stage of IP management, the third research question has been reformulated as: how to manage the creation of proprietary knowledge. In answering this question, the discussion of the technological regime returns. The basically different views of the pharmaceutical research process are starting points for continued modeling, constructing a typology and two activity systems, using the SSM. Two modes of IP management in this stage of the TLC have been constructed on the perceived relation between the research process and the strategy process. The related activity systems are referred to as the creative system and the planning system. If the research process is considered uncontrollable, the creative system will dominate the strategy process. The planning system has the role of facilitating research and the forms of control would be intrinsic. If the research process is considered controllable, the planning system will dominate the strategy process. The planning system has the role of steering research and the forms of control would be extrinsic.

Such a systemic approach may seem rather trivial, but the kind of problems found in this and other researchers' studies on real-world problems in the appreciation of IP (mainly patents) support the development and consequent use of models of managing knowledge in the research process starting from the appreciative system as described in this chapter.

5.2 CONCLUSIONS

In this section, some of the academic discussions on this subject will be highlighted in relation to my main findings.

The roles of patents

Considering protection as the primary role of patents underexposes the patent as a means of information exchange and, therefore, as a knowledge management tool. Though, depending on the technological regime of an industry, protection is what a patent provides, a patent can do and mean a lot more. In innovation-based competition, it first of all functions as a means of absorbing information. Provided that the public dissemination of research results from universities and other organizations in the public domain is effective and enables every pharmaceutical company to (equally) bear on them, the technological capabilities of these companies are highly influenced by their ability to create and exploit knowledge appropriated on the basis of this public knowledge base. In this early stage of innovation, knowledge management is aimed at translating verbally encoded (articulated and codified) knowledge – like articles from scientific journals or reports from cooperating research institutes – and proto-information into proprietary knowledge; a more or less important part of the corporate technology. How firms consequently use patents in the process of turning an invention into an innovation, is expressed in their IP strategy.

IP strategy as the relationship between the creation and the exploitation of proprietary knowledge

Differences in IP strategies would have to be explained by the ability of management to bring IP practices in line with corporate strategy. For such organizational purposes as learning, information systems development and cultural change, IP management will be the primary interface between the research system and the planning system. As the key mechanisms to purposefully influence these organizational processes, management should consider: appreciation and appropriation. However, developments in science, biotechnology, information technology and regulation concerning the appropriability of (codified) knowledge seem to challenge existing basic views of the research process in pharmaceutical innovation. In other words, the changing technological regime will, in my point of view, affect the way knowledge and, therefore, IP can be managed. The IP management model contrasts two basically different views which are logically developed into two organizationally different activity systems. The simple line of argument to be followed in redesigning managerial activity systems is that if people concerned with patenting would predominantly belief that the development of the corporate knowledge base can not be purposefully influenced, than management would have to follow mode 1. Of course, for mode 2 the opposite would apply.

The IP management model

Various distinctions in the conceptualization of IP management are made along the

two dimensions discussed in this study. Along the time dimension, a hierarchy of life cycles is used. First, the technology life cycle (TLC) refers to the concept of the technological trajectory which, in this study, is considered to be the sum of scientific and technological activities aimed by a multitude of research organizations at the same (part of a) therapeutical solution. A TLC can consist of a large number of rivaling products and patents. A product life cycle (PLC) can consist of more than one patent, as it will mostly do in pharmaceutical business, but always refers to one product. Patents also have a life cycle on their own. If a (NCE) patent ever comes to product introduction it sometimes exceeds the PLC in cases of product introduction failures, but blockbusters' and other successful products' life cycles will be extended by improvements to the existing, but expiring, patent or find new indications (medical application areas).

Furthermore, the time dimension gave rise to a distinction between the creation and the exploitation of patents in IP management. The basic difference between the stages of creation and exploitation is the direction of the money flow. Creation is characterized by investment, exploitation by returns. But in both stages action requires the appropriation of results. Creation is to result in the rights to inventive ideas, exploitation is to result in the recouperation of the investments made to appropriate these rights. The creation of patents is very much related to other forms of publication. It is an aspect of the investment in technology to be developed into a product. Besides exploitation of the technical knowledge by marketing the product, the exploitation of patent(s) is done by granting rights, licensing, or selling. Considering the patent life cycle as part of the TLC also means considering related forms of intellectual property, such as copyright. Therefore, I have been using the term IP management instead of patent management.

The organizational dimension of IP management gives rise to a distinction between organizational levels of managerial activity. Though the concept of strategic planning is probably as well known as the life cycle concept, the distinction between the corporate, business and functional level has in this study also found its IP specific form. Activities are defined on the basis of these system layers.

The IP management practice

Patenting is considered a conditio-sine-qua-non to particularly those research activities that are aimed at the creation of efficacious new chemical entities and which (still) form the core business of innovative pharmaceutical companies. But political, economic and technological developments are changing the institutional as well as the opportunity conditions under which pharmaceutical innovation takes place. The industry's attention to the proprietary conditions for innovation has led to arrangements for pharmaceutical patent life extension in all the three major markets

of the world to compensate for the gradual loss of effective patent protection since the increase of governments' (safety) regulations for pharmaceutical products. Furthermore, competition of generics is increasing with the increasing number of products going off-patent. And the time lag between patent expiration and generic entry has gradually decreased. Increased competition from generic products has become part of the pharmaceutical business. In favor of the (still, relatively low degree) of acceptance of generic products, many national governments advocate generic substitution in drug dispension, for instance through reimbursement stimuli but also by changing the regulation of drug dispension itself. And biotechnology changes the relations between research activities in the private domain with those in the public domain. Altogether, patents are a vital aspect of business in the pharmaceutical industry. Without them the rate of innovation is claimed to decrease to unacceptable levels.

In influencing research results in this context of a 'patent race', management is reported to be concerned with the researchers' attitudes toward IP. The model indicates that control is to be focused on the appreciative systems in both the research and the strategy process. Intervention is proposed to concentrate on the perceptions of agents. Existing (and developing) tools of knowledge management, using patent data and information, can be of great support to this managerial process.

5.3 SUGGESTIONS FOR FURTHER RESEARCH

Of course, many other intermediate forms of research projects based on this study are possible, but in this section, two main lines of further research are suggested. These suggestions have not been elaborated, but indicate two basically different strategies of building on the model proposed in this study.

Testing

Starting from the control dimension in the proposed management model as two idealtypical forms of IP management, a taxonomy of these and (possibly) intermediate forms could be constructed on the basis of a comparative (multiple) case study. The participating firms need to be selected, for instance, on the basis of experts' opinions discriminating IP planning attitudes of the (bio)pharmaceutical companies they are familiar with. An alternative for this classification criterium would be to use the description of characteristics of the three generations of R&D management, as described in figures 3.2, 3.3 and 3.4 by Roussel, Saad and Erickson (1991; 31-40). The two modes in the control dimension in my IP management model could then be connected to the first and third generation. The relationship between the perceived technological regime and existing activity systems defined would then have to be questioned and uncovered, preferably, using the principle of method triangulation (interviews, observations and documents). As an alternative method of inquiry, SSM could be used in group settings. Participation is a possible restriction. The model thus developed would have to be operational in terms of empirically sound patterns of managerial behavior that can be made subject to testing. Then, a survey could be conducted in order to validate the extended, operationalized model to be able to statistically generalize it to the whole of the pharmaceutical industry. A cross-industry, parallel case study could be aimed at analytical generalization of the model, followed by a more extended survey research than the one suggested in order to extend validity to other industries.

To an instrument for intervention

Developing the theoretical model proposed could also be aimed at an instrument to support the change process needed to shift the IP management practice along a perceived increase in controllability of R&D. Contrary to the proposed model which underscores controversy, the instrument would then, first of all, have to build consensus over this issue. Some existing knowledge management tools already apply to consensus engineering. The instrument should be made of use in the relation between information systems and human knowledge in research organizations. A cross-industry, sequential case study design could be followed in order to adjust

findings, taking the experience of each subsequent case into the next one. The instrument should build on the supporting function of SSM as a participative method of organizational intervention, for the theoretical model proposed has been formed using some of the categories (conceptual instruments) of this methodology.