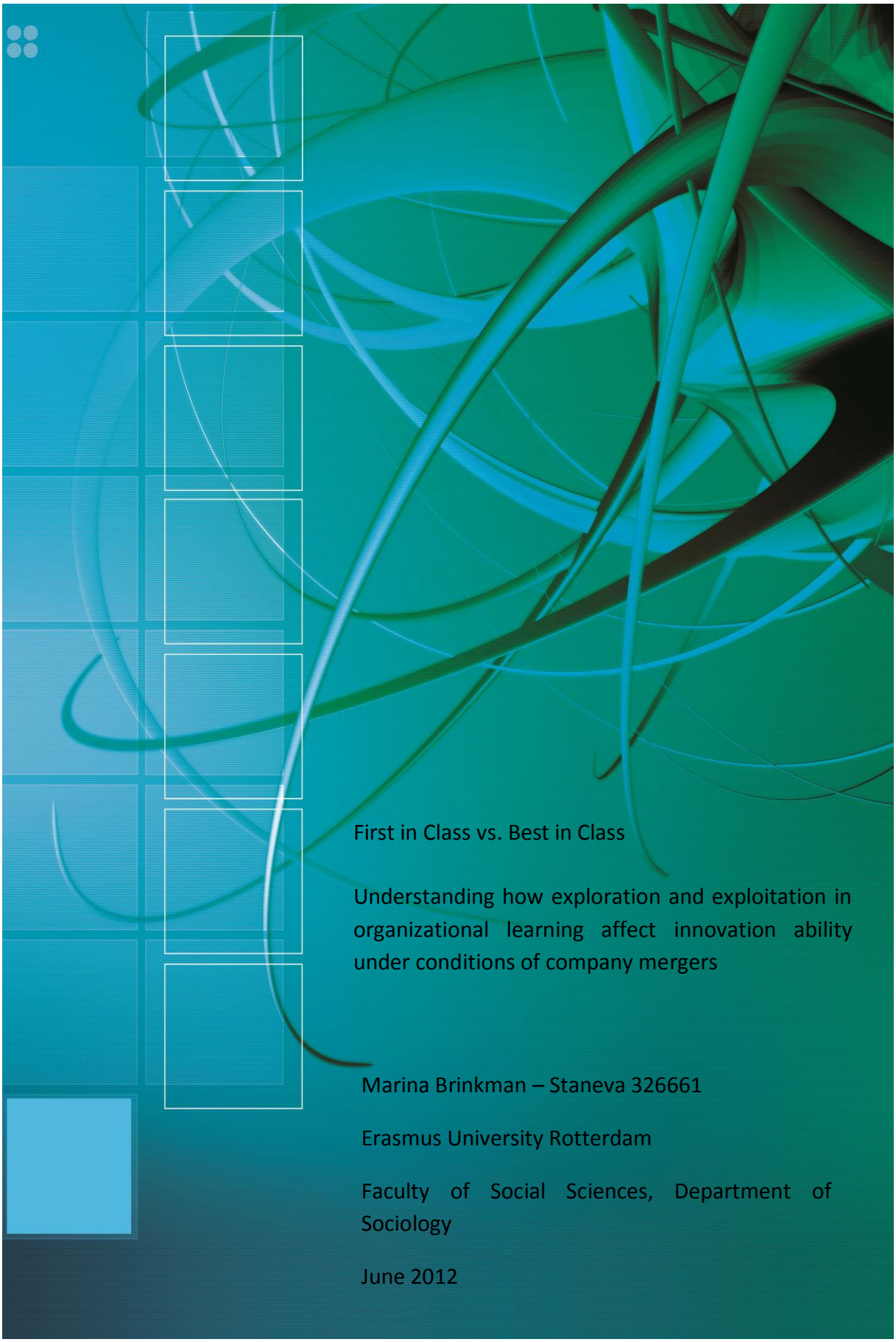


First in Class vs. Best in Class

Understanding how exploration and exploitation in organizational learning affect innovation ability under conditions of company mergers

Marina Brinkman – Staneva 326661

Erasmus University Rotterdam

Faculty of Social Sciences, Department of Sociology

June 2012

Master thesis in Sociology, profile AOM (Labour, Organization and Management)

Members of examining committee:
Dr. H. Pruijt, supervisor
Prof. Dr. J. Heilbron, 2nd reader

Preface

This thesis has been written as part of the Master's programme in Sociology, profile Labour, Organization and Management, and it serves as the final project in completion of my studies at Erasmus University, Rotterdam.

Without the assistance and cooperation of many people, my whole Master's-adventure would have been a much tougher experience. I would like to thank Dr Pruijt for his supervision during the last phase, the writing of the thesis. The regular Organon-group meetings we had together with Pascal Dérogée and Prof. Dr. Heilbron always challenged and inspired me. My gratitude goes to them too. I am also thankful to all the other lecturers who were involved in teaching the evening sessions over the past four years. In particular I would like to thank Mr Braster, who inspired my interest in research methods and techniques: '*Measure what you want to know'* is a phrase I won't forget.

A handful of scientists from the R&D laboratory in Oss also made this thesis possible. They welcomed me into their homes and shared their experiences with passion and patience. I am also grateful to many colleagues and students at the NHTV Academy of Hotel and Facility Management; their support was something I could always count on. A big thank you goes to my family and friends in the Netherlands and in Bulgaria. Finally, a special note goes to the person who contributed not just moral support but who corrected assignments and helped in so many other ways – my husband. Without you, there is no me.

Marina Brinkman – Staneva

June 2012

Abstract

The purpose of this single case study is to examine those changes in structural characteristics and organizational actions which affect the innovation ability of an organization under acquisition. This study's context was pharmaceutical innovation. The closure of the Research and Development laboratory in one of the most prominent pharmaceutical companies in the Netherlands has prompted speculation as to the likely effect on the Dutch knowledge society. This topic is politically sensitive as the Dutch government has invested substantially in life sciences and health in recent years – money has gone into knowledge development at universities and a range of industries to strengthen the country's competitiveness in this field. Life science is one of the areas the government wishes to see contributing to a common knowledge agenda shared by industry, government and society. The closure of the Oss laboratory affects the overall R&D intensity of the Netherlands, measured as the percentage of GDP invested in research and development. In turn this affects whether the country can reach its 'Lisbon indicator' investment target, set as part of the EU-2020 strategy.

The study was shaped by the organizational learning perspective, specifically the exploration and exploitation model of James March (1991). March presents an organizational learning model which posits that in an appropriately organized system, individuals do not learn directly from their own experiences but from each other. Organizational processes may involve both the development and the use of knowledge: they may require investment in new ideas and take advantage of existing ones. These two types of organizational process are framed in organizational learning as exploration and exploitation respectively.

Following March's ideas, nine propositions were formulated. These propositions address those structural characteristics and organizational actions which have been identified as significant in the quest to strike a balance between exploration and exploitation. The propositions formed the reference point for the data collection and analysis and were refashioned into three topics, namely diversity vs. specialization, communication and coordination, and use of resources. A series of open sub-questions was then formulated around these topics for use in eleven in-depth interviews with scientists involved in various steps in the discovery and development of drugs.

The research process has been structured around March's model. By basing the analysis on a pharmaceutical company, this report helps us to assess the applicability of the model to this industry. Furthermore, given the specific history of this company, i.e. two acquisitions, it also helps indicate the applicability of the model to the acquisition process and its value in predicting and explaining the effects of such processes on innovation ability. The study found that changes in strategic actions had the strongest influence on organizational innovation ability. Decisions made during the acquisition process indicated that the company aimed to be 'best in class' by bringing products onto the market which were the result of low or no risk projects. Before the acquisitions the organization's strategy was to be first in class

– to be first on the market with innovative products, even if this meant becoming involved in high risk projects. The level of risk associated with each of these strategies reflects the level of innovation in the product being developed; a product based on a new molecular entity is considered to be more innovative and consequently more high risk than a product based on an existing molecular entity. With the change of strategy organizational characteristics such as task division, decision-making power and communication lines altered, resulting in the emergence of a vertically integrated and centralized structure, with many phases, especially in the discovery process, being outsourced. The change in structural characteristics and organizational actions reflected the company's new strategy: to pursue stable performance by taking advantage of existing knowledge.

Table of Contents

List of figures

1 Introduction

The central theme of this thesis is the innovation dynamics in high-tech globalized industries such as the pharmaceutical industry. This industry has a continuing need for highly skilled employees and it plays a role in strengthening the knowledge society; hence it is a platform for social innovation. Social innovation may result when conditions are created which encourage the constant development of human capital and the better use of this human capital, for example by implementing flexible working practices which empower employees (Task Force Social Innovation, 2005). The twin goals of employability and lifelong learning are examples of the wish to create a win-win situation for the employee, the organization and the country. In short, social innovation means investing in knowledge; individual as well as organizational. It involves utilizing human competencies to develop talent and achieve excellence, to foster organizational innovation and thereby improve organizational performance (Task Force Social Innovation, 2005, p. 2). Improvement in organizational performance implies that some kind of learning has taken place at both individual and organizational levels. Organizational learning indicates that organizational knowledge has been changed in some way, for example by adding to, reducing or transforming it (Schulz, 2002). Organizational learning can also be defined as a process through which organizations change. Paradoxically though, this change does not necessarily involve improvement and innovation as organizations tend to get trapped in their competencies (Baum, 2002).

In his influential study, March defined organizational learning as a self-limiting process (March, 1991); this is the perspective adopted in this thesis. His model sheds light on the relationship between the quality of organizational learning and primacy – being first among one's competitors. As the aim of the pharmaceutical industry is to develop and produce innovative medicines (De Weerd, 2010), the industry offers a suitable site for the investigation of the effect of learning and knowledge on the ability to innovate. Understanding this relationship will help us better understand how organizations use learning as a tool to achieve a set performance level.

The main question in this thesis is inspired by the apparent decline of the knowledge society, at least within the pharmaceutical industry (Rozendaal, 2010). Companies are closing their research and development (R&D) divisions but not necessarily their production units. In the summer of 2010 MSD-Organon (known as Merck & Co. in the US and Canada) announced that 2,175 jobs, half of them at the research laboratory in Oss, would be relocated to the United States. It was announced that another 510 jobs at the Abbott laboratory in Weesp, which had been recently taken over by Solvay Pharmaceuticals, would also disappear. Internationally, approximately 50,000 jobs across the top 10 companies have vanished as a result of mergers and fusions (*Het Financieele Dagblad*, 2010, December 31). Among others, Astra Zeneca phased out 8,850 jobs, Pfizer 8,480 jobs, GlaxoSmithKline 5,201 jobs and Bayer 4,500 jobs.

According to *The Economist*, (2009, March 14) big drugs companies believe that mergers and fusions will solve their various problems, especially the shortage of new blockbuster drugs coming through their research pipelines, the strong competition from generic drugs as patents expire and the global economic crisis. Dutch newspapers have repeatedly produced similar reports (Rozendaal, 2010; *Het Financieele Dagblad*, 2010, December 31).

This may be the reasoning behind MSD-Organon's reorganization and the resulting closure of its R&D laboratory in Oss. But the case is somehow ambiguous. On one hand, the company has invested billions of dollars in an R&D laboratory with a proven record of success (Schering-Plough, 2008). On the other hand, media reports have suggested that the pipeline is empty. How can highly educated research and development professionals, the building blocks of the knowledge society, stop being innovative? How can this change in the innovation process in Oss be explained?

This thesis attempts to answer this question from the perspective of the learning organisation, already introduced as the main topic. It adopts the qualitative approach to investigate the effect of learning and knowledge on the ability to innovate. The following chapters represent the steps taken. First, the problem is defined; this chapter is followed by a discussion of the theoretical background of the research. Chapter 3 presents the research method and gives a brief history of the case company. The next chapter presents the results of the research, followed by a conclusion.

2 Problem definition

2.1 Problem definition

Understanding the innovation dynamics at MSD-Organon is the central theme of this thesis. As already mentioned in the introduction, a company with a past record of success has been labelled by the media as lacking innovation abilities and without a future. According to the Annual Report produced by Schering-Plough in 2008, Organon BioSciences was not then operating with an empty pipeline or experiencing financial troubles (Schering-Plough, 2008). In other words, lack of finance for research and development is unlikely to have been the reason for closing the laboratory. This leaves the possibility that the cause was actually its failure to innovate. It should be noted here that the aim of this research is not to identify the reason why the laboratory was closed, but to understand the various factors that influence an organization's ability to innovate.

The focus is on understanding the process of organizational learning and interpreting how this leads to innovation and change, using the influential model devised by James March (Baum, 2002, p. 426). March distinguishes two modes of learning: exploration and exploitation. He argues that organizations seek to strike a balance between these modes for two reasons. Firstly, organizations engaged mostly in exploitation are essentially re-using

existing knowledge, and are in danger of stagnating. Secondly, organizations engaged mainly in exploration pay the costs and take the risks associated with innovation with no guarantee that they will reap any benefits. The chances of outperforming the competition are improved if companies have a diverse staff; they are reduced by lack of resources and organizational attempts to impose conformity and standardization (March, 1991).

This all begs the central question: How has the organizational learning process in MSD-Organon affected its innovation ability?

The resulting sub-questions have arisen from the consideration of the theory of organizational learning and innovation. These questions will be formulated after the theoretical background has been presented.

2.2 Relevance of the question

The future of MSD-Organon and specifically the possible loss of the research and development competencies of almost 1,000 people is a question which is keeping the Dutch government and society in general busy. Two main issues are being discussed by both politicians and the media.

First, approximately 2,500 people will lose their jobs over a period of three years. This number does not include any possible effects on suppliers and small companies in the region – such as the baker across the street from the laboratory. According to the mayor of Oss, each job at Organon ensures another one in the city (Snijders, 2011). Given the rich history of Organon and its place in the lives of generations, it is not surprising that few understand why Merck & Co. wants to close the R&D department but refuses to sell it. One employee was quoted in *NRC Handelsblad* as saying: 'Merck betrayed us, as there was a very good offer. But they were ultimately afraid of the competition' (*NRC Handelsblad*, 2011, March 5). The strength of protest against this decision forced the company to postpone the start of the reorganization, to look for another solution[1].

The second issue is the political sensitivity of this case. It has got onto the politicians' agenda for two main reasons: firstly, the Dutch government has invested substantially in life sciences and health in recent years – money has gone into knowledge development at universities and a range of industries to strengthen the country's competitiveness in this field (Jansen, Van de Vrande & Volberda, 2008, p. 17). MSD benefits from a number of government-supported projects, particularly the Top Institute Pharma and the Centre for Translational Molecular Medicine. MSD is an active participant in these programmes, contributing around €17 million (the government contribution is in total as much as €280 million). In addition, the Ministry of Economic Affairs invested €5 million in BioConnection, a

[1] On 11 March 2011, the court in Amsterdam decreed that Merck &Co. should give all documentation and information about this anonymous offer to the Advisory Board (the body representing Organon employees) (Actualiteiten: Uitspraak kort geding Organon, 2011).

production facility where MSD is a shareholder. This contribution is in the form of equity provided by the Brabantse Ontwikkeling Maatschappij. The province of North Brabant and the municipality of Oss have also invested a total of €2 million in BioConnection (Van der Hoeven, 2010 (a); Van der Hoeven, 2010 (b)).

The second reason why the case is of interest to politicians is because government policy explicitly aims at strengthening the knowledge society. Life science is one of the areas the government wishes to see contributing to a common knowledge agenda shared by industry, government and society. The government has set out its goals, which are to strengthen the competitiveness of the Netherlands through innovation, fundamental and applied research, and to create a favourable business climate by effectively managing legislation, training and knowledge (drs. Verhagen, 2010). But the R&D intensity of the Netherlands, measured as the percentage of GDP invested in research and development, declined between 1998 and 2009, as shown in figure 1. As a result, the so- called 'Lisbon indicator' investment target – that 3% of GDP should be invested in research and development by 2010 – was not reached (Vereniging Innovatieve Geneesmiddelen Nederland, 2011, pp. 48-49). The adjusted EU-2020 strategy renewed this goal for 2020, while the National Reform Programme published in April 2011 set the percentage at 2.5 for the Netherlands (Europe 2020 targets, 2012; Vereniging Innovatieve Geneesmiddelen Nederland, 2011). The government regrets the decision of MSD-Organon as it affects not only those directly involved but the Dutch knowledge society as a whole.

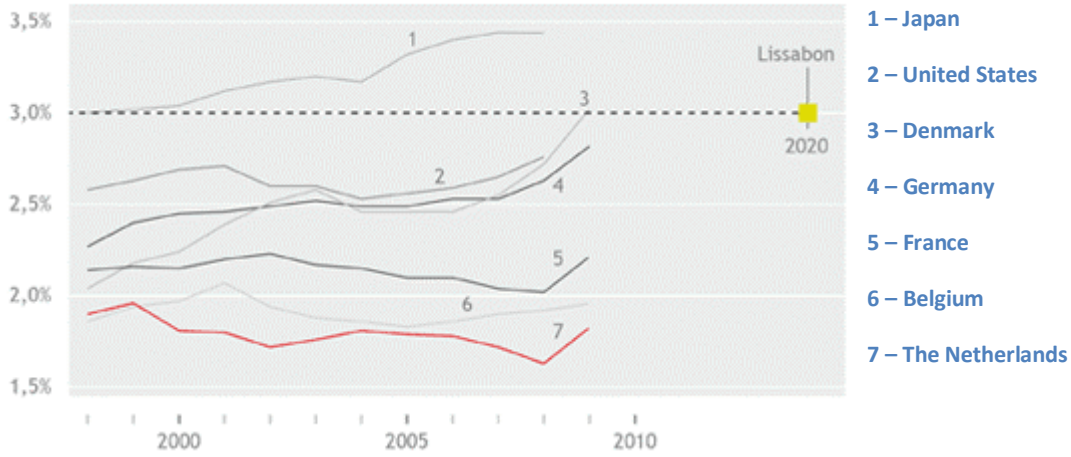


Figure 1: R&D intensity in comparison with the Lisbon indicators, 1998 – 2009. R&D intensity is the percentage of GDP invested in research and development.

Source: (Vereniging Innovatieve Geneesmiddelen Nederland, 2011, p. 49) originally cited in CBS/Eurostat, 2010

By understanding the mechanisms that drive organizational learning and ultimately innovation in the pharmaceutical industry, we will be better able to recognize such mechanisms in emerging biotechnological firms and other industries such as telecommunications and software. A common characteristic of all these fields is the drive to

achieve primacy in products and services; this is still considered the number one revenue driver (Van Wijk, 2010).

3 Theoretical background

The study draws upon the field of organizational learning, and specifically March's (1991) exploration and exploitation model, to formulate propositions regarding those structural characteristics and organizational actions which have been advocated in the quest to strike a balance between the exploration and exploitation modes. AnneLee Saxenian's 1994 study of Silicon Valley's regional advantage over Route 128 is then used to review these propositions in the context of company acquisitions. The propositions are subsequently used to formulate sub-questions in the research method section and lead the analysis. Finally, March's exploration and exploitation model is refined based on the findings of the thesis.

3.1 Organizational learning: the trade-off between exploration and exploitation

In his influential paper (1991), March presents an organizational learning model which posits that in an appropriately organized system, individuals do not learn directly from their own experiences but from each other (Rodan, 2005). The basic mechanism of the model is functional; it expresses the self-limiting nature of the learning process. This limitation becomes obvious when organizations get trapped either in their failures or successes. Failure leads to the search for new ideas and change, leading to further failure and more searching, and so on. Even a successful innovation needs time to be proven successful (Levinthal & March, 1993). Exploring new ideas, procedures and organizational forms may yield poor results in the short term. On the other hand, the positive feedback generated by a success may just lead to the same activity being repeated over and over again. The organization may develop more advanced competencies, but within a limited range of activities. In the long run, this is self destructive, as such organizations seem to become unable to adapt to environmental changes, for example (Levinthal & March, 1993). Organizational processes may involve both the development and the use of knowledge: they may require investment in new ideas and take advantage of existing ones. These two types of organizational process are framed in organizational learning as exploration and exploitation respectively.

Organizations trapped in a state of exploitation may see themselves improving steadily in certain competencies, with overall efficiency being the result. This state can be described in terms of certainty, short-term gains and instant rewards. The state of exploration, on the other hand, involves searching for new ideas, new markets, new products and services. This state can be described in terms of uncertainty and long-term gains. The exploration of new alternatives may adversely affect the mastering of existing skills, while improvements in competencies with existing procedures may make experimenting with new ones less attractive. What makes the trade-off even more challenging is that these processes occur at all levels of the system – individual, organizational and social (March, 1991). March argues that the exploration state is a vulnerable one because outcomes are less certain, more

remote in time and further away from the point of action. Following this line of thinking, basic research and new ideas offer less certain outcomes than does the development of existing products. It can be argued that incremental innovations occur rapidly as they are the result of exploitation, while radical and revolutionary innovations occur slowly as they are the result of exploration.

Because the exploitation of existing knowledge can have positive effects, organizations develop rewards for engaging in such exploitation. But this can lead to path dependence and, in the long run, to self-destruction. March argues that organizations should support a reasonable level of exploration in order to prevent this from happening. The trade-off between the two modes is dependent on the particular nature of the social context in the organization, formulated by March in terms of the mutual learning relationship between an organization and the individuals within it, and on how organizational learning is conducted in the context of the competition for primacy. Based on these features, he describes two models. These models are relevant here as they elaborate on the relationship between exploitation and exploration and identify some reasons why organizations might want to control organizational learning.

The first model of organizational learning describes a mutual learning paradigm, in which organizations and individuals learn from each other. An organization stores beliefs, routines, norms and procedures, accumulated over time by its members. New members adapt to these and, simultaneously, the organization adjusts to their individual beliefs. This form of learning has consequences for the trade-off between exploitation and exploration because of the inherent conflicts between short-term and long-term concerns, and between gains to individual knowledge and gains to organizational knowledge. March (1991, p. 75) defines the mutual learning of an organization and the individuals within it as follows: '*over time, the organizational code affects the beliefs of individuals, even while it is being affected by those beliefs. The beliefs of individuals do not affect the beliefs of other individuals directly but only through affecting the code.'* He presents some basic elements of this model as it operates in two types of systems: closed and open.

March does not define in detail what he means by closed and open systems. He refers to the former as '*a… system having fixed organizational membership and a stable reality*' (1991, p. 75) and to the latter as '*a…system* [where] *organizational membership is treated as changing* [and] *environmental reality is treated as changing'* (1991, p. 78). In the absence of detailed definitions it is necessary for the sake of clarity to outline what they represent in the field of organizational learning. In closed systems, also known as rational and natural systems, organizations and their environments are regarded as separate entities, divided by clear boundaries (Baum, 2002). These organizations are characterized by a stable and easily distinguished membership. In the open system perspective, the focus is on the relationships and interdependencies between organizations and their environments. Organizations are seen as being dependent on the flow of resources, personnel and information from the

environment, which in turn is shifting and ambiguous (Scott & Davis, 2007). Although the short definitions given by March seem to be in line with this view of closed and open systems, they will not be adopted in this thesis. Instead, it adopts the contemporary perspective on organizational learning. In this perspective, closed and open systems are seen not as competing but as complementary, as they either focus on different organizational phenomena or highlight different aspects of similar phenomena (Baum, 2002). The four basic elements of mutual learning among organizations and individuals, as outlined by March, are further elaborated below.

The model presents two key elements which operate when the environment is stable: the effect of learning rates and the effect of learning rate heterogeneity. March states that an organization only learns from individuals who deviate from the organizational code. This means that the longer it takes for individuals to adjust to this code, the longer a degree of diversity is maintained, and the longer the organization can continue to learn and explore. Eventually, a stable condition is reached in which individuals and organizations share the same beliefs. The second element is the effect of learning rate heterogeneity. This effect is based on the idea that organizations might benefit from having a mix of slow and fast learners; rapid individual learning might give an individual short-term advantage, but in the long term it has an adverse effect on the organization. A higher level of organizational knowledge is reached when a group of learners is heterogeneous. The problems, March argues, are that individuals choose their learning rate independently, and there are seldom incentives for slow learners.

In a dynamic environment, the model again identifies two specific elements: the effect of personnel turnover on learning and the effect of environmental turbulence. March states that there is a strong positive relation between length of service in an organization and individual knowledge – the higher the turnover, the shorter the average length of stay and the lower the average individual knowledge at any point. The effect of turnover on organizational learning is more complex as both learning rate and turnover rate play a role. Employing a preponderance of individuals who rapidly learn to follow the organizational routines and adapted beliefs reduces exploration, while a modest level of turnover and the hiring of less conformist staff increase it (unfortunately, March does not define what he means by ‘modest turnover rates’). The level of organizational knowledge increases in line with the level of individual knowledge among long-serving staff. This increase is not the effect of superior knowledge of the newcomers but an effect of their diversity. What they know is less redundant for the organizational routines and beliefs, and occasionally better, thus more likely to contribute to improving organizational learning. The second element is the effect of environmental turbulence. Under conditions of environmental turbulence, mutual learning declines in the long term: as individual and organizational beliefs diverge, the rate of change in the environment outstrips the ability of individuals to change with it. Organizations can avoid this by implementing moderate personnel turnover and selecting new staff according to clearly defined criteria. Candidates holding views similar to the

prevailing organizational beliefs should not be hired as this will significantly reduce the potential of turnover as a way of stimulating exploration.

March's second model of organizational learning shows how characteristics of the internal and external competitive environment contribute to the creation and use of knowledge. The external competitive environment relates to the position of an organization in relation to its competitors. March describes a competitive environment characterized by the need for primacy, as in the pharmaceutical industry. He stresses the effect increased variation in performance, the result of variation in knowledge and learning processes, has on competitive advantage when there is more than one competitor in the field. To put it simply, the more pronounced the variation in performance, the greater the contribution to the organization's competitive advantage and the more likely it is to achieve its aim of coming first. March goes on to argue that some learning processes increase both average performance and variability, while others do not:

> *'Increased knowledge seems often to reduce the variability in performance rather than to increase it. Knowledge makes performance more reliable. As work is standardized, as techniques are learned, variability, both in the time required to accomplish tasks and in the quality of task performance, is reduced…The likelihood of finishing last in a competition among many is reduced without changing the likelihood of finishing first…Knowledge may easily decrease the chance of being best among several competitors even though it also increases average performance.'* (March, 1991, p. 83)

Variations in the learning process can be the result of adopting a new technology, introducing a new body of knowledge or new elements of cultural diversity, for instance through the introduction of employees with untypical skills, attitudes, ethnicity and gender. These new features may strengthen the competitive advantage regardless the problems of lack of familiarity and limited experience when dealing with them.

March extends his argument to consider the effect of close collaboration and cooperative information exchange within organizations. Organizations that develop effective communication and coordination are expected on average to do better than those that are more loosely coupled, but this comes at a price – as their reliability increases, their chance of coming out ahead of their competitors is reduced.

Lastly, March adds strategic action to his list of considerations for organizations seeking primacy among their competitors. In the long term, strategic actions represent the result of organizational choices between investment in learning (exploration) and in consumption of current competencies (exploitation). If an organization's relative position in the field matters, as it does in the pharmaceutical industry, and the number of competitors is growing, strategies designed to increase variation in performance, and thus variation in knowledge and learning processes, will become more attractive compared to strategies for raising average performance and knowledge.

Gupta, Smith and Shalley's article (2006) further clarifies the concepts of exploration and exploitation. The authors summarize seven papers on the management of exploration and exploitation and address four issues which are particularly relevant to this thesis. One of the summarized studies takes the organization as the level of analysis and presents the role of exploration and exploitation – specifically, certain organizational designs for achieving exploration – as an independent variable (Siggelkow and Rivkin, 2006 cited in Gupta, Smith & Shalley, 2006). The authors conclude that loosely coupled structures, especially at lower organizational levels such as departments, can facilitate more extensive exploration and increased organizational performance. This supports one of the main ideas in March's model. The authors go on to draw on empirical evidence from the summarized studies to address three other key questions. Their discussion offers some further insights into March's model.

The first question addressed by Gupta, Smith & Shalley is: what do we mean by exploitation and exploration? There appears to be a consensus that exploration refers to learning and innovation i.e. the creation of new knowledge. However, there is no such consensus on whether exploitation refers to the use of existing knowledge or to the use of new knowledge which is different in nature from that associated with exploration. According to Benner and Tuschman (cited in Gupta, Smith & Shalley, 2006, p. 694), exploitative innovations involve improvements in existing technology, whereas explorative innovations involve different technology. Learning and new knowledge play a part in both the exploitation and exploration processes. Other studies cited by Gupta, Smith & Shalley appear to treat all activities associated with learning and innovation as examples of exploration, and the use of past knowledge as exploitation. One example is Rosenkopf and Nerkar's study of the impact of the search for knowledge on patent quality. Building on March's assumptions, Gupta, Smith & Shalley conclude that all activities involve some kind of learning. They go on to differentiate between the types of learning which occur during exploration and exploitation, and which result in either radical or incremental innovations. The pharmaceutical industry, which has the broad aims of curing the patient and improving their quality of life (De Weerd, 2010), defines innovation in similarly broad terms (this will be explained in more detail later). Gupta, Smith & Shalley (2006) build on March's ideas by introducing the notion that different types of learning result in different types of innovations: either radical innovations – the development of new drugs to cure illnesses; or incremental innovations, which aim to improve quality of life by improving existing drugs. Their argument is especially relevant to the idea that variation in performance increases an organization's chances of coming out first, as variation in performance is closely linked to variation in knowledge, and the nature of this knowledge will be shaped by the type of learning employed and whether it leads to radical or incremental innovations.

The second question addressed by Gupta, Smith & Shalley (2006) is whether exploration and exploitation are fundamentally incompatible. They refer to a number of empirical studies in their discussion of March's arguments, concluding that exploration and exploitation

activities are compatible across different and loosely coupled parts of an organization. They argue that the allocation of resources to both the exploration and exploitation of knowledge is more easily accomplished at group or organizational than individual level, and they challenge the assumption that it is lack of resources that prevents organizations from attempting to pursue explorative and exploitative activities simultaneously, pointing out that organizations often have access to diverse external resources (the authors distinguish between internal and external resources) such as information and networks. On the other hand, support is provided for March's logic of incompatibility. Within a single domain like an individual or a department – where individuals may have different focuses – exploration and exploitation may well be mutually exclusive. Those who focus on creativity, experimentation and exploration may be intrinsically motivated, while staff that focus on acting appropriately may be extrinsically motivated by the prospect of rewards. The role of organizational resources is also discussed by Makri and Geiger (2006). They argue that in R&D-intensive firms, an excess of resources has a positive impact on the use of science in innovation. For example, these firms are able to employ more scientists than necessary and to be less concerned about the risks of exploration. Thus, these studies add organizational mindset and organizational resources to the list of elements affecting the trade-off between exploration and exploitation.

The third question addressed by Gupta, Smith & Shalley (2006) is whether every organization needs to pursue both exploration and exploitation, or whether under certain conditions, long-term success is more likely by specializing in one or the other. The authors argue that specialization can be an appropriate tactic for some organizations if exploration and exploitation are considered at the level of a broad social system. To put it another way, if one organization operating in a dynamic environment and another operating in a stable environment are bound by their shared use of mutually complementary resources, then the first organization might specialize in exploration and the second in exploitation. There is a market relationship between the two organizations, which makes specialization an effective strategy in the long term. As learning occurs at all levels in a system, this strategy might also be viable at sub-system level. A strategy allowing the various sub-parts to specialize in one of the modes might assure the long-term survival and success of both: one has an ongoing need to explore, while the other has an ongoing need to exploit. This argument is relevant to the current research as it might be applied to the R&D function: different parts of the laboratory might specialize in either radical or incremental innovations.

3.2 Propositions

Following March's idea that the quality of organizational learning is affected by the ways in which the organization pursues primacy, nine propositions have been formulated. These propositions address those structural characteristics and organizational actions which have been identified as significant in the quest to strike a balance between exploration and

exploitation. They underlie the analysis of the primary data. The analytical techniques used will be described in detail in the research method chapter.

Proposition 1: Individuals who adapt slowly to the organizational code are associated with raising the level of diversity within the organization, and by extension the time spent on learning and exploration.

Proposition 2: A combination of fast and slow learners is closely linked to the level of organizational knowledge reached in the long term.

Proposition 3: New employees who adapt slowly to the organizational code are more likely to contribute to exploration.

Proposition 4: Modest turnover combined with rules for selecting employees is associated with exploration.

Proposition 5: The combination of learning types and learning processes is closely related to an organization's ability to achieve competitive advantage, when its aim is to come out first.

Proposition 6: Less coordination and more loosely coupled organizational parts are related to an organization's potential to make radical innovations.

Proposition 7: An R&D laboratory balances exploitation and exploration by allowing sub-parts to specialize in one mode, thereby contributing to long-term competitive advantage.

Proposition 8: Both organizational resources and a range of mindsets are associated with the simultaneous development of both incremental and radical innovations.

Proposition 9: Strategic action may be taken to increase variation in performance by varying learning types and learning processes.

3.3 Lessons from the organizational changes in Silicon Valley

AnneLee Saxenian's 1994 study of Silicon Valley's regional advantage over Route 128 provides valuable insight into the effects consolidation has on the ability of firms to innovate against a background of accelerating market change. At the same time the study offers understanding of traditional organizational structures and how these affect the ability of organizations to respond to market changes.

Firstly, the once leading companies along Route 128 were unable to respond adequately to the technological changes of the 60s. Their rigidity was partly caused by the organizational structures of the firms and the region. In general, these firms operated as self contained industrial systems, characterized by vertical integration, formal hierarchies and corporate secrecy. The companies maintained only distant relationships with local institutions such as universities. These organizational cultures and structures reflected the region's Puritan character, with its well-defined social structure, long family histories and a strict division

between work and private life. Social gatherings with colleagues would rarely involve work-related discussions. The traditions of the region shaped organizations which valued stability, loyalty and risk-avoiding attitudes. Job hopping was unusual, and entrepreneurial ambitions were not encouraged. The investors of the region reflected its character; they too were formal and conservative, willing to invest only in those with a proven track record.

Collectively, these regional characteristics fostered companies with a desire for self-sufficiency and vertically integrated production. Start ups imitated the structure of traditional, mass production companies by hiring executives with long experience of working within formal organizational structures and operations. The boundaries of companies were strictly defined, and a high concern for corporate secrecy steered the organizational culture. The decision making process was formalized, with long and formal communication streams. Ultimately, these characteristics adversely affected the ability of firms on Route 128 to respond to the pace of change in the semiconductors market.

Silicon Valley firms outperformed their competitors on Route 128, developing a competitive advantage by focusing at regional level on rapidly bringing new products and services to the market. Silicon Valley firms in the 60s and 70s were the opposite of those on Route 128. The region developed a network-based structure with many start ups, horizontal integration and a culture of openness. Risk-taking and opportunism were encouraged, as was job hopping. Information exchange was informal and ongoing in and outside firms. Collective learning was encouraged through the building of relationships within firms, between firms, and with regional institutions such as customer groups and universities. The flexibility of the firms and the region supported the ability of Silicon Valley to respond to changes in the semiconductor and personal computer markets. The industry was expanding, highly competitive and technologically complex. Firms achieved significant competitive advantage by introducing new products or processes in quick succession. In the early 80s, the industry started to stabilize, and the learning curve became less steep. The focus shifted from the continuous innovation of products and processes to the improvement of existing technology, designs and products.

By the mid-80s, firms in Silicon Valley had transformed from small, flexible, high-technology ventures to large and mature corporations. A wave of mergers and acquisitions consolidated the region, producing a couple of large, independent firms. This consolidation led to fundamental organizational changes. The practices of informal collaboration and open information exchange which had facilitated the development of innovative products were no longer seen as valuable, since the aim was now to produce standardized products. These organizations abandoned the local culture and their relationships in the region and created functional hierarchies. Production was spatially detached from research and development.

Around this time, Japanese firms entered and came to dominate the microelectronics market. Silicon Valley entered the worst recession in its history. The Japanese advantage was not cheap labour or market protection, but a distinctive combination of innovation that lent

itself to mass production and domestic policies and institutions that promoted such innovation. Japanese firms, which produced innovative products of consistently high quality, were organized in integrated yet flexible structures, promoting collaboration. But the firms in Silicon Valley, failing to recognize the advantages the region had previously enjoyed, adopted a more traditional model of mass production. Organizational flexibility gave way to bureaucratic organizations with centralized authority, undermining the autonomy of previously independent parts. Strong functional groups steered the creation of matrix organizations, creating confusion and conflict. The management distanced themselves from the employees and introduced formal communication processes with long chains of communication. Engineering and design were separated from centralized manufacturing facilities, reducing opportunities for interactive learning and improvement and further undermining the ability of the region to improve products or to respond quickly to market changes.

The above account suggests that an organization's innovation ability can be negatively affected by consolidation. Managers who fail to recognize the advantages of a flexible organization, information sharing and mutual collaboration may be sacrificing the organization's potential for continuous innovation. A new generation of ventures able to respond to changing markets and technologies can then win market share from large and traditionally organized firms, as was the case throughout the 80s in Silicon Valley.

The company that forms the focus of this thesis has undergone the acquisition process twice in a relatively short period of time. Companies may make acquisitions for a number of reasons. They may use consolidation as a strategy to gain long-term competitive advantage by acquiring a company well known for its innovative ability. If the company recognizes that this ability is linked to the region, it may allow it to keep its existing structures, established products and pipeline. Alternatively, the company may be using consolidation as a strategy to gain market share and to grow; the larger firm will impose its own structures, regardless of the consequences for the smaller firm and the region. In this case, and assuming the larger company has the less flexible structure typical of bigger organizations (Mintzberg, 1989, p. 106), some assumptions can be made about the trade-off between exploration and exploitation. The larger organization will probably favour exploitation, as this mode is characterized by predictability and short-term gains. The dominant structures will favour individuals who adapt quickly to the organizational code, who are loyal and who demonstrate a stable learning style and process. Regular, formalized communication and coordination between the several parts of the organization will raise its average performance. In such circumstances, the research and development facilities will focus on exploiting existing knowledge and skills, i.e. on improving current products. Organizational resources will be put to use to support this task rather than to discover new products. Finally, the organization will take strategic action to ensure stable organizational performance.

3.4 Innovation in the pharmaceutical industry, trends and market developments

Understanding the mechanisms of organizational learning in relation to innovation ability in the pharmaceutical industry demands firstly a basic understanding of what is actually seen as innovation in the industry, and secondly an awareness of those trends and market developments which colour the institutional context in which the company operates.

Morgan, Lopert and Greyson (2008) argue that much of the innovation in the pharmaceutical industry is commercial rather than pharmaceutical. Their definition of pharmaceutical innovation covers radical, substantial and incremental innovations. Radical innovations are moderately to highly effective treatments which have fewer negative effects than existing treatments. Radical innovations are aimed at conditions which significantly reduce quality of life or length of life or both. Substantial innovations are treatments of modest to fair effectiveness (though they are usually substantially better than existing treatments) aimed at patients whose health care needs are less serious. Minor to moderate improvements are offered by incremental innovations; these are aimed at patients with moderate to minor health care needs. The authors argue that most commercial activity in the industry is focused on the development of new products they classify as incremental innovations, while the proportion of effort being spent on product development of drugs qualifying as radical is much less. They reveal that patent applications relating to new molecular entities accounted for only one third of the total applications made to the US Food and Drug Administration (FDA) between 1993 and 2004. Between 1970 and 1989, the FDA approved an average of only 20 applications relating to new molecular entities per year, while in the next 20 years this number rose to 27 (Vereniging Innovatieve Geneesmiddelen Nederland, 2011). Set against the rise in R&D costs, these numbers raise questions. International investment by US pharmaceutical companies was 2 milliard dollars in 1980, against almost 48 milliard dollars in 2008. European companies have adopted a similar investment policy, raising R&D expenditure from 7 milliard dollars in the 90s to 27 milliard dollars in 2009 (Vereniging Innovatieve Geneesmiddelen Nederland, 2011).

Baregheh, Rowley & Sambrook (2009) propose a general definition of innovation, stating that: *'Innovation is the multi-stage process whereby organizations transform ideas into new/improved products, service or process, in order to advance, compete and differentiate themselves in their marketplace'*. Given that pharmaceutical companies produce treatments, and that new molecular entities are what earn patents, it can be concluded that in this case, innovation is essentially about 'new and improved products'. However, broader developments like the ageing of the population, the increased prevalence of chronic disease and concerns about the cost of health care mean that the 'process' through which these new and improved products are discovered, developed and launched is also significant (Jansen, Van de Vrande & Volberda, 2008).

The costs and pace of discovery and development are under pressure not just because of the above mentioned reasons. The specific nature of the patent system in the industry is also a

factor. Inventors are forced to reveal their invention early in the discovery process (Lehman, 2003), which limits the effective patent life left at launch. In Europe and the US it is possible to apply for a supplemental protection certificate, but this does not compensate for the time spent on clinical trials and registration. Moreover, registration periods, which generally cover the period from the filing of the patent to launch, are getting longer, particularly in the case of drugs which may provide significant therapeutic advantages and for compounds under licensing agreement[2] (Magazzini, Pammolli, & Riccaboni, 2009). In the case of patents under supplemental protection, the patent owner's right to exclusivity is restricted, making it possible for generic companies to use the compound to test and develop a generic alternative (Lehman, 2003). Magazzini, Pammolli & Riccaboni (2009) established that generic companies entered the market faster in the period 2004 – 2008, especially for products going off patent. They explain this entrance pace with the substantial price competition induced by the generic companies. The Dutch health care system and the price and label preference policy have strengthened this competition by placing a premium on drugs which have gone off patent. At the same time, more drugs are losing their exclusive regulatory marketing rights than are being added by the FDA (Higgins & Rodriguez, 2006). These rights prevent generic companies from entering the market.

In response, pharmaceutical companies are challenging their traditional business model and shifting their interest from common and easily treated diseases towards more complex and unusual conditions (PwC, 2008). This may be in response to currently unmet medical needs for treatments for more complex diseases which are more difficult to comprehend, control and hit (Cockburn, 2004). However, the patents of many blockbuster drugs are due to expire over the next few years; Merck & Co. is predicted to see an 18%[3] erosion in revenue by 2015 as a result of the sale of generic products (PwC, 2008, p. 3). At the same time organizations are forced to deal with the considerable time delay and costs incurred during the regulatory phase, and with numerous changes to patent law (Cockburn, 2004). Another reason for changing the traditional business model is the fundamental change of the structure of the industry itself. Over the past thirty years, many small firms have disappeared, to create big pharma, while the entry of biotechnology firms into the market has changed the relationship between academic and commercial research. Academic scientists have played a crucial role in founding the biotechnology companies, leaving their academic careers or combining academic and commercial work. The majority of these firms have become specialist suppliers of leading edge technology; currently, between 25 and 40% of big pharma sales are products which had their origins in drugs discovered by biotech firms. Another considerable change organizations have had to face is that drug discovery has become increasingly science-intensive, with major breakthroughs being made in our understanding of physiology and the molecular basis of disease. Throughout this period, R&D practitioners have sought

[2] Licensing agreements are set between marketing and originating companies.
[3] Compared to revenue in 2008. Only the base revenue is taken into account, including products already on the market but excluding any pipeline products.

collaborations with external parties, with the focus being on publication and the sharing of information. At the same time, scientists have been forced to develop managerial and organizational skills in order to handle increasingly complex research projects.

4 Research method

The single case study approach was adopted because it is best suited to the in-depth, empirical investigation of the phenomenon of innovation in its real-life context (given that innovation and its context are hard to separate) (Yin, 2009). The R&D-intensive character of MSD-Organon is typical of the pharmaceutical industry, which is known to have the highest R&D intensity in terms of both expenditure and personnel (Wilen, 2007)[4]. Understanding organizational learning and its relationship to innovation abilities in this industry might also assist us to understand how this relationship works in other high tech industries such as computer manufacturing and telecommunications. Other characteristics such as its rich history of producing innovative products, its R&D laboratory and its recent acquisition (twice) by other pharmaceutical companies make MSD-Organon a representative example of the pharmaceutical industry. The organization was also chosen for pragmatic reasons: namely, the R&D laboratory will be closed in the near future.

4.1 Data collection

The case yielded multiple sources of evidence, including secondary data such as annual reports from the period 1995-2008 and primary data such as in-depth interviews with researchers from the R&D laboratory. Data relating to Organon's research and development policy were sought mainly from the annual reports of Akzo Nobel and Schering-Plough, as these organizations specifically describe Organon as a sub-division. However, the annual reports of MSD itself do not mention Organon as a sub-division; thus, it was not possible to isolate data relating to the plant in Oss after 2008. During their interview, researchers were asked to reflect briefly on the innovation ability of the organization.

In-depth interviews with researchers were used as the primary source of information; these interviews were recorded and then transcribed. The theoretical propositions relating to organizational learning formed the reference point for the data collection and analysis. The propositions were refashioned into three topics, namely diversity vs. specialization, communication and coordination, and use of resources. A series of open sub-questions was then formulated for use in the interviews; these questions sought to address the interviewees' experiences both before *and* after the acquisitions:

[4] This Eurostat publication (Wilen, 2007) shows the distribution of R&D expenditure and R&D personnel across the range of economic sectors in Europe. Manufacturing industries account for the lion's share of R&D expenditure (81% of the total), with the pharmaceutical industry being one of the most R&D-intensive sectors.

Diversity versus specialization:

a) What is the background of the researcher and what are their scientific achievements?
b) What is the turnover rate?
c) How quickly do newcomers adapt to the shared practices and beliefs? How does this process affect their innovation abilities and why?

Communication and coordination:

a) How do researchers working on multiple projects communicate and coordinate?
b) How do researchers perceive this communication and coordination as contributing to the generation of new ideas?

Use of resources:

a) How are the available resources described and perceived by the researchers?

The interviewees were requested to review the first draft of the case study report and to verify the descriptions and interpretations included therein. The interviewees, as mentioned above, were researchers and assistants working in the research and development laboratory. This department was specifically chosen because its primary task is to discover, develop and launch innovative medicines. The R&D department might be seen as the core department of any pharmaceutical company, where millions are invested in technology and people. If there is such a thing as two modes of learning, as March claims, and if they do indeed influence innovation, they should be recognizable in an R&D laboratory. By focusing on this R&D laboratory, the study is effectively applying theoretical sampling. Eleven people, found through the snowball sampling method, were interviewed between May and September 2011. Particular attention was paid to their position within the R&D department. Conversations with the first two interviewees revealed that they were involved in the development but not the discovery of drugs; it became evident that to understand how learning influences innovation ability, it would be necessary to interview researchers who were involved at various stages in the discovery *and* development of drugs. At the time of the interviews, six of the researchers were contributing to the discovery and exploratory development of drugs; four were contributing to the clinical development of drugs and one former researcher was functioning as head of the registration department. Two of the clinical researchers interviewed were no longer employed by MSD-Organon, having recently left the company.

4.2 Data analysis

All of the primary evidence was analysed according to the 'explanation building' technique. According to Yin (2009, p. 141), to explain how and why a phenomenon occurs, it is necessary to assume the existence of a set of causal links. He argues that the better case studies are those in which the explanation reflects some kind of theoretical proposition. The process of explanation building began here with the formulation of a series of propositions

regarding the key influences on innovation ability in a learning organization balancing the modes of exploration and exploitation. These propositions were then compared with the first interview transcript and revised as necessary. The transcript was then re-examined against the revised propositions. This process was repeated for all transcripts and at the end all revisions were compared. The case company

Organon, a pharmaceutical company of Dutch origin, was established in 1923. Its R&D laboratory is famous worldwide for its work in the field of gynaecology, including areas such as contraception, infertility, osteoporosis and endometriosis. It also plays an important role in immunology research. In 1969 Organon and AKU merged to create Akzo Pharma, the pharmaceutical division of Akzo Nobel, a medium-sized multinational firm (Gilsing & Nooteboom, 2006). Then, on November 19, 2007, the company was acquired by Schering-Plough. Less than two years later, in March 2009, the next fusion was announced. Merck & Co. bought Schering-Plough and began operating in Europe under the name MSD. According to *The Economist* (2009), Merck & Co.'s main reason for buying Schering-Plough was to double the number of drugs it had in late-stage development. The acquisition of Schering-Plough has also brought in significant over-the-counter and international sales, with 70% of the company's revenues coming from outside the United States. Following reorganization in 2011, it is expected that Merck & Co. will make cost savings of $3.5 billion a year. According to Merck & Co., the research teams in the two firms are complementary and do not overlap. This led people to wonder whose jobs would be cut. The question was answered in July 2010 when it was announced that eight R&D divisions would disappear the following year, one of them being the department in Oss[5].

The case seems simple at first – the shareholders of this pharmaceutical giant want a high return on their investment. An average of $5.8 milliards per year is spent on R&D activities, equal to 24% of the company's revenue, and centralization of these activities makes for increased efficiency, i.e. cost savings. The closure of the research laboratory in Oss alone represents a saving of about $130 million (Couwenbergh, 2011). But the question remains why Merck & Co. bought Schering-Plough in the first place. According to Higgins and Rodriguez (2006), one of the reasons why pharmaceutical companies merge with others is to supplement their R&D activities. Firms often adopt this strategy as a way of redressing their own R&D failings and for the positive effect it can have on their product pipeline and portfolio, post-acquisition. This was evident in Merck & Co.'s 2004 acquisition of Aton Pharmaceuticals Inc., a privately held biotechnology company. Describing the acquisition, Merck said: *'The acquisition will enhance its [Merck's] internal research efforts to develop potential new medicines for the treatment of cancer'* (*Wall Street Journal*, 2004b, cited in

[5] Merck & Co. plans to phase out operations at eight research sites over the next two years. These sites include: Montreal, Canada; Boxmeer (Nobilon facility only), Oss and Schaijk, Netherlands; Odense, Denmark; Waltrop, Germany; Newhouse, Scotland; and Cambridge (Kendall Square), Massachusetts, U.S. (Merck & Co., 2010).

Higgins & Rodriguez, 2006). Higgins and Rodriguez's argument is borne out by the fact that, in November 2003, only two out of the 11 products Merck had announced would be launched in 2002 were actually on the market.

Likewise, the acquisition of Schering-Plough in 2009 filled gaps in Merck & Co.'s pipeline. According to the company's Annual Report of 2008 (Schering-Plough, 2008) the acquisition of Organon BioSciences from Akzo Nobel has extended the current pipeline with key new projects (including asenapine[6] for schizophrenia and bipolar disease and sugammadex to reverse deep anaesthesia), as well as adding *'significant talent, including in key research and development functions'* (ibid., p. 3). Schering-Plough assigned $3.8 billion to acquire in-progress R&D projects from the laboratory in Oss, including projects studying animal health, women's health, the central nervous system and anaesthesia. These research projects are expected to generate cash flows in the period 2008-2013 (ibid., p. 43).

Nevertheless, from 2007 onwards, the number of patent applications being registered by the division in Oss declined steadily until the closure of the laboratory in July 2011 (Overbeeke, 2011). This tendency is visible in the following figure:

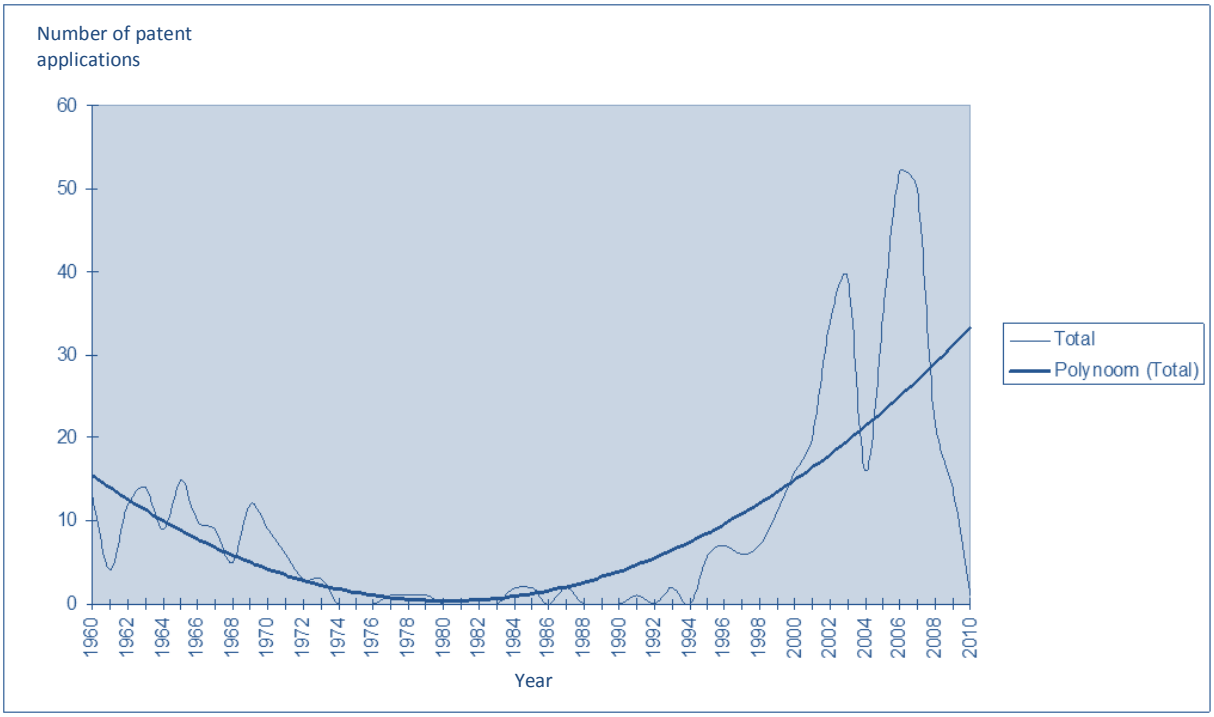


Figure 2: Number of patent applications per year

Source: (Overbeeke, 2011), adjusted by MB

The question remains how the innovation ability of an organization is affected by the process of organizational learning when the organization in question is undergoing acquisition.

[6] This was developed by Organon, then brought to the US market by Merck & Co. in 2009 under the name Saphris (Schering Plough, 2009)

5 Results and discussion

This chapter presents the findings and analysis in three main stages. It begins by describing the various phases of the research and development process. The information in this section is mainly drawn from the websites of Nefarma, the Dutch association of Innovative Drug Manufacturers (Vereniging Innovatieve Geneesmiddelen Nederland) and PhRMA, Pharmaceutical Research and Manufacturers of America[7]. The research policy and innovation ability of MSD-Organon are then described. This section makes use of secondary data, combined with the reflections of the researchers on the innovation ability of the organization. The final section describes and discusses the experiences of the interviewed researchers at each phase in the discovery and development process. Initially, the aim was to mainly investigate researchers' experiences in relation to those structural characteristics and organizational actions that influence learning and innovation ability and outline those specifically for the pharmaceutical industry. However, it quickly became evident during the conversations that the nature of these experiences had changed over the years, with the two acquisitions within a relatively short period of time being noted as turning points. Accordingly, the presentation and analysis of the results now addresses two sub-questions (both related to the main research question of how the organizational learning process in MSD-Organon has affected its innovation ability):

Sub-question 1: What structural characteristics and organizational actions are evident in Organon, a typical pharmaceutical company, and what has been their effect on learning and hence innovation ability?

Sub-question 2: How have these structural characteristics and organizational actions changed in the context of company acquisition, and what has been the effect of these changes on learning and hence innovation ability?

5.1 Phases in the research and development process

The process of discovering and developing a drug takes on average 15 years and costs billions of dollars. Only one in 10,000 molecules is selected and eventually comes onto the market as a therapeutic drug (Pharmaceutical Research and Manufacturers of America, n.d.; Vereniging Innovatieve Geneesmiddelen Nederland (b), n.d.). The process of discovering and developing innovative drugs is a complex one, demanding investment in people, technology and time by the pharmaceutical companies. It has a number of recognizable phases; although the titles of the various steps may differ slightly between companies, they do represent commonly shared definitions.

[7] MSD BV in the Netherlands and Merck & Co. in the US are members of these associations respectively.

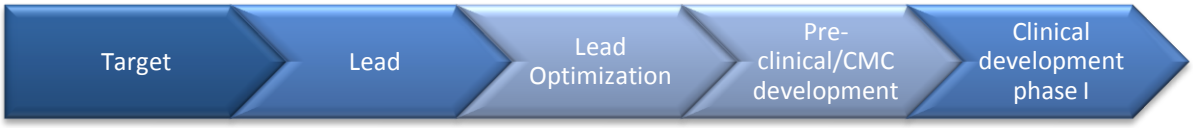
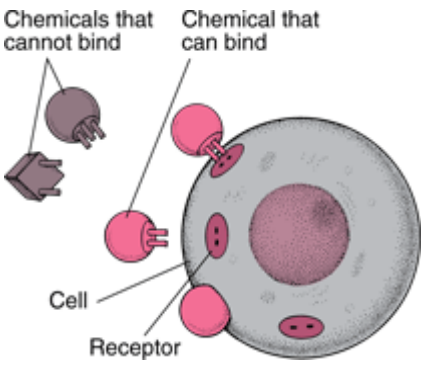


Figure 3: Research phase, a.k.a. discovery and exploratory development

The very first step in the process of drug discovery is the identification of the ***target***. This is the site in the human body which is intended to interact with the drug. This interaction involves the interaction between the drug and human cells or substances such as enzymes. The former is best explained by visualizing a key fitting into a lock. On their surface, most cells have many different receptors. A receptor is a molecule with three-dimensional structure, which enables substances outside the cell, such as hormones and neurotransmitters, to interact with it and thus to influence the activity of the cell. Drugs imitate those substances and use receptors in the same way, as shown in figure 4.



Instead of receptors some drugs target enzymes, which regulate the pace of chemical reactions in the human body. For example, the cholesterol-lowering drug Lovastatin decreases the rate of action of an enzyme called HMG-CoA reductase, which is critical in the production of cholesterol (Moroney, 2007). To sum up, the identification of the target involves specifying the molecule or enzyme which plays a crucial role in a particular disease.

Figure 4: A perfect fit

Source: (Moroney, 2007)

The next step in the drug discovery phase involves screening thousands of compounds for biologic activity on the target in order to identify '***lead*** compounds'. Once identified, even though they already possess desirable properties for interacting with the target, these molecules need to be modified to achieve optimal effectiveness and minimal toxicity, a process known as ***lead optimization.*** Out of this step potential drugs are developed, though on average it takes 12 years for a new molecular entity to reach the patient. Four years are needed for ***pre-clinical/chemistry, manufacturing and control (CMC) development,*** six years for clinical research and two years for registration and marketing and sales (Vereniging Innovatieve Geneesmiddelen Nederland (a), n.d.). In general, pre-clinical development involves animal testing to test the efficacy and toxicity of the new drug. In the Netherlands, the Law on Animal Testing forbids testing on animals unless there is no alternative way of proving the drug is safe to be tested in humans. When this has been established, the drug development enters ***clinical development phase I.*** Now the potential drug is tested on a small number of healthy, usually male, volunteers. The aim is to discover how the drug

affects humans, especially in terms of safety and toxicity. The toxicity level is determined; that is, at what dose toxicity first appears.

Figure 5: Development phase, a.k.a. full development and launch

Next, the efficacy of the drug is tested, i.e. whether it is effective against the selected target. In addition, the optimal dose is developed, where optimal stands for effective and safe. In this ***clinical development phase II*** a small group of patients participate in controlled trials, in which a comparison is made between the effects of the new drug and a placebo. ***Clinical development phase III*** is the next step in the drug development process. This phase evaluates the efficacy and safety of the selected dose in large groups of patients. Just as in the previous phase it is a matter of controlled trials, but this time the new drug is compared with existing ones.

When sufficient data have been collected, the drug registration process starts, followed by the actual sales of the product. Development continues even after the drug has been introduced to the market. ***Clinical development phase IV*** involves studying unforeseen side effects, interactions with other drugs and the effect on special groups such as pregnant women and the elderly.

5.2 MSD-Organon research policy and innovation ability

5.2.1 Documentary evidence

The annual reports produced by Akzo Nobel between 1997 and 2006 include extensive documentation of the research agenda of the company's pharmaceutical subsidiaries, with Organon as a principal contributor. One of the economic indicators of innovation (Jansen, Van de Vrande & Volberda, 2008), R&D expenditure, calculated as a percentage of revenues, grew from 14% in 1997 to 19% in 2006. The average R&D expenditure in the Netherlands in 2006 was reported to be 13% (EIM report, cited by Jansen et al., 2008, p. 18), which puts Organon in an above average position and indicates a capital-intensive innovation process.

The annual report from 2006 (Akzo Nobel, 2006) reveals Organon to be operating in four main therapeutic areas, namely gynaecology, fertility, neuroscience and anaesthesia. In the first two areas the company has a proven record going back over 75 years, while it has been doing pioneering work in the field of anaesthesia for the past 35 years. 'Innovative prescription medicines' are the company's trademark; its ambition in 2006 was to strengthen its existing portfolio while reinforcing its neuroscience portfolio and starting initiatives in the field of biotechnology. Immunology and specific areas of oncology also

featured as research areas. At this point, the company strategy was one of growth, with products being distributed in 100 countries. In terms of the pipeline, the report describes the company as having multiple products in the late development stage and the ambition to file at least one major compound per year on average.

Similar messages concerning the pipeline are to be found in the annual report of 2005 (Akzo Nobel, 2005). One distinctive point here is the focus on collaboration, specifically in the field of biotechnology. The facilities in Oss and Newhouse were seen as crucial for developing New Biological Entities in cooperation with diverse partners in the US and France for instance. Initiatives were also put in place to supply family health programmes in developing countries. A point worthy of note in the annual report of 2004 (Akzo Nobel, 2004) is the radical change in R&D structure and policy. The organizational structure was adapted to cover the entire process from the early exploratory phase to the showing of proof of concept. It was believed that this structure would help generate new, creative ideas and fill the pipeline with innovative products. The annual report of 2003 (Akzo Nobel, 2003) notes that R&D teams have a role to play in ensuring an optimal balance between the development and launch of promising products. The pipeline at that time was evaluated as 'high promise' for a medium-sized pharmaceutical company.

The company's ambition to discover and develop innovative prescription drugs is evident throughout all its annual reports.

5.2.2 Interviewees' reflections

The researchers saw the products already on the market as indicators of Organon's innovative ability. They referred to the market size and diversity of these products. The general view was that Organon was mostly known for its women's health products. Traditional women's health markets like Europe and the US were seen as relatively small compared to the markets emerging for such products in India and China. According to some researchers, Schering-Plough's portfolio of women's health products was aimed at these new markets. Moreover, the general impression was that the organization has the twin aims of producing compounds for known targets which offer significantly better results than existing products, and of producing compounds for unknown targets. The number of targets was felt to be important, as working on more targets, or taking *'more shots at the goal'*, was seen as a way of maximizing the potential of the organization. Researchers saw working on new targets as a challenging but desirable part of their work.

The researchers also described the pipeline as a suitable measurement tool for assessing the innovation ability of a company. According to the interviewees, the pipeline composition changes when decisions are made concerning clinical trials, especially in the late development stage. For instance, adjusting the investment in a clinical trial from 20 million to 200 million is an indicator of the potential importance of the drug – this is reflected in the pipeline projections. Under both Organon and Schering-Plough, around 10 to 15 projects

were being conducted at any one time in any one area, for instance immunology. The researchers were convinced that running this many projects maximized the likelihood of their being the first to come out with a radical innovation. But their experience changed with the MSD acquisition. The number of projects was downsized to about three and, according to CJ (2011), they *'got the feeling it was not going well'*. The desire for innovation was replaced by a desire to stay safe. He elaborated:

> *'The big companies are cutting research out; they do not wish to concentrate on innovation, but to play safe. And you play safe when you concentrate on products already on the market, which can be improved. A lot of research has already been done, it's easier to know what can be improved and it may be faster. Besides, the generic companies do not find this very interesting, they are keen on finding new issues they can quickly jump on.'*

Another relevant indicator, according to the interviewees, was the number of patent applications. Usually, these were filed in the early discovery phase, ideally, to protect a class of compounds. In some cases it was not at all certain that the compound eventually used for a drug would even be part of this class of compounds; the group might contain the appropriate generic characteristics, but the optimization process might identify an alternative compound which was ten times more effective. A new compound patent application would then have to be filed. In addition to compound patents, there were at least three other kinds of patents: device patents, application patents and composition patents (PvW, 2011). Device patents protect the devices required for the administration of some drugs, for example pens. Applications refer to the therapeutic area the compound is aiming at. In the development process it may be discovered that a compound originally targeting rheumatism also targets cancer. In such a case, two separate patents are filed. Composition patents protect specific combinations of main compounds, excipients and dosage form. The diversity of patents is an indicator of the breadth of a department's research activities. In this case, the number of patent applications dropped after each acquisition as more projects in discovery and early development were halted (PvW, 2011).

5.3 Structural characteristics and organizational actions typical for Organon

As outlined in the theoretical background, March's model was used to formulate nine propositions. These propositions address the structural characteristics and organizational actions to be considered by any organization striving to be first to bring a new product onto the market and seeking to strike a balance in its exploration and exploitation of knowledge. The following paragraphs assess the applicability of the model to the investigated company before the acquisitions and offer a pharmaceutical innovation prediction model.

5.3.1 Slow learning rate

The first proposition stated that individuals who adapt slowly to the organizational code are associated with raising the level of diversity within the organization, and by extension the

time spent on learning and exploration. Organizational code may be defined as the beliefs, routines, norms and procedures within an organization. A desirable level of diversity is maintained when employees have the time and freedom to experience how teams work, without being forced to adjust to the established norms and procedures. The researchers engaged in discovery and exploratory development enjoyed this advantage when they were working under Organon's management. One of the researchers explained:

> *'It is important to understand what the others are doing. I know when I started in my first lead optimization team, I knew a bit about what the pharmacologist was doing, but the theory he was dealing with was all new. And then you learn a lot from talking to people and they learn from you, you learn from them...it doesn't take one day, it is just, sometimes you need to hear stuff five times and only then you understand...In the beginning it was sometimes frustrating, I didn't understand anything. Time passes by and you understand more. When you do not understand stuff, you need to estimate, OK is this important for me at this moment and for the whole team and for the topic we are dealing with, to want to understand it all?'* (CJ, 2011)

The above quote shows the researchers had a degree of freedom to decide what was relevant to their work and what was not, and how long to spend investigating a new area. Projects were allowed to continue because somebody believed in the ideas and resources were found accordingly. In some cases the organization committed itself to long-term projects in which even those involved started to doubt if there would be any useful outcome. Diversity is preserved in the discovery and exploratory research phase as long as researchers are free to decide which topics are relevant to them. By extension, the more time individuals have to adjust to an organizational code, the greater the long-term benefit to that code.

The researchers engaged in full development and launch phase had a different perspective on the need for adjustment to organizational beliefs, norms, routines and procedures. The routines and procedures in clinical trials are strictly regulated by The Human Subjects in Medical Research Act[8]. The safety of the participants is paramount (Ministry of Health, Welfare and Sport, 2005), and the process is linear and transparent in nature: *'...the procedure in clinical trials is almost the same; you need patients, hospitals, time lines and quality...safety on top. When you finish phase II you move to phase III'* (JE, 2011), and: *"You have a protocol but also how to write a protocol, you can't change anything, everything is regulated to ensure you stick to the rules, that you are working in a tidy and neat way'* (EH, 2011). Consequently, researchers are expected to learn quickly how things are done and to follow the prescribed structures. Under the Organon management, the organizational code was flexible enough to allow individuals to take over the tasks they were most interested in.

[8] Also known by its Dutch abbreviation WMO, Wet Medisch-wetenschappelijke Onderzoek met Mensen.

As one interviewee put it: *'Everyone is unique, everyone functions in their own way'* (EH, 2011).

Another point mentioned was that researchers were given the time to work on new studies as they arose; one interviewee was involved in a range of clinical trials, including the testing of a drug for treating breast cancer in menopausal women and a study related to thrombosis indications. Giving researchers the opportunity to switch between trials in diverse therapeutic areas, and the time to investigate them thoroughly, is a key mechanism for promoting long-term diversity in an organization. According to Argote & Ophir (2002), the movement of employees from one organizational unit to another may also be seen as a mechanism for transferring knowledge. Such employees are in a position to transfer both tacit and explicit knowledge; assuming they show willingness to both share and be influenced by new knowledge, they become effective knowledge channels. In organizational units with a focus on creating knowledge, and where units are engaged in similar tasks, employee movement has been shown to contribute to the creation of new knowledge and the improvement of organizational performance.

Overall, it can be concluded that the interviews highlighted the importance of specific structures and actions in stimulating diversity. However, the proposition that individuals who adapt slowly to the organizational code are associated with raising the level of diversity, and by extension the time spent by the organization on learning and exploration, appears to be valid only in the discovery and exploratory development phase. In the full development and launch phase, quick adaptation to the organizational code by employees helps bring innovative products onto the market. In this second phase, diversity is stimulated by transferring employees between organizational units carrying out similar tasks.

5.3.2 Learner heterogeneity

The second proposition stated that having a combination of fast and slow learners is closely linked to the level of organizational knowledge reached in the long term. The 'learning' involved is the process of adjusting to the organizational code and, as already mentioned in the theoretical background, there is seldom any incentive for people to learn slowly. On the contrary, in some settings, as will become clear later in this paragraph, it is advisable to learn quickly. For a researcher involved in discovery and exploratory research, however, learning quickly can leave them 'stuck in the middle' of a project; they may have a clear idea of what the problem is and its possible solution, but still not have found *the right* solution:

> *'We see sometimes that if somebody new looks at it, somebody who has not been working on it for years, they might see other options. I noticed this when working with two medicinal chemists on a project, as projects do not always run parallel. The last one I joined already had a chemist who had been working on it for two years, but it was a big project so a second chemist was needed. I joined and had a different approach from the person who had been dealing with it for two years; it very often works that*

way. The problem [the therapeutic area] is very clearly defined and often the approach to solve it as well. Why don't we try a completely different approach and why shouldn't we do this?' (PC, 2011)

In this situation, mixing individuals with different ideas about the treatment had a positive influence on the project, and it became a candidate for clinical trials. The individuals involved here were not necessarily fast and slow learners, but the second chemist was able to suggest a different approach because he was not locked into the pre-existing mindset. Under the Organon management, this was a structural characteristic which made it possible to mix learners and approaches. Although there is insufficient evidence to suggest that it happened regularly, it was possible, and as the quote indicates, it led to positive results. Argothe & Ophir argue that 'divergent thinking' supports creative solutions, quoting Nemeth's definition of divergent thinking as '*the process of considering an issue from multiple perspectives'* (Nemeth, 1992, cited by Argote & Ophir, 2002, p. 190). A heterogeneous group consisting of members with diverse views, functions and backgrounds contributes to innovation, especially in new product development (2002).

By contrast, new members of the clinical trial teams do not necessarily contribute to innovation. Under Organon management in such multidisciplinary teams, each member has knowledge about and is responsible for a specific part of the trial. A new team member does not yet have an overview of the whole process, nor the experience to spot the flaws in it. According to one of the clinical researchers, who had worked for Organon for many years: '*What you get one meeting later is that the work is not done, because they had no time for it or were inexperienced and I needed to get somebody else and obviously that was not done yet'* (JE, 2011). In this example, the researcher was referring to data which needed to be processed and analysed so that the team could see their results to that point, how many compounds had been identified, and what effects – specifically what side effects – had been registered. It might be argued that it is important to learn quickly in this part of the development process because of the need to accurately follow clinical trial protocol. This protocol offers structures, guidelines and time lines, and it is essential to follow these for a successful trial (Ministry of Health, Welfare and Sport, 2005).

In conclusion, heterogeneity among learners was found to have a positive effect in the discovery and exploratory phase, but not necessarily in the full development and launch phase; the former is characterized by the need for diverse ideas and approaches and the latter by the need to quickly develop the potential innovation. It seems reasonable to conclude that encouraging scientists with the same specialization but diverse approaches to collaborate during a project might lead to higher level of knowledge on the long run, especially in discovery and exploratory research, or when a new scientist is joining an established project.

5.3.3 New employees' adaptation rate, turnover, and rules for selecting new employees

The third proposition is related to new employees and their adaptation to the organizational code. It states that new employees who adapt slowly to the organizational code are more likely to contribute to exploration. This effect is detected in combination with modest turnover rates. The rules for selecting new employees also contribute positively to the effect of turnover as a source of exploration. New employees are seen as major contributors to exploration and innovation. Given the close relationship between new employees' adaptation rate, turnover, and rules for selecting new employees, the third and fourth propositions will be analysed together.

From the interviews it became clear that working for Organon was like a best friend relationship; it was a long term commitment for many interviewees. The shortest time spent by the interviewees at the company was 6 years, the longest 27.5 years. One of the respondents got to know the company after his graduation in 1988, took a liking to it, was hired and had worked there ever since. The researcher with the shortest time at the company observed that if you didn't work there for at least for 10 years, you didn't actually count. Another researcher provided further clarification:

> '*Those people [referring to employees already at the company when he wanted to lead a project] had 10 years of experience, before you can actually oversee it, you cannot just start and say I want to be a project leader, it doesn't work this way. It is too complex and difficult. You work with Americans, Japanese and Chinese, many cultures, you need to have some luggage and you should stand steady on your feet before you can lead such a process.'* (DZ, 2011)

Two researchers commented that many people worked for the company for 40 years – these were considered the 'old timers', rather than those who had been there a mere 10 to 15 years. Overall, it can be concluded that there was a slow turnover rate in research and development at the company. What was consistently reported though was regular turnover within the department, with little difference between discovery and exploratory development and full development and launch. For instance, one respondent, who had worked there for 14 years, changed positions every two to four years. As drug discovery and development takes several years, the team working on a project changes through the years. There are two main reasons for this. First, when the project has to be moved forward to the next step, for example from lead optimization to pre-clinical development, the project is literally handed over to the next group of people. Second, some people become so attached to a project that they request a position change and move forward with the project to the next team. Thus the researchers develop along with the project. This practice seems to be common. Other researchers stick to working in one team. One of the respondents characterized this as the organization developing generalists and specialists. Project leaders emerge from among the generalists, while having specialists means there is someone to turn to when test results need to be reviewed. As one of the researchers commented: '*At any*

given moment, you know very well what expertise there is in the company, whom you can turn to, to discuss the outcomes, review the results and ask to think along with you' (MvdV, 2011). This 'who knows what' knowledge or transactive memory system (Wegner, 1986 and 1995, cited by Argote & Ophir, 2002) has been found to improve group performance in terms of knowledge creation as employees are able to recall task-related knowledge and make fewer mistakes. This group awareness of expertise facilitates the sharing of information and the recall of unique information, processes related to knowledge transfer.

The slow but regular turnover within research and development can be seen as having a positive effect on the department's collective learning curve. It allows some researchers to grow within the organization and keep the know-how in-house. At the same time, researchers move from one team to another, sometimes even from one therapeutic area to another, making it possible to explore their knowledge. Others specialize in a particular area, making it possible to exploit their knowledge. These findings are in line with the conclusions of Miller, Zhao & Calantone (2006), who extend March's model by adding the importance of interpersonal learning and tacit knowledge in organizations. Citing Polanyi, they argue that skilful action implies some kind of tacit knowledge, which they see as complementary to the explicit knowledge captured in the organizational code. They go on to argue that without tacit knowledge, the organizational code cannot be exploited. In their model they show that slow personnel turnover contributes to the accumulation of tacit knowledge and to the stimulation of interpersonal knowledge creation. This is especially the case when a knowledge domain includes a large number of elements which have to be learned; these take longer to master and diffuse than simple knowledge.

Another positive effect of such position changes is their impact on researchers' motivation and satisfaction, which has implications for innovation and diversity. One of the researchers reported:

> *'In 1999 I started doing something else. It became boring, always the same...at a certain moment, you have seen it all. The immunology group was different, very enthusiastic, and it still like this. It is just inspiring to work there. I learned many new things, I could start new stuff, think it through For example, what do you already know about how a compound works in humans and what do we have to look at when controlling for side effects, like diabetes, bone fractures, these kinds of issues; which compound should we use to check the blood and such kind of things.'* (MvdV, 2011)

Another researcher shared a similar experience:

> *'I started in the lab, working on chemical synthesis for 12 years. And in those years I really liked it, but I found myself becoming more interested in questions like: why am I making compound A and not compound B? Maybe B is much better. And then I started to wonder why the boss was making certain decisions. One day you start discussing the issue with your boss and then a moment comes when he says: "You do it yourself." So*

step by step, I became a leader of a group of chemists and took on the responsibility.' (PC, 2011)

Both researchers highlighted how their change in position helped stimulate learning and generate new ideas. A third researcher described how a change in function had the same effect; in his case, the change was not in therapeutic area but in the type of tasks he was called upon to perform:

'As a senior scientist you guide junior employees. You also have to present the results and lead discussions in bigger settings, and present to the management. Such tasks make this job so much fun for me, exciting and diverse. And up to last year I was happy…yes, to work as a researcher in such an environment, such an innovative environment, it is just very innovative. Everything you make is new, as every molecule you make is a new molecule, which does not exist in the world, at least you hope not. If you make something that is already known, you cannot put a patent on it and ultimately, you can never earn money with it. But every time, you get a kick out of thinking of something and making a molecule out of it.' (CJ, 2011)

A third reason was suggested why a slow turnover rate can have a positive effect on discovery and development. Staff changes increase the risk of inexperienced staff making mistakes, compromising the results of clinical trials and leading to significant delay. Minor changes in animal testing for instance can lead to the experiment not running anymore. A change in statistics professional not experienced in IVF clinical trials is another example, as a change like this during a trial led to a delay. A researcher working in the discovery function commented on the effect numerous management changes can have:

'The longer a project stands, the more chances it has to succeed…a lot of changes in management, mergers, every new manager prioritizes the portfolio again, otherwise he does not get his own signature on it. At the end this impacts the productivity, for the simple reason that if you have one project for two years and another one for two years you actually have two halves, so it means you end up with nothing.' (JU, 2011)

As will become clear in the discussion of the strategic actions taken after Organon's consolidation, this was indeed the case with Organon; a number of projects were halted early in the process and all previous efforts at exploration were lost.

In addition to the delays and ideas lost as a result of turnover, it was repeatedly reported that a significant idea generator is the knowledge which has been built up over the years. This knowledge involves understanding the diverse functions and limitations of molecules. PC described this process:

'The characteristics of the compound determine whether it is absorbed by the bloodstream from the intestines. Some compounds are absorbed and some are not. So if a compound fits the target, if it is also selective, but it is not absorbed by the

> *bloodstream, you have nothing. But OK, the knowledge built up through the years makes you think, I know what I need to change in the compound for it to be absorbed. It might work with the next compound. Or you might have to make a hundred compounds first, as you also have to think of all the other things – among others, it has to come in the bloodstream, it has to be selective and it should be metabolic stable enough.'* (2011)

Robert J. Sternberg's investment theory of creativity offers an insight into how the above-mentioned motivation and thresholds of knowledge influence creativity. According to this theory, creative people are those who persistently pursue unknown or unfavourable ideas (Sternberg, 2006). He argues that creativity is largely a matter of choice, not merely a skill and as such, it can be developed. The creative process relies on six interrelated resources: knowledge, intellectual skills, thinking style, personality, motivation and environment. However, it is too simplistic to say that together, these make up creativity. Minimum thresholds are required for some, below which creativity is impossible even if the other resources are present – knowledge is one of these. The ability to see the functions and limitations of a molecule simultaneously requires researchers to have crossed such a knowledge threshold. In different contexts, some resources may compensate for the lack of others, for example motivation may compensate for environment. High levels of intelligence and motivation may serve to strengthen the other resources. Sternberg asserts the value of motivation, claiming that people are rarely creative if they do not really love what they are doing. Interviewees were not questioned specifically about their love for their work, but they repeatedly spoke about the essence of their work with enthusiasm, pride, interest and warm feelings.

All the above does not support the notion that modest turnover contributes to the exploration of new ideas. It suggests that *slow* turnover within a pool of researchers has positive effects on idea generation and development in the context of drug discovery and development. However, the effect must also be taken into account of deliberately selecting new employees who will adapt slowly to the organizational code. As the majority of the researchers interviewed were recruited long ago, it was not possible to establish the current selection criteria, though they were able to explain how and why they were able to change position within the department, some frequently. Two main kinds of selection rules emerged. The first group related to expertise and capacity, for example knowledge about new technology used mainly for discovery purposes, such as computer modelling, or capacity to lead a team. Specific knowledge was seen to matter more than experience: *'When I started I knew nothing about research and development in the pharmaceutical industry, I knew all about fertility. I learned about research'* (EH, 2011). This researcher commented that in the early days she had a mentor she could turn to with questions. During the first clinical trial she had to lead, the mentor was present and guided her. The second time, she had to lead it alone and the third time, she organized the trial as she had been taught to do. It is not obvious whether this adaption process went slowly or quickly. By

learning on the job and showing growth and understanding of the whole process, a researcher is able to earn more and more responsibilities and eventually lead a team or a project. The second group of rules for selecting employees from the researcher pool related to their willingness to change positions and even therapeutic areas. In some cases, this willingness was more important than having specific knowledge, and would lead to them being asked to take on key positions. JH started as a chemist; after some years he moved into regulatory affairs, where he dealt with registration issues. He was then asked to join the clinical trials. For this transfer a Master's degree was needed, so he completed a Master's in pharmaceutical medicine in England. The majority of the interviewed researchers described similar career paths within research and development.

It cannot be concluded that clear rules were applied to ensure the selection of employees with new and different beliefs and norms. Neither can it be said that there were any incentives for slow or quick learners. What is revealed though is a flexible organizational code, with norms and beliefs which stimulated employees to learn and develop by pursuing higher education and changing positions; they were encouraged to feel free to explore and exploit ideas related to the process and content of drug discovery and development. All the interviewees described their changes in position under the Organon management with enthusiasm. The chances they were given to grow are evidence of an inspiring environment where people were valued for their expertise, capacity and motivation, and were appointed accordingly. Ultimately, the slow turnover within the pool of researchers helped the company collectively reach a knowledge threshold which in turn positively affected idea generation and development.

5.3.4 Variation in performance

The fifth proposition relates variation in performance to the competitive position of an organization. Variation in performance is seen as the effect of variations in knowledge and learning process. Variation in knowledge is a result of variation in the type of learning; the learning process is varied by the introduction of new features such as technology and people into the organization. Certain combinations of learning types and learning processes help an organization achieve a competitive position when its aim is to come out first.

The first element affecting variation in performance is the presence of learning aiming at radical innovations and learning aiming at incremental innovations. Researchers in both discovery and exploratory development and full development and launch reported knowledge diversity within the organization, describing how there were chemists, biologists, pharmacologists, researchers working with computer modelling, researchers working in the laboratory with petri dishes and fume cupboards, while others set up animal models. Clinical trial teams included toxicologists, statisticians, marketing specialists, regulatory affairs specialists and doctors. The above represents just a fraction of the knowledge diversity in the R&D laboratory under Organon management. All these specialists are involved in the

process of drug discovery and development, working in carefully appointed teams whose composition changes regularly.

There was clear evidence of the interdependence between individuals and between teams, arising from the specialized nature of their knowledge. The knowledge held by one individual or team represents one part of the total knowledge base needed to get a potential compound on the market; for example toxicologists research the toxicity of the potential drug before the drug is administrated to an animal and the bioavailability checked. This sequential interdependency was also reported between teams from the two main phases in the process, namely the discovery and exploratory development teams and the full development and launch teams. As one of the clinical researchers commented:

> *'There weren't a lot of new Ideas for the development of new products; there were ideas about how to specifically develop a compound but those were figured out and decided upon before the compound came to us. For example we had ideas about the use of the contraception ring, the Nuvaring, but to be able to do something with those ideas you need the exploratory research.'* (EH, 2011)

This comment is in line with the clear distinction between discovery and exploratory development, and clinical research trials. The clinical trials teams depend on the ideas generated and developed by the lead optimization teams. Clinical researchers generate and develop ideas aimed at optimizing clinical trials, often by experimenting with numbers of patients, and introducing specific measurement moments and report writing structures, while teams in discovery and exploratory testing apply technology such as computer modelling. It is reasonable to conclude that these experiments and technologies lead to variations in learning process at different stages of drug discovery and development.

However, all the teams are ultimately working on one potential compound or series of compounds, all aiming at developing and launching an innovative drug – activities in line with the goals and strategy of Organon. This potential compound or series of compounds might be active against a known or unknown target. The nature of the target determines the level of risk associated with a project, and by extension the type of learning involved. It is reasonable to conclude that where an unknown target is involved, learning aims at radical innovation, while where a known target is the starting point, learning predominates that aims at incremental innovation. Sternberg (2006) coins these processes as the different ways creative contributors use their creativity, distinguishing between what he calls redirections and replications. It is the type and amount of creativity involved in these distinctive creative modes both implying an act of development. In the context of drug development, where a distinction is made between radical, substantial and incremental drugs, it can be concluded that learning types and processes vary. What is even more significant and empirically based is that the diverse range of expertise is organized in teams where, as it will be explained later, the team members are in frequent contact. This structure, which is typical in large and traditional pharmaceutical companies, has many advantages over the so-called layer-cake

approach (Nathan, 2007). Optimal drug development requires the simultaneous involvement of experts from a range of disciplines from the beginning, for instance to combine chemical and pharmacologic viewpoints when choosing compound libraries or selecting and modifying early lead compounds.

5.3.5 Coordination between parts

The sixth proposition states that less coordination and more loosely coupled parts are related to an organization's potential to make radical innovations. March bases this argument on the idea that organizations that develop effective communication and coordination are expected on average to do better than those that are more loosely coupled. They become more reliable; however, this reliability has a price – it reduces the chance of coming out first among competitors.

The notion of loosely coupled systems goes back to Weick (Eisenhardt & Bhatia, 2002). Loosely coupled systems maintain the identity and uniqueness of their basic elements. They have the potential to produce a greater number of novel solutions and are more effective in adapting to changing environmental conditions than are tightly coupled systems. This superior performance is the result of having many independent elements that 'know' the environment and are more skilled at sensing when and where to change than tightly coupled systems. Saxenian's Silicon Valley study addresses this issue; she describes the interconnectedness of firms and sub-units within firms in Silicon Valley, implying they are loosely coupled systems (Eisenhardt & Bhatia, 2002). She describes an open culture and shows how employee transfer between firms was the norm, demonstrating how this contributed to the adaptation ability of the region during the 80s. By contrast, the firms on Route 128 failed to adapt to the emerging personal computer market, as the region was made up mainly of standalone and vertically integrated organizations. She points out that the main production unit in Silicon Valley was the loosely coupled engineering team, which consisted of individuals with a strong sense of entrepreneurship. These would be organized around a technologically driven project and were linked to the various levels and functions in the company by means of intense, informal communication. The above leads to the question how can the type of system be recognized as loosely or tightly coupled where two possible candidates stand out: the elements themselves and the way those elements create order. The elements represent the parts in an organization, i.e. the result of how the work is divided. The ways the elements create order represent the way the parts coordinate in order to get the work done. According to Orton & Weick (1990), investigating both leads to a definition of systems which can help preserve the dialectical character of the loose coupled concept.

For this reason, the first point of relevance for this proposition is the division of work. In general, the structure under Organon was a hybrid of process and matrix structures. On the one hand, the core processes in drug discovery and development were handled by multidisciplinary teams: these were the target discovery, lead finding, lead optimization, pre-

clinical development and clinical trial teams, representing the major steps in the process. Over the years, an overlapping team also emerged, the so-called proof of concept team, which combined functions from lead optimization and pre-clinical development. Each team consisted of functions necessary to complete one step related to the final product, a new drug. These teams were usually managed by a process owner, who was also a representative of one of the disciplines in the team. This is typical for a process-structured organization (Cummings & Worley, 2005, p. 280).

On the other hand, signs of a matrix structure were also detected. There were dual chains of command; for instance a pharmacologist in a lead optimization team would have to report to both the lead optimization team manager and the functional manager of all pharmacologists. The functional managers represented those disciplines practically related to drug discovery and development. It was possible for a discipline representative, for example a chemist, simultaneously to be a member of a lead finding team and the manager of a group of analysts. The main teams, known as project teams and organized around the core processes in drug discovery and development, showed high levels of interdependence, indicating the sequential character of product development. For example, drug safety and effectiveness had to be established to be at a certain level, a step taken at the beginning of the process, before the project could be handed over to animal testing. The level of interdependence was related to the content of their work, i.e. the characteristics of the compound. The sub-teams, known as groups, showed no direct relation with each other and represented one specific discipline each.

Another distinctive feature of the organization was its creation of one division per therapeutic area. These therapeutic areas represented the company's drug profile, and included women's health, immunology, anaesthesia and analgesia. This profile was subject to change when the company adjusted its strategic direction – for example when it decided to enter the field of oncology – and interested researchers were given the opportunity to switch from one area to another. Researchers in discovery and early development found it easy to switch between existing therapeutic areas, as PC explained:

> '*Let me put it like this, I can just switch. I am working for an immunology project right now, but the next one could be in women's health. For me as a chemist, medicinal chemist...fine you need to read about it and become familiar with the topic, but in principle it is making a new structure [a compound] which has to meet the criteria; it should fit the target, it should be absorbed, it cannot metabolise, so it doesn't matter if it is women's health or immunology.'* (PC, 2011)

However, researchers in full development and launch reported the opposite experience. One graduate physician and clinical researcher in fertility projects found it very difficult even to switch between specialisms within fertility:

> '*You actually had three branches in women's health: fertility, contraception and menopause, which was later stopped [menopause].But if you're in fertility, then you did nothing with the other two branches. But then the menopause group had to stop, and then you had those people being transferred to the other two branches. This sometimes made it difficult for those people. For example, in fertility there were three of us, two that had been working there for a very long time and me; I have a PhD in fertility. It is very difficult when you know nothing to reach a certain level.'* (EH, 2011)

In short it can be concluded that, although the main project teams were typical multidisciplinary teams, the ones in discovery and early development were more flexible than the ones in full development and launch in terms of who actually represented those disciplines.

Directly related to the division of work and repeatedly mentioned by researchers in both discovery and early development and full development and launch was the multidimensional character of the work itself. The researchers agreed that the diversity of tasks was what made their work interesting and enjoyable, as they were expected to focus on content, process, short- and long-term issues simultaneously. They were used, for instance, to coming up with an idea, thinking of a plan of approach, writing it down, acting upon it, reporting the outcome and following up accordingly (MJvL, 2011). PC reported how his contact with diverse disciplines supported his own idea generation:

> *'You have to deal with so many things. I actually graduated in chemistry, but gradually became involved in biology. Biologists are in the project teams as well as people working with computers, with computer modelling of proteins, that kind of stuff. So you need to know a little bit of everything, to know where you get your ideas from, to be able to translate it towards your task, the making of a molecule that is the optimal compound. This is why it is so nice, it is not just chemistry anymore.'* (PC, 2011)

Clinical researcher EH described having similar experiences:

> '*I am a physician, I have studied medicine, and I was responsible for the content of medical studies. So writing the protocol, the report, but also during the study ... it's a bit tricky, because when it was still Organon, we were involved from our positions, in one or two studies. And you were truly responsible for everything in that study, the project management, budgeting, ordering medication, contacting CRAs [clinical assistant researchers], selecting the countries in which the study would be conducted, and writing the protocols and answering medical questions during the study. Also when the data was entered into the system, it had to be reviewed to see if it was logical, or there could be questions about it. We were, you were actually there for the entire study, with the clinical trial team, with the people who build the data, with the statisticians, with the people handling the medication, dealing with the regulatory affairs, and contact with the authorities. This was the position I was in at Organon*.

> *That was a really nice feature, you felt responsible for a study, and that actually worked out very well, very busy but also great to do.'* (EH, 2011)

This is illustrative of Organon's approach of combining content and process-oriented tasks. It also reveals another related characteristic of the division of tasks in the organization, namely the level of responsibility and the authority given to the teams. This was repeatedly mentioned by researchers in both discovery and early development and full development and launch. Being 'truly responsible' was described as a nice feeling; individuals responded positively to the sense of team responsibility. Researchers repeatedly used phrases like 'highly motivated', 'you do it together', 'transparency' and 'hard workers', linking them to the achievement of the final goal. EH explained: *'In general we always worked hard in Oss, everybody felt very responsible for what was going on and that's why studies were done very quickly and very effectively'* (EH, 2011). Another researcher said: *'You always work in a project team with experts who are very competent in their own fields, but collectively, the team has to work towards one goal'* (WD, 2011). On the one hand, the researchers felt individually responsible; on the other hand, they were dependent upon each other – hence, the central role of the teams.

This central role meant teams not only had responsibility for achieving the desired results as a group, they also had the authority to decide how to do this. The interviewees referred repeatedly to the freedom they had to make decisions regarding the content of action or the form this action would take:

> *'Together with my bosses, the statistician and with more people from other departments, we were doing the work. Few people actually interfered because there was nobody else with as much knowledge about the trials and the new research outside the department. You could do what you wanted, until the results were given to people in higher management for review. If they understood what we said, then it was good.'* (EH, 2011)

WS also elaborated on this topic:

> *'The team had some authority to make decisions; the programme management of course had the final responsibility for the new drug. Let's take Livial; it works against hot flushes, osteoporosis and other indications, so there are multiple teams around it. I was the leader of the group related to osteoporosis, so the people in the team, the different disciplines, monitored the qualities and quantities according to the set rules. There was a very direct, very short link with the management via the programme manager.'* (WS, 2011)

Unresolved Issues like the safety profile of a drug were brought to the attention of the different teams during regular meetings, so teams took measures to investigate these (WS,

2011). The target discovery team was another example of a team empowered to decide on sub-projects and the deployment of manpower:

> *'So you were in a team with other people who all had their own targets, and you looked to make improvements. The project was called Oocyte Embryo and Implantation, and everyone in this project looked at a different target, at different proteins. So you were actually by yourself searching for literature and possible external cooperation to evaluate the target and its possibilities. But as a team you sat together to monitor the whole and to decide which were the best targets to continue working on and which should be prioritized. Sometimes you had to compromise with manpower, with your own analysts, if one target didn't go that well and another went much better. So you would allow two of your own analysts to assist the others. In this way you try to help the whole team move forward.'* (MJvL, 2011)

The second point of relevance to this proposition is the coordination of work under Organon. Researchers in both discovery and early development and full development and launch had regular meetings with their teams. For instance, the target discovery team met once per week, the lead optimization team once per month, single discipline sub-teams once per week and the clinical trial teams once every six weeks. Some clinical trial team meetings were scheduled a year ahead. In between the meetings it was common practice to call a colleague or stop by their room. During meetings, the progress of the work was discussed and monitored by the teams. As a result of these discussions, decisions were made, for instance about which compounds merited further investigation:

> *'I was meeting my team once per week, for about an hour: how does the work look this week and what have we done? Because the steps follow one after another. See, while this group is working with the results of the first group, the first group starts testing the next series of compounds. It is like a line in a factory. At the end you choose two or three compounds to test further in the mouse and then the bio-analysis has to be done.'* (WD, 2011)

Similarly, meetings were the chosen forum for coordinating with partners outside the organization, such as hospitals:

> '*So you sit with the whole group: How is it going? Where do we stand? You also meet with the doctors who are involved in the trials in the hospitals, they are their patients. It's about transparency. We often had international meetings during trials, where the doctors would come together, for example from Eastern Europe, from Western Europe, from the States. Then we discussed the status of the trials, everyone, including the researchers, believing we were obliged to keep each other informed if we wanted people to believe in it and work harder for it.'* (JE, 2011)

The researchers reported few layers of management under Organon. In general, they described their experiences with the management as having a positive influence on their work, observing that short communication lines and the possibility for informal discussions were paramount. The managers, often also members of diverse teams, were themselves graduates in disciplines related to the pharmaceutical industry and had usually worked for the organization for many years. Moreover, the physical proximity of the management was seen as an advantage by the researchers, especially when discussing ideas such as the proposal to invest in developing a new dosage form for Livial. The managers seem to have played a supporting and facilitating role in the teams.

In addition to the regular meetings and informal communication, work was also coordinated in other ways, including through the standardization of output and norms. Standardization of output involves the formulation of objectives designed to lead to the desired final result. Standardization of norms was evident in the types of projects prioritized under Organon management. Mintzberg argues that organizations cannot rely on a single coordination mechanism, but that they usually place a premium on one (Mintzberg, 1989). This assumption is supported by what the interviewees revealed of the organization under Organon management. The three coordination mechanisms identified by the researchers seem to have reinforced each other, but the standardization of norms seems to have been the prime mechanism. For instance, the belief that the organization stood for innovation in the pharmaceutical industry was what underlay both its transparent and informal communication with all involved parties, and the formulation of team objectives aimed at coming out first. This belief steered both the forms and the topics of communication. The topics the organization chose to discuss were in turn directly related to the desired outcome.

On the whole, the division of work under Organon was reflected in the creation of flexible, multidisciplinary teams that favoured informal communication as a coordination mechanism. The teams enjoyed a degree of authority in decision-making; selective vertical and horizontal decentralization allowed the power to make certain decisions to be dispersed among the various layers and disciplines in the organization. The central place of the teams was also evident in the organization's chosen performance measures and compensation terms, which focused on team output (this will be discussed later). Initiative and creativity were valued by everyone in the organization; the teams can be seen as platforms of knowledge development, as loose parts of the whole, needing each other to bring the completed drug onto the market. Similar mechanisms were reported in Silicon Valley (Saxenian, 1994), where, initially, small companies were organized in such a way as to benefit from each other's discoveries and achievements. The composition of the teams, particularly in discovery and early development, changed regularly, in the same way that employees in Silicon Valley moved between companies. And yet a shared team spirit within Organon supported a feeling of belonging, and the discovery and development of drugs was seen as the company's shared goal, however limited one's individual contribution might be.

5.3.6 Specialized sub-parts

The seventh proposition states that an R&D laboratory balances exploitation and exploration by allowing its sub-parts to each specialize in one mode, thereby contributing to long-term competitive advantage. Balance is also sought between specialization in radical and in incremental innovation. This again raises the question of what constitutes a radical innovation and what constitutes an incremental one.

Within the industry, the compound itself is considered the most valuable discovery, along with indication areas and application forms. The discovery of a new compound may therefore be regarded as radical, while discoveries based on existing compounds may be called incremental. One interviewee, the head of the patents department, explained that for a compound to be named a radical discovery, it must satisfy three basic criteria:

> '*a) it has to be new; b) it has to be inventive, so not obvious; and c) it has to be usable. The last one is usually do-able. The first criterion, newness, is the focus of the department's literature search group. The second criterion is a subject of discussion. For instance, adding a hydrogen atom to a complex formula may leave it looking the same, but this could be considered inventive. It is inventive if everyone says it won't work, you cannot make this, but the researcher thinks of a method to make it, then it is clear, it is inventive. But if the literature says this method is standard procedure, it is no discovery and you cannot place a patent on it.'* (PvW, 2011)

The interviewed researchers agreed that Organon stood for radical discoveries, for '*really new compounds, not yet existing, for illnesses without cures*' (DZ, 2011). But there were also discoveries Organon was proud of, particularly in women's health, which were based on existing compounds but which offered substantially improved relief. Examples include Implanon, a contraceptive implant which offers protection for three years with minimal side effects, and Elonva, used in fertility treatments to replace multiple-days injections. These discoveries have been successful in terms of dosage forms, safety and effectiveness. Each discovery had its own dedicated team, focusing on either a previously unknown compound or on improving an existing compound, and seeking to optimize dosage form, safety and efficacy. As many teams would be working simultaneously, it happened regularly that the work of one would be prioritized. This was reported by researchers in both discovery and exploratory development and in full development and launch:

> '*Sometimes when we thought a big product was coming we prioritized it. This would influence the rest of the timeline, as often the same people were needed. But we thought: It could be a blockbuster, nothing must go wrong; we have to get to the finish line quickly. Those changes in timelines happened without any problems. When we needed something, we had to work on it, it happened.'* (JE, 2011)

In short, evidence was found that, under Organon, specialized sub-parts operated within the R&D department, and that a premium was placed on radical discoveries.

5.3.7 Organizational resources and mindsets

The eighth proposition addresses the contribution organizational resources and diversity of mindsets make to the development of radical and incremental innovations. March argues that within a single domain like an individual or a department, radical and incremental innovation will be mutually exclusive, as organizations have limited resources and individuals have different focuses. Researchers who focus on creativity, experimentation and exploration may be intrinsically motivated, while those who focus on acting appropriately, especially where rewards are concerned, may be extrinsically motivated. Gupta, Smith & Shalley (2006) question the assumption that exploration and exploitation are fundamentally incompatible, arguing that they are compatible where the various parts of the organization are loosely coupled. At the organizational level of analysis this is plausible, as it is easier for an organization to allocate resources for the exploration *and* exploitation of knowledge than it is for an individual. Gupta et al. challenge the assumption that it is lack of resources that prevents organizations from attempting to pursue explorative and exploitative activities simultaneously, pointing out that organizations often have access to diverse external resources (the authors distinguish between internal and external resources) such as information and networks. Makri and Geiger (2006) even argue that for R&D intensive firms, having an excess of resources has a positive impact on the use of science in innovation.

The interviewed researchers reported that two main types of resources are required, namely knowledge and technology. Knowledge is accessed in two ways: through publications and literature, and from other people. Under the Organon management, all the researchers had sufficient access to literature and publications.

Access to the knowledge of other people was cited as the researcher's most important resource, whether it is access to colleagues for information exchange or access to external contacts for the same reason. Researchers in discovery and exploratory development added that external contacts are important to idea generation. Idea generation is the end result of combining access to literature, cooperation with external parties, negative results and many discussions with colleagues (MvdV, 2011). *'You try to get ideas from anywhere possible. The teams have contacts with universities. You do nothing alone; actually you do it with the rest of the world. The team just tests those ideas'* (WD, 2011). Interviewees also referred to the role played by conferences:

> *'In this period [of discovery] it is also important to visit conferences, to stay up to date about the newest developments, to know where the ideas are going to. There were always good opportunities to do this...the most important conferences for our team were listed and it was decided who would go where, trying to divide the visits equally. If there was a specific congress about your target, you went, of course.'* (MJvL, 2011)

These visits were not just meant to generate ideas and enable researchers to stay up to date, but also to put the company on the map. They were seen as a long-term investment,

particularly in light of the opportunities they afforded for cooperation and networking with universities.

A second kind of external contact was seen merely as a resource by researchers. Whenever the organization is understaffed, it hires smaller companies to help out, for example with clinical trials. In discovery and exploratory development, tasks are outsourced not only because of understaffing but often because the company lacks the particular skillset needed to perform an activity. WD, a senior researcher in lead optimization, explained:

> '*A lot of the work we deal with here, what you are actually supposed to do, we might not have available. There are many small companies specializing in a particular issue and that might be the exact skill you need to buy in. It could be an animal model, for example. We have here an animal model for rheumatoid arthritis, but sometimes you want to test it in another model. So you just outsource it.'* (WD, 2011)

Access to internal knowledge from colleagues was highlighted as important. PC, a medicinal chemist, explained:

> '*Other resources are your colleagues. You talk a lot to colleagues, if there is an issue about absorption of an important compound, then you can discuss this with colleagues, you get and give tips. At any moment you know whom to turn to for which question. In past years there was a lot more scientific knowledge. We use the computer, but the process doesn't really differ. The only thing is that lately there is a lot more knowledge available, it feels like there's stacks of information you must go through.'* (PC, 2011)

For the researchers in full development and launch, specific disciplines were seen as the most important:

> *'First I think of the statistician, he is the most important in order to set up a study and to be able to work together, to be able to perform an analysis, to write a report, to answer questions from the authorities; you need a statistician to calculate the number of patients, to exclude some issues, that's the most important. But also other people involved in the study, people who know how to handle the contact with authorities, who know how to wrap up medication, actually everyone who builds the database.'* (EH, 2011)

Technology was the other key resource cited by the researchers. For the chemists, for instance, the software program used in synthesis was indispensable. This software was in fact developed within Organon.

No distinction was made between the above-mentioned resources in terms of their relative importance when working on new or existing compounds. Hence, no support was found for March's idea that individuals and departments choose resources specifically either for exploration or exploitation. Rather, the findings support the idea that the two modes are

compatible across different parts of the organization, as the organization itself is capable of allocating resources for both. This conclusion is strengthened by the evidence presented in the next section regarding the type of projects Organon chose to invest in. Referring to the questions whether an individual focus fosters either exploration or exploitation, and whether this is further stimulated by means of intrinsic or extrinsic motivation, no evidence was found of any extrinsic motivators such as individual rewards for prescribed behaviour. The next section discusses how Organon's targets revealed a focus on team rather than individual rewards.

5.3.8 Strategic actions

The ninth proposition relates to strategic actions aimed at increasing variation in performance. According to March, strategies for increased variation in performance, and hence variation in knowledge and learning process, are more attractive than those aimed at raising average performance and knowledge. In the long term, strategic actions represent the result of the organizational choice between investment in learning (exploration) and the consumption of current competencies (exploitation). If a company's position in the field matters, as it does in the pharmaceutical industry, and the number of competitors is increasing, it may well choose to focus its investment on learning.

Whether there was a strategic focus on exploration-related learning became apparent when the conversation turned to the type of projects pursued in Organon, the type of objectives set within the company and the type of planning it employed. These represented organizational routines which reflected the organization's intended strategic direction. The management enacted their plan to achieve competitive advantage by focusing on specific types of projects, objectives and planning. As will become clear in the following paragraphs, Organon's management recognized the importance of both existing and newly acquired knowledge. This is in line with Kirjavainen's argument (2009) that only knowledge which has been taken on board by top management and incorporated in an organization's operational model can contribute to a sustainable competitive advantage.

The first topic discussed was the type of projects handled by the. Research and development is usually structured around strategically chosen therapeutic areas. Organon is best known for its women's health products, especially infertility and contraception drugs. But the company also sought success in other areas such as immunology and CNS[9]. A researcher explained that it was the wish of the company to be less vulnerable; however, he described Organon's portfolio as still being quite limited: *'It has to do with the size of the company; to be able to get to the final stage you need huge resources. Imagine you wish to be active in five therapeutic areas; that needs many people, around 50,000'* (DZ, 2011). According to this interviewee, to be successful a company needs to specialize; even therapeutic areas are physically located in one place so that all associated with one specific area enjoy physical

[9] CNS stands for Central Nervous System. It includes conditions such as depression and schizophrenia.

proximity. For instance, Organon moved its CNS projects to the laboratory in Newhouse, England some years ago. The lack of capacity was and still is solved by outsourcing tests to a subcontractor who has the specialized knowledge to perform those tests in the needed time frame. Hiring and training personnel takes a long time; for this reason, according to this interviewee, subcontractors are being used more and more.

Apart from the focus on a limited number of therapeutic areas, there was a consensus among the interviewed researchers that Organon found striking a balance between innovative and less innovative projects challenging. Discussion about radical and incremental products changed during the research process into a discussion about high and low risk projects. They described the company as predominantly innovative and in favour of high risk projects. Target discovery was an activity of interest in Organon, and an area in which the company invested. There were projects nobody else had, projects in search of new molecular entities, which had been initiated by searching databases and focusing on targets with zero hits, or by generating ideas around a known disease or a syndrome. An almost tangible sense of pride was evident during the interviews. When a new product was launched it was traditional to celebrate; the entire staff was treated to cake, ice cream or a drink. A researcher shared her feelings about those moments with pride: *'Really ours, really ours; look we did this! Sometimes you were more closely related to the launch than others. But this was our company; yes'* (MvdV, 2011). This quest for innovative products was supported by the freedom to experiment, described as the most important condition: *'Being able to experiment from time to time without the necessity to ask permission for every concept idea I have. It is often a matter of believing in it, and you can show some evidence later; just see what happens with the belief*' (JU, 2011).

Such projects were regarded as high risk because of the danger that toxicity might not be discovered until much later in the process, after years of experimenting and testing. Another factor was the size of the market; the small size markets which were attractive to researchers were high risk in terms of revenue potential. PC reported:

> *'We have been working on a couple of targets; we find them very interesting and think they could really work out in the future. I worked myself on a project where there was nothing on the market. Of course, it's extremely nice to be involved in such a project, but there are lots of discussions about why there is nothing out yet, like the market is not as big as oncology or rheumatism. Fine, but we still think it will work and the market is big enough to generate money.'* (PC, 2011)

Although the focus was on high risk projects, the researchers recognized that Organon sought to balance this with low risk projects involving compounds of proven effectiveness and safety. PC gave an example:

> *'It can be a product which in general works well in humans like an injection; if you are able to transform it to a pill, then you take a huge step forward. You do know in*

advance that the compound in the injection is active against target A or target X. So you know if you fine-tune the compound, it will be active...Of course, this involves a lot less risk than searching for a whole new target and lock. I might develop something without knowing if it will be effective at all.' (PC, 2011)

Elonva is one such product developed under Organon management. Elonva is used in infertility treatments; it replaces the first seven injections in any daily ovarian stimulation treatment prior to IVF and as such reduces the psychological impact of the treatment (Devroey et al., 2009). In short, Organon typically combined high and low risk projects aimed at relatively small markets.

However, the researchers reported that the approach to high risk projects in discovery and exploratory development gradually changed. This change mainly involved target discovery and, according to the interviewees, it reflected developments in the industry in general. Big drug companies tend to avoid this initial step in the early discovery phase because it is seen as the riskiest stage. MJvL, a researcher engaged in the discovery phase, observed:

'This part [i.e. target discovery] is something the big companies are not dealing with anymore and this is actually the most risk taking step. It is very difficult; how do you prove that a certain enzyme or a receptor is involved in a particular disease? So gradually the universities are taking over and big companies are shopping for target. If they find it interesting, let's see if we can find a compound related to it. At the beginning Organon was doing this [i.e. target discovery] as well, but it is done less and less; that's why it is now called lead finding, it means we are looking for a compound and not the target anymore...when Schering-Plough took over this became even more common practice. The whole target discovery bit was thrown out. In any case it was a lot less.' (MJvL, 2011)

Another researcher described this development as 'me too' practice, meaning that companies are simply looking at what the competition is doing and trying to be faster:

'I think 90% of the pharma companies are monitoring each other carefully. When somebody publishes an article stating that a certain protein is unregulated at breast cancer, they all jump on it. Organon was doing this as well; are we behind, are we ahead? But I have to say this has happened in the past few years. When I came, we had projects no one else had. We had unique dosage forms like Nuvaring and Implanon, and sublingual tablets [referring to Saphris]. We were good at it. That kind of thing was seen as very risky. You have to perform a lot of work before you have the evidence all sorted out and it turns into a good project. These were the first things to be lost.' (JU, 2011)

The second potential indicator of the strategic focus within Organon was the type of targets set by the company. The researchers revealed that under Organon, team and individual

targets were set. The team targets arose out of the broader goals defined by the management. To the researchers it was evident that the organizational goal was to bring a certain number of products onto the market each year, which was translated into a given number of clinical trials and a minimum number of projects in target discovery. Researchers in both discovery and exploratory development and full development and launch reported similar experiences here. Examples of team targets in discovery and exploratory development included: starting a set number of new projects, presenting a set number (e.g. three) of targets, or writing a set number of lead optimization programmes following the lead finding phase. Examples of team targets in full development and launch covered the number of patients' files processed, and the completion of preliminary reports and data analysis in preparation for the next step in clinical development. For all team targets there were clear timelines. These were generally based on experience, according to MJvL, a researcher working in the discovery phase: *'Those are fairly standard timelines, which you know more or less. Normally, target discovery takes about two years, lead finding as well, and lead optimization takes around four years'* (MJvL, 2011). In addition to the commonly understood general timelines for each phase, the researchers reported that clear milestones were also set in conjunction with the management. These milestones were interim moments along the timeline of each team, and in the words of the researchers: *'reaching those milestones determines your chance of reaching the overall organizational goals'*.

Under Organon management, the team targets and milestones seem to have been strictly formalized, at least as far as the full development and launch teams were concerned. DZ, the Director of Clinical Research – Anaesthesia & Analgesia, reported:

> *'It was strictly regulated. With Organon it was stricter, there were diverse guidelines a project team had to follow, there was also strict planning, the teams had to commit themselves to this planning and the agreements were entered in the computer system. If you were delayed by one day in ten years you had to justify why, it was quite formalized.'* (DZ, 2011)

Although this was seen as annoying and obstructive, at the same time, researchers realized it was the driving force behind targeted and very concrete working methods which yielded positive results. The researchers involved in discovery and exploratory development reported slightly looser practice, although those in exploratory development observed that their team targets became more formalized over time. The following sheds light on this development:

> *'The criteria were communicated in advance, they were also on paper. In the beginning, it wasn't so tight, but in time the criteria became tighter. At one point, I think before we merged with Schering-Plough, there were forms you had to fill in when starting to work on a target. You had to tick off what you had checked: are there knock-out animals, how is the expression, what is known in the literature, how are the*

patents...On a team you had many of these forms, but the idea wasn't to be able to tick off everything, but to see if the target was a good one.' (MJvL, 2011)

This practice of filling in forms and strictly monitoring a project was perceived as a tool for estimating the risk involved and eventually deciding whether to continue or not. In discovery also, criteria were clearly set in advance, though some, like the required level of selectivity, bio availability or activity, could be raised or lowered. The same went for the timeline. Managers might tighten up final deadlines if they had good reason, just as researchers could request and be granted more time if they provided well-founded justification.

The achievement of team targets, content and timewise, was rewarded with a monetary team bonus. Another bonus was also possible, the so called Result Derived Bonus, which was based on the organization's overall profit. Individual monetary rewards were not common practice under Organon management until late on. Shortly before the company was taken over, individual awards were introduced which affected salary payments; the decision whether or not to award an employee a raise was based on whether they had reached their individual targets. The researchers did not experience this for long under Organon management; they associated the linking of individual targets with appraisal and salary more specifically with Schering-Plough and MSD. Un (2007) connects team rewards with psychological safety which in turn, she argues, influences evaluative pressure. When cross functional teams are rewarded for team performance, a state of psychological safety is created which encourages individuals to experiment with novel ideas for new products. The cross functional team itself contributes to knowledge integration across diverse functions as individuals get acquainted with employees with different backgrounds and perspectives. Team rewards reinforce the adoption of these different perspectives by the team and by extension influence the amount of allocated resources to achieve team targets.

The individual targets under Organon management were extensively discussed by the interviewees. The first type of individual target mentioned was project-related. These targets represent professional development as they are directly derived from the organizational and team targets. The example given by one biologist was typical across all disciplines:

'*When the targets for 2011 are set, they are worked out down the line: fine, what does this mean for everyone involved in biology? They need to have this part ready. There are eight people so what does this mean for each one of them? The long-term organizational goal, followed by the yearly organizational goal, then by the goal per discipline lead to the individual target. So with each one of us it is agreed what it is [i.e. individual targets] and if everyone sticks to the agreements, we will make it. The team leaders negotiate the criteria and timelines with the management board and then these are chopped into pieces. Those pieces are negotiated further with each individual in the team and eventually we work with the whole team to reach them.'* (WD, 2011)

These individual targets, derived from the projects and representing professional development, were discussed annually. If they were not reached, the employee was expected to explain why not. Over the years, these conversations became better documented, and plans such as Personal Development plans were used to structure agreements and consequences. Not reaching these targets was interpreted as not functioning as required, and resulted in a reduced salary raise (MJvL, 2011).

The second type of individual target mentioned was related to personal development. These individual targets were also documented, but unlike the previous targets, they had no direct influence on the salary raise. These targets represented the wish of the employee to develop either as a manager in the organization or as a specialist in a certain topic in the field. Accordingly, these targets were usually related to training and putting what had been learned into practice. In general, this training was experienced as stimulating and a sign of management trust, although it was frequently noted that the initiative to start a course or training had to come from the employee. The general expectation that employees would invest in themselves was illustrated by CJ, a chemist:

> *'You have to do it. Sometimes you see people falling behind; usually it has to do with the person himself. If he doesn't want to invest in himself and to develop, say as an employee, he needs to be careful or he will be left behind. With Organon you had many possibilities to build a career, to develop, but you yourself had a huge share in it. If you do not meet the required level, you are left behind...even if you hit your head against a ceiling, you need to maintain your standard, do not slip down. Otherwise, the management won't be satisfied and will ask what you are doing. You have to make it fun for yourself.'* (CJ, 2011)

The third potential indicator of strategic focus is the type of planning implemented within the organization. One senior researcher described adopting innovation planning as a strategy to facilitate the regular bringing of new products to the market. The industry was described as typically goal centred, with a methodological approach geared towards discovery. *'You cannot just give a bag with money and a bag with chemicals to a researcher and say go sit in the lab and discover. It doesn't work this way'* (DZ, 2011).

Similarly, the researchers in discovery and exploration described the ambiguity which lay at the heart of the planning under Organon: on one hand, it was structured; on the other, it was generally felt that 'luck' was needed to make a discovery. There might be 15 to 20 projects in development at any one time, meaning there might be 15 to 20 targets to work on. The lead finding teams were described as structured – they worked with a budget and had representatives from different disciplines. A project was assigned milestone moments, but these were not completely fixed. Reaching fixed milestones in the timeline *'would be nice; you want this in research but it is very hard. The next compound I make might be selective but it might also happen that in three years no selective compound is actually made'* (PC, 2011). This 'luck' factor was managed by means of regular progress discussions between

team leaders and management. These might result in the compound testing period being extended by three or six months, with the proviso that the project must show progress within this timeframe or be terminated. Alternatively, if there were irresolvable issues with a class of compounds, researchers themselves might suggest they stop working on it. Interviewees working in lead optimizing teams reported similar practices there. Every three months, the status of projects was discussed in relation to the timeline and the agreed criteria. The teams were expected to give a prognosis of when they expected to deliver a compound for the next phase, the clinical trials.

Researchers in discovery and exploratory development dealt with the time issue in a distinctive way, through their 'Friday afternoon experiments'. Under Organon, there was an informal rule that researchers could spend Friday afternoons experimenting with ideas without having to report to management or ask permission. This might plausibly be seen as a deliberate strategy to create the optimum conditions for serendipity or 'luck', as the researchers themselves called it. According to WD, a senior researcher in lead optimization:

> *'You have an idea and you spend some manpower to work it out and figure out if it is a good idea; and you keep it to yourself for a while, whether it is a bad or a good idea. Especially if it turns out to be a good idea, it is very nice to announce it...fantastic ideas came out of this. I think in this field you shouldn't over-manage, as you rule out surprises, positive surprises. When you manage you have everything nicely under control, but there are no positive surprises anymore, as you ruled them out in advance.'* (WD, 2011)

But according to PC, a medicinal chemist, there is more involved than just luck*:*

> *'In some projects you know the structure of the target and the proteins that resemble your target. You know the differences and you hope, using your knowledge, to optimize it. Sometimes you just have luck. I change something, then I test the compound and damn, it turns out to be selective, but this is not always so. I do not always believe in luck. It is just one piece, being selective, but how do we make sure the compound gets into the blood stream?...the knowledge you have built up over the years makes you think you know what to change in the molecule. It might work out with the next compound, or you might have to make a hundred before it all works out.'* (PC, 2011)

In short, creating the conditions for serendipity means setting up an environment in which individuals can freely experiment in their own time and develop specific knowledge. At Organon, this was then combined with structures to monitor progress and predict outcomes.

As for the timelines in the full development and launch phase, Organon managers implemented straightforward planning (DZ, 2011) based on the products already on the market and when they were due to go off patent. The idea was simply that knowing when a patent expires means knowing when a new product will need to be brought to the market, if

a drop in organizational income is to be averted. Accordingly, the management set final dates and then calculated backwards. On average, it takes 12 years from compound discovery to patented product; hence, for products due to reach the market in 2014, the full development and launch phase had to start in 2004. If the organization's goal is to launch a new product every two years, this reverse planning reveals which activities have to be performed concurrently. According to the researchers, Organon implemented this kind of planning system. One of the senior researchers visualized it as follows:

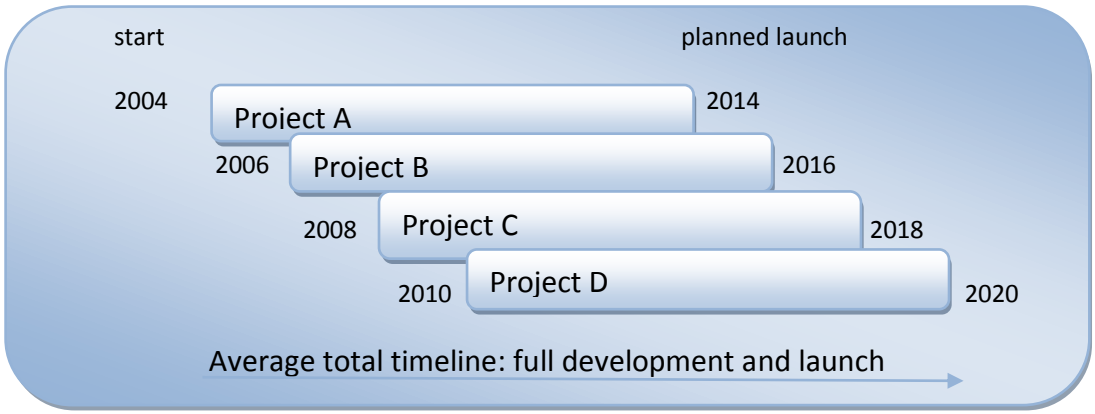


Figure 6: Full development and launch phase, start moments based on planned launch moments

Interim milestones were set by programme managers and team leaders along the line and combined with team and individual targets. In the core clinical trial teams there was a planner, whose job was to monitor when milestones were attained and to predict the registration and launch moments. The same planner updated the team members and warned them if there was a chance to get to a critical path. The milestones were subject to adjustment either by the management or by the team, as long as the end point was not jeopardized. Thus, if the actual discovery of a promising compound and its exploratory development were delayed, the next phase simply had less time allotted to it (DZ, 2011). Similarly, if the clinical trial team said there was going to be a delay, the protocol might be adjusted or additional manpower would be brought in (WS, 2011). The downside of teams having such an influence on the milestones was felt in cases where one core team was simultaneously involved in multiple trials. EH reported finding it difficult to prioritize trials, as putting more effort into one would negatively affect the others. She felt that Organon's management did not make it explicitly clear how to deal with such situations. Nevertheless, the overriding feeling among the interviewees was that if researchers believed in the project, the milestones became important to everyone, and it was usually possible to reach them (JE, 2011).

Overall, it can be concluded that Organon's focus on variation in performance represented a deliberate strategy to be first on the market. A culture of exploration was evident in the balance of high and low risk projects, and the fact that the discovery of new molecular entities took priority over the improvement of existing ones. The encouragement of

professional and personal development in the context of team performance is one way of increasing variation in knowledge. Team targets and rewards strengthen the idea of the central place of the team, in turn creating a platform for individual development, free experimentation with novel ideas and risk-taking behaviour, all in the name of discovering an innovative drug as a team. Another way in which the company increased variation in performance was by allowing greater latitude in terms of planning to researchers in discovery and exploratory development, and then implementing stricter time lines in the full development and launch phase.

5.4 Structural characteristics and organizational actions after acquisitions

In the following paragraphs March's model will be assessed in terms of its applicability to the acquisition process. The changes in structural characteristics and organizational actions observed in Organon after the acquisitions are used to explain and predict the effects of these events on the organization's innovation ability. As a result an acquisition innovation prediction model emerges.

All propositions apart from propositions three and four are applied when describing the organizational changes. None of the interviewees reported experiences with new employees or staff turnover during the acquisitions; accordingly, analysis of these issues is limited to section 5.3.3.

5.4.1 Slow learning rate

The first proposition stated that individuals who adapt slowly to the organizational code are associated with raising the level of diversity within the organization, and by extension the time spent on learning and exploration. A desirable level of diversity is maintained when employees have the time and freedom to experience how teams work, without being forced to adjust to the established norms and procedures.

Before the acquisitions, researchers had a certain degree of freedom to decide what was relevant to their work and what was not, and how long to spend investigating a new area. Whether this practice changed under Schering-Plough (SP) and MSD was not discovered.

One researcher in discovery and exploratory development (JU, 2011) spoke of the shift in beliefs and norms which took place under the new management, especially in terms of which projects were halted and which were allowed to continue. The researchers were not given time and space to adjust to the new organizational code following the change of management between SP and MSD. SP stopped projects usually based on data. Conversely, MSD was perceived by the interviewees as a very 'top down' organization, in which all projects were assigned or stopped by senior managers. One researcher explained:

> *'...people come with new ideas and start working on them, then it is said from above, you must not work on this anymore. And when you stop, it is kind of a waste, you need to conclude earlier that you wish to work on this and then you commit yourself to it...or*

> *a 'head' is swapped after you've worked for a year on a project and then a new team leader is set… we promoted the guy. And the first thing he says is: "The way you've worked for the past years, I do not believe in it." Then many things are done again, the project is given a new direction, you waste again. You should not produce a Toyota in Fukushima and tires in Kyoto and then send it to Minneapolis, you should keep everything closer together.'* (JU, 2011)

In the context of discovering innovative products, changes in organizational beliefs and norms affect the perceived value of projects; forcing through rapid changes to these norms may lead to the structural loss of potentially profitable ideas.

The researchers engaged in full development and launch continued to follow the routines and procedures related to the conduct of clinical trials. No changes were reported in terms of the directives to be followed, but the flexibility they previously had to take on the tasks they were most interested in was curtailed. As will become evident later in the analysis, these researchers were forced to re-apply for positions which offered a significantly reduced range of duties and responsibilities.

It can be concluded that the level of diversity and by extension the time spent by the organization on learning were affected by the acquisitions. In the case of new product discovery and development, which takes years of commitment, changing the organizational code without involving the researchers and forcing a new code on them may well have led to the loss of knowledge and innovative ideas.

5.4.2 Learner heterogeneity

The second proposition stated that having a combination of fast and slow learners is closely linked to the level of organizational knowledge reached in the long term. It was not evident whether the experiences of researchers in the discovery and exploratory phase changed with the acquisitions in terms of the mix of learners and approaches in the department. On the other hand, new members of clinical trial teams continued to make little contribution to innovation. Under SP and MSD management, learning had to be done quickly; one of the clinical researchers revealed that 90% of training courses had to be completed by the whole department within a year, while two clinical development plans had to be written in the same time span.

In conclusion, heterogeneity among learners, found to have a positive effect in the discovery and exploratory phase but not necessarily in the full development and launch phase, was not affected by the acquisitions.

5.4.3 Variation in performance

The fifth proposition relates variation in performance to the competitive position of an organization. Variation in performance is seen as the effect of variations in knowledge and

learning process. Certain combinations of learning types and learning processes help an organization achieve a competitive position when its aim is to come out first.

Variation in knowledge seems to be affected by the acquisition process. Interviewees reported both positive and negative experiences, both at individual and organizational level. One of the researchers described both acquisitions as giving new impetus to the research and development process. His position in the organization meant he was able to take on new roles such as presenting team activities and progress to the management team. This interviewee repeatedly mentioned having learned much from Schering-Plough and MSD, and that he would not have wanted to miss the experience. He valued his newly acquired knowledge not least because it is transferable in other organizations. He also compared the pace of learning, stating that with Schering-Plough the learning curve was steeper than it was with Organon. But this knowledge will not be re-invested in the organization, owing to MSD's decision to close the R&D laboratory. He explained his frustration:

> '*For a great company like Organon this outcome is worthless, but I did learn a lot. It is such a waste for Organon, and for Dutch pharma this is dramatic...for everyone who is studying biology, chemistry or laboratory science, the option to work for Organon is gone. So I think it is such a waste for the whole field.'* (WD, 2011)

This quote reveals the negative effect of the acquisitions on the organization; the variation in knowledge they stimulated was never given the chance to help the company achieve its aim of primacy. It also highlights the importance of variation in knowledge across the field as a whole, beyond individual and even organizational level; knowledge diversity within the field may well be affected if certain specialisms are no longer sought by employers.

Interviewees also reported the negative experience of not being able to use previously acquired knowledge and skills. Following the acquisition by SP, the tasks associated with clinical trials were divided into two sub-parts, called science and project[10]. One clinical researcher, who had been working as project leader for years, ended up working on one specific part of his previous job. He described this organizational practice:

> *'I always say, while working for Organon I did the work of six persons. Now I have a small specialism and can do a lot more in detail. The six persons now added to the team took over my tasks...Because I am not a project leader anymore I am distanced from operations. I am in the science part now, in the protocol part, and this means that I don't know what is going on elsewhere. I do hear about the problems but I don't know what they do about them and I don't have the authority anymore...I find it very difficult to work like this, my fingers are itching to do something about it of course, because of my background...it is sometimes frustrating.'* (WS, 2011)

[10] The division of tasks and its effects will be discussed more in detail in section 5.3.5.

Under Organon's management, another researcher was able to progress to a leadership position, for which she followed specialized training and which she enjoyed very much. But

> *'When Schering-Plough took over they said people who only had a degree from a higher professional education could not be group leaders anymore. Since then there has been no development. At the time you don't see it, but looking back now I can say I have been standing still since 2007.'* (MvdV, 2011)

The new management introduced a solution to this, which they called Shared Accountability Management. Under this system, two managers are responsible for each employee: the 'new' appointed group leader, who acts as the line manager, and the 'old' manager, who is involved in daily operations and who knows how the employee functions. Appraisal interviews are conducted by both managers. Even so, this researcher described feeling 'held back'. The above examples illustrate another negative effect of the acquisitions on knowledge variation; existing knowledge diversity was denied the chance to contribute to primacy, and ultimately reduced.

Variation in learning processes also seemed to be affected by the acquisitions. One researcher in discovery and exploratory development outlined a positive effect the first acquisition had on the learning process. Under Organon, there might only be one specialist, while under Schering-Plough the number of specialists grew. In immunology, for example, the number went from one to four. This meant researchers had access to more experts in a particular field. He described the effect of this change in numbers:

> *'The four immunologists had their own subtle view on things and a lot more contacts with academia in the US then we did. We were very happy to be able to have conversations on this level and to be able to discuss our projects with these experts. The presentations were in the US, we received feedback and it all improved a lot.'* (JU, 2011)

However, this situation was reversed after the next acquisition. According to the interviewee, the tendency of MSD was to stop all projects in discovery and exploratory development and to outsource this phase to another company. Those projects which were allowed to continue through both acquisitions were joined by new team members whose fresh insights boosted the work.

One clinical researcher described how, under Schering-Plough, the whole department was obliged to undergo 80 online training sessions within a given time period. The sessions were followed with a test and a certificate for each person. Presumably, similar training sessions were organized in all therapeutic areas. The training was meant as preparation for clinical trials and standard operating procedure (SOP). According to EH, *'Under Organon management it was also necessary to be trained in the SOP of a trial and you got tested. However, it wasn't arranged so well and there was nothing on the internet'* (2011). It is

possible that this arrangement reflected Organon's trust that its employees would follow SOP. It may also reflect Schering-Plough's focus on risk avoidance. The requirements for the conduct of clinical trials in the European Union are set out in Directive 2001/20/EC of the European Parliament and of the Council of 4 April 2001 (European Comission, 2012 last update). Complying with these requirements ensures that the resulting product can be registered and sold. They represent an external influence on the set up and execution of a clinical trial and aim at standardization and predictability. By extension, they reduce variation in learning processes. Creative ideas and experimenting during a trial have become undesirable, not to say impossible. These experiences did not alter after the second acquisition.

Interviewees also reported another change in organizational practices which had an effect on knowledge and learning processes. Under Organon management, it was common practice to visit important conferences related to the therapeutic field the researchers were working in. One of them referred to these visits as one of the most important resources in the discovery phase:

> *'Actually the most important is indeed the access to knowledge in the shape of publications, for example, or in the shape of people you know. In this period it is important that you visit many conferences, that you are up to date about the latest developments and that you know where the ideas are going.'* (MJvL, 2011)

But this researcher observed how this changed under MSD, which she described as being reluctant to bring in ideas from outside the company and not keen on publishing. The conference visits, and the sharing of information, happened less and less. She reflected:

> *'It is a pity that you are not allowed to talk with people outside the company, it is in a way a bad thing as the company itself gets isolated. A lot of people had no idea anymore what we were busy with, while before, people in the Netherlands had a fair idea of what Organon was working on.'*

This reduction in conference visits may well have affected knowledge variation; researchers were not being given the chance to discuss their ideas with other experts in the field and generate further ideas of their own in consequence. Through all the conversations with researchers in discovery it became obvious that ideas for possible targets and compounds are not generated by individuals in isolation. The process seems to be stimulated by experts sharing their knowledge, though it is the act of sharing itself that stimulates exploration, not necessarily the content of the shared ideas (the content is often bound by legal issues, and researchers may not want to share ideas where there is a chance of patent registration). Thus, visiting fewer conferences makes it harder for researchers to stay up to date on the latest technology and to broaden their network, both key factors in the variation in learning process. An interesting parallel may be drawn with the case of Silicon Valley. Saxenian (1996) describes the experts in Silicon Valley as part of a technological community. Informal

socializing in the pubs was one way of discussing ideas and spurring new idea generation. Another more or less formal way of cooperating was to visit trade association meetings and industry conferences with the aim of transmitting market and technical information. Stanford University, the University of California at Berkeley and the California State University played a vital role in the region's education and training by encouraging research collaborations between firms and individual faculty members. A formal and informal network was created which, amongst many other functions, formed a framework for mutual learning and adjustment. This framework reflected the paradox of the valley: competition demanded continuous innovation, and hence cooperation among firms.

In conclusion, the acquisitions appear to have affected organizational learning processes mainly in a negative way. Previously acquired variation in knowledge, and the variation in knowledge stimulated by the acquisitions themselves, was not given the chance to help the company achieve its aim of primacy. This became evident when the company halted all those projects in discovery and exploratory development and outsourced this phase to another company. The curtailment of conference visits may also have affected knowledge variation. Variation in learning processes was reduced as a result of the company's strict compliance with the requirements for the conduct of clinical trials in the European Union. The effect of this compliance is double-edged: while ensuring a product will be able to be registered and sold, it also encourages standardization and predictability which in itself reduces variation in learning processes.

5.4.4 Coordination between parts

The sixth proposition states that less coordination and more loosely coupled parts are related to an organization's potential to make radical innovations. Organizations that develop effective communication and coordination are expected on average to do better than those that are more loosely coupled. They become more reliable; however, this reliability has a price – it reduces the chance of coming out first among competitors.

The first point of relevance to this proposition is how the division of work changed after the acquisitions. The researchers saw changes in the division of work, particularly in terms of the authority teams had to make decisions and the multidimensional character of the work itself. The researchers in discovery and early development compared themselves with their colleagues in the States, concluding that Dutch teams had more task variety and freedom. In general they were still able to work the way they were used to, but found it difficult to navigate their way through the hierarchy. MJvL described the differences she noticed:

> '*The biggest difference was actually that we were used to doing a lot ourselves; in a team you had many tasks. Like...you think of a plan, you write it down, you act upon it with your colleagues, report the outcome and contact the toxicologist, the clinical researcher, the chemist. You did a lot by yourself. And in the States they are in boxes, more like compartments; this is your task and you are not allowed to go beyond it.*

> *When you want something, you need to hand it over to another person whose task it is and you are not to interfere with it then. We had to get used to this…we were used to taking responsibility for our work and being able to make decisions. We might suggest the management do this or that, and in almost all cases they accepted our suggestion, saying, "You thought this through well and we will do it as you say." And sometimes we could say [to the management], "You must decide as we don't know either."'* (MJvL, 2011)

The team that combined tasks from lead optimization and pre-clinical development, the so-called proof of concept team, was wound up by the MSD management. This team was originally created by researchers to streamline the testing process and avoid duplication and miscommunication between teams. WD, a senior researcher in lead optimization, attributed the move to MSD's size: *'MSD does it all big. So I understand that my responsibility now is only for this team; however, it is a team with 48 people…and it takes all my time'* (WD, 2011).

The first acquisition caused fundamental changes to the multidimensional character of the work done by the full development researchers. Tasks were split into project and scientific categories, and everyone had to reapply for a job in one or other section. Project managers were then seen as operational managers, responsible for things like budgets, timelines, contact with clinical research assistants in hospitals and filling in spreadsheets. Scientific researchers were held responsible for tasks such as the writing of protocols, the writing up of findings for the authorities, answering questions from the authorities and the writing of leaflets. All of the clinical researchers interviewed described the changes as a negative experience:

> *'Everyone found it such a pity the situation was changed, it became smaller and that's not nice. The most regrettable thing was that suddenly all the things you were responsible for before, you had to give away to the next person to work on and only receive the results later. Luckily, we knew each other well and it was less black and white.'* (EH, 2011)

> '*The team spirit changed completely. You were hired for a small part of the process and when you were ready you handed it over and you started again with another small project… whilst before, you did it all…it became less of yourself; what I have on my desk today I will work on for couple of months and then just hand it over.'* (JE, 2011)

> '*The motivation went down. People started to work less, they worked their 38 hours. I never saw this before; it was always a lot more.'* (JE, 2011)

In short, generalists in clinical development were forced to become specialists, in the process losing their overall view of the trial process. This job degradation adversely affected motivation and satisfaction, and even impacted upon the basic structure of the multidisciplinary teams. The dual chain of command became less important as the functional

managers gained power. This change in power relationships affected the decision-making process, and multidisciplinary teams virtually ceased to exist. These practices were well illustrated by WS, a clinical researcher:

> '*The basic structure was loosened a little within Schering-Plough and then further within Merck. It became much more of a line. My boss within the clinical department has authority and the data manager has another boss who also has authority. In fact the teams operate within the line management. Your line boss, who also evaluates you, became much more important. And I think that that is the problem today, making it all so tragically slow. Because that's what you hear now. There used to be a decisive team in my view; in a short time, we were able to make decisions as a team. We were still controlled by another team, appointed by management. Now your direct boss may have very different interests than the one product you are working on, because he obviously has many more products... Oh well, my boss is a clinical researcher; someone in statistics may think about it very differently. And within Merck, there is an extra layer of approval for each protocol. Say for example I devise a protocol, but a protocol consists of several components, of course. And I am ultimately responsible for it, but I can't write the statistics part, a statistician has to do it. There are also parts that now have to come from the clinical research assistant (CRO) you hire, or the lab... And you can imagine everyone has his own boss and he is saying, "You need to meet my standards." So again the lab takes part of the writing, saying it should be within those limits. But that might not fit my protocol. But they do not care about that; it still must conform to their standards. And that makes it very difficult for such a protocol to be finished. It only used to need a few months, and now you need a minimum of a year to get all the committees in line. It's not only your boss who can determine something, no, that boss can make a mistake too, according to Merck. So they have many clinical researchers from other disciplines and they will all have their say about a protocol that they really do not know about, like about Livial. They think it should fit a pre-agreed pattern, and if it does not comply it is not good. And that makes for a discussion that lasts indefinitely. There are far fewer decisions made as a result.'* (WS, 2011)

The second point of relevance to this proposition is how the coordination of work changed. Following the two acquisitions, the researchers generally felt that the form and content of communication changed. For one, the teams became bigger and even more discussions were needed:

> *'The team became bigger as Schering-Plough and Merck saw this as a big project. More group leaders arrived in medicinal chemistry...there were more consultations. The four of us came together and discussed which plans we were not pursuing, which plans we were. Before, I was alone and the only thing I had to do was talk with the boss or a colleague to ask what he thought about it. At the end I said, "We will go this way" and we did. Now with more people, you need more discussions and more time.'* (PC, 2011)

For another, the communication lines became longer: '*When we had to report progress it happened quite quickly in the clinical development teams. Now everything had to be sent to the States, and an answer would come much later*' (JE, 2011). This view was echoed by another interviewee: '*It's a cumbersome organization, almost like a government, thousands of people work there, it is big and it takes a very long time before a decision is made and very often it is unclear who you need*' (PvW, 2011). The longer communication lines often caused delays and frustrations, as explained by JU, a researcher specializing in the target discovery process and molecular pharmacology:

> *'With Organon there were five departments and they met once in three months for project review and then decisions were made. But with MSD there was the discovery research committee and the development research committee and they met once per month. You have to try hard to be added to the agenda. Then people who never heard of your project ask detailed questions: "Did you perform this experiment?" You get very frustrated; if you had known this two months ago you could have worked out the answer precisely. But because you were not allowed to have contact with these people, you have to delay the project by two months, for the sake of a dull experiment no one in Oss thinks should be performed. However that one person finds it important and for the sake of politics it is still performed. Two months are lost. Such mechanisms mean big pharma lose out eventually.'* (JU, 2011)

For another researcher, the communication became more formal, with the centre of gravity shifting towards the management, particularly under MSD. MJvL, a researcher working in the discovery phase, described her experience on a project in search of an alternative for Prednisolone. Her account reveals not only how the form of communication changed, but also how the decision-making power shifted:

> *'In the States you could talk with people from the floor, everyone says interesting, nice idea, we have to do it. And then you think we are following this idea, but: "No, first we need to discuss it with the big boss." And then the big boss comes by and he says something completely different: "No, we are going to do this and that." And with this, the whole chapter is closed; no consultations or discussions about what we think. People start talking in line with the boss's ideas; the boss wants it like this so you are not going to talk against him. This is very strange as we just discussed something else and then the boss comes along and it seems whatever we discussed before doesn't matter anymore. The boss said it, so we are following. The hierarchy is strict, you do not answer your boss back; if the boss wants something you adjust to it.'* (MJvL, 2011)

This interviewee gave another example of how power, which had previously rested with the team, shifted under MSD:

> '*Under Organon management, it was like this: if the toxicologists said you shouldn't continue, you followed their advice. If the toxicologists said something like that, it is*

their expertise, so you just followed it. With MSD, the higher management started thinking, "Yeah, you say so but we decide about that." And then everyone started talking about it...and still we do. "Do we know enough about the compound?" Endless discussions and the same discussions, do we want this or not. It seems like there is a kind of mindset: a huge fear of making the wrong decisions; this dominates.' (MJvL, 2011)

A third issue related to communication flow was a perceived reduction in transparency, both in top-down communication about decisions made and the future direction of the organization, and in horizontal communication between individuals or teams that were no longer in physical proximity. For instance, a decision might be made not to invest in a trial, but the reasons why were often not communicated to the researchers involved. As a result: *'The enthusiasm became less, and you thought to yourself, I am not going to stay till 10 tonight when I know this can be stopped tomorrow; if not they will wait a day longer'* (EH, 2011). Often, it was not clear to either researchers or their direct managers which project they should prioritize:

'Often everything was a priority; we sometimes had many things to do and we knew we could not finish them all. Or you started with one while you were waiting for another to start, so it wasn't clear. The direct managers didn't hear it from the higher management, they tried to find out what should be prioritized but often without success.' (EH, 2011)

Lack of physical proximity with colleagues was a problem for some researchers; even contacting them could be difficult, and if they eventually did they were likely to be told: '*No, you need to talk to your boss first'* (MJvL, 2011). The outsourcing of some parts of the work, such as the creation and screening of molecules, to companies in China became more common under MSD management. PC, a medicinal chemist, described this as being less efficient:

'It is always less efficient in comparison with having the people on site and having a good interaction with them on a daily basis. Maybe in ten years it is just standard work...but the efficiency is for me having the people in the lab next door and being able to go back and forth to inform each other and discuss issues...You can react much quicker if there is an issue when they are next door.' (PC, 2011)

This lack of transparency and physical proximity apparently influenced some researchers' feeling of belonging. One researcher reported:

'The company became too big. You lost the overview you had before. With Organon I had the feeling I knew what departments there were and who was involved in what. With Merck you don't have this at all, nor with Schering-Plough. They were also big. You don't even know where the company is situated, which places, and not at all what

> *they do. It became less, you felt less attached. Previously I could say, "Yes, this is our product" and now you don't have that anymore. You are not aware of them at all.'* (MJvL, 2011)

To sum up, with the two acquisitions, the flexibility of the teams declined as more meetings and endless discussions became necessary, and it took longer for (usually higher) managers to make decisions. The authority of the teams shifted towards managers who often lacked the project-specific insights to justify their decisions. Simple tasks replaced the multidimensional character of the work, limiting creativity and knowledge development, and failing to exploit researchers' existing knowledge and skills. The teams themselves, particularly in full development and launch, became less decisive as they started to lose their multidisciplinary character. Informal communication gave way to more formal practices, encouraged by the physical distance between the various parts of the organization.

It is reasonable to conclude then that the organization experienced a shift from a decentralized and informal structure to one that was centralized and formal. Later on it will become evident that this shift was influenced by changes in organizational environment and external control as well as by the acquisitions. The level of interdependence between the parts grew as they were restructured to deliver more simple and predictable outcomes and decision making power shifted. As will be clarified later, this reflected MSD's strategy to be the best pharmaceutical company in its class rather than the first to market.

5.4.5 Specialized sub-parts

The seventh proposition states that an R&D laboratory balances exploitation and exploration by allowing its sub-parts to each specialize in one mode, thereby contributing to long-term competitive advantage. Balance is also sought between specialization in radical and in incremental innovation. Evidence was found that, under Organon, specialized teams operated within the R&D department, and that a premium was placed on radical discoveries. However, the subsequent acquisitions happened over a relatively short period of time – according to accepted wisdom within the industry, too short a time for any real specialization to develop. Moreover, the decision to close the R&D laboratory was made shortly after the second acquisition. Consequently, it was not possible to detect the effect of specialization within the laboratory itself. Instead the interviewees shared their opinion about specialization at industry level.

The industry makes a distinction between innovative and generic companies. Organons was in theory and practice an innovative company; every drug it produced was developed by the organization either alone or in close collaboration with external parties like universities. A generic producer, on the other hand, sells drugs whose patent period has expired. The majority of the interviewed researchers reported a general change in the nature of the competition within the industry, which had affected specialization in radical and incremental discoveries. According to one interviewee:

> '*Lots of patents are going off. The generic producer doesn't have the costs, also not the failed projects. So many are going off, this means that they [the pharmaceutical companies] are having a problem and if you do have enough money it is important to fill in the pipeline, and you can do this by buying smaller companies. You see, research, and I expect even more in the future, is outsourced. It becomes part of other companies, who can do the research and then sell it to big companies who can proceed with clinical trials and marketing. Maybe this will also be split in the future, so just the clinical trials. All done separately, you have in theory less risk.*' (PvW, 2011)

The closure of R&D laboratories worldwide and the emergence of Life Science Parks support this idea that some companies are shifting strategy, from having a fully equipped R&D laboratory to having a laboratory specializing in one or other phase of the drug discovery process. This shift in strategy might be one of the reasons for MSD not to keep the laboratory in Oss open. It seems that market relationships are developing on a broader, social system level, as argued by Gupta et al. (Gupta, Smith & Shalley, 2006). Similarly, members of the industry are increasingly adopting either a federated or diversified business model (PwC, 2011). The federated model consists of a network of organizations connected by shared principles and infrastructure, in which companies outsource most or all activities, or manage these. The diversified model consists of a network of firms owned by a single parent company. The two models are not mutually exclusive, but the federated model is likely to become the more popular because it is economically attractive and quicker to implement. Cockburn (2004) argues that vertical disintegration will not necessarily make the industry more productive, especially in the case of early stage pharmaceutical research. One of his arguments focuses on knowledge development, which in academic research is driven by social norms and the availability of resources and not by commercial gains. He suggests that if parts of the system specialize further, collaborations with universities and for-profit firms will develop along with property rights, placing a premium on market potential over scientific value.

On a regional level, however, specialization and diversification led to the revival of Silicon Valley in the 80s. The tight-knit community of earlier years had disappeared, but the culture of relative openness and the existing platforms of knowledge sharing and development were kept intact (Saxenian, 1994). Many start up firms failed during this period, but these failures were seen as a way of accumulating local knowledge, and this knowledge was eventually exploited to experiment not just with technology but also with organizational forms. Close collaborations developed between buyers and suppliers, blurring the firm boundaries. In general, flat organizational structures rewarding individual initiative were favoured. While some firms grew in size they preserved their focus and flexibility by adopting highly decentralized organizational structures. The region was able to introduce state-of-the-art products in a much shorter discovery and development cycle than its competitors.

To sum up, external developments such as diminishing protection from patents may force organizations to specialize solely in one aspect of drug discovery and development, and to develop market relationships on a broader social level. This might be the case with MSD. However, this degree of specialization is not guaranteed to lead to long-term competitive advantage; market relationships may enter the phase of early discovery and development and influence collaborations between universities and for-profit firms (Cockburn, 2004). These relationships can influence the knowledge development focussing on commercial rather than scientific gains.

5.4.6 Organizational resources and mindsets

The eighth proposition addresses the contribution organizational resources and diversity of mindsets make to the development of radical and incremental innovations.

Under the Organon management, all the researchers had sufficient access to literature and publications; however, following the first acquisition, by Schering-Plough, the experience of researchers in full development and launch differed from that of their colleagues in discovery and exploratory development. One of the three subscriptions made to fertility journals was stopped, meaning *'there was no online access. So often there was an interesting publication, you had to request access and had to wait for two days before you got it'* (EH, 2011). In contrast, the researchers in discovery and exploratory development experienced growth in terms of publications and literature access, as if '*with one click all the articles ever published would appear on your screen'* (JU, 2011).

Before the acquisitions, conference visits were seen as a long-term investment, particularly in light of the opportunities they afforded for cooperation and networking with universities. As already described in section 5.4.3 'Variation in performance' the conference visits, and the sharing of information, happened less and less, in particular after the MSD acquisition. MSD was described as being reluctant to bring in ideas from outside the company and not keen on publishing.

No other changes were reported in the organizational mindset or resource allocation (for example in terms of internal knowledge and technology) after either acquisition. A plausible reason for this may be the relatively short period of time within which both acquisitions took place. The closing of the laboratory also makes it difficult to detect any changes at the organizational level. As will become clear in the next paragraph, the choice to specialize in either radical or incremental innovation at the broader social level, and the strategic choices a company makes in relation to this specialization, will influence how it utilizes its organizational resources.

5.4.7 Strategic actions

The ninth proposition relates to strategic actions aimed at increasing variation in performance. The type of projects the organization pursued after the acquisitions, the type

of objectives set within the company and the type of planning it employed all reflected the acquiring organization's intended strategic direction.

The first topic discussed was how the type of projects pursued changed as a result of the acquisitions. Both acquisitions seem to have accelerated the process of outsourcing the target discovery phase. Moreover, the approach towards type of projects changed by swopping back and forth between therapeutic areas until just dropping out promising projects. Just before the Schering-Plough acquisition took place the decision was made to start new projects in oncology as this was seen as a growing market. For two years, the focus was on these projects and less on other areas such as women's health. Following the acquisition, the oncology projects moved to the US and the women's health and immunology projects were restarted, but the feeling dominated that the oncology projects had been allowed to 'fall into the ocean' and disappear. Following the next acquisition two years later, it became clear that early discovery and development would be done parsimoniously and that there would be no new team structure for this section. One high profile project did continue for another six months, but after it was announced that the R&D laboratory would be closed, no one had any further expectations of the project, and there was no further development. The overriding feeling of the researchers was that MSD was following a strategy of avoiding risks; the company was described as careful, afraid of lawsuits and rather conservative. Even the decisions about which projects to continue were taken by people not directly involved in them, but by people in certain positions. Position brought privilege, regardless of the individual's actual knowledge and understanding of the possible success of a project. WD, a senior researcher in lead optimization, shared his experience:

> *'They want to hear my boss, not me. You must see and know all details around the compound to be able to decide if it can turn into a product or not. I am absolutely convinced that as a decision maker you need to see all the details to be able to make a well-founded decision. However, as the information is shared gradually now, I do share all the details with my boss, but he forgets some because he is not involved in the project every day, he cannot remember it all.'* (WD, 2011)

The dominant view among interviewees was that MSD was playing 'safe' by buying smaller companies with high-risk potential products rather than investing in high-risk projects itself. The feeling of being part of an innovative organization diminished every day. Many researchers summed up the philosophy of the company in the words of their American colleagues – 'For us it is important, it is nice to be first in class, but it is better to be best in class' – explaining that this meant focusing on compounds that have already been proven effective and safe, instead of focusing on completely new ones. The company had had repeated negative experiences, especially with generic drug companies, when it had been unable to gain a return on its investment, mainly because products had gone off patent too quickly. In short, MSD had decided to focus on low and no risk projects for relatively big

markets. Moreover, MSD seemed to have the capital to start and continue broad clinical studies, something Organon had not been able to do alone for the previous ten years (CJ, 2011).

The second topic discussed was how targets changed as a result of the acquisitions. The majority of interviewed researchers felt that the way the organization dealt with personal and team targets changed with the acquisitions by Schering-Plough and MSD. For one thing, it was suggested that there was no timeline under MSD management; in its absence, researchers felt they were going nowhere (DZ, 2011). Much was said about the relationship between timelines and project planning, and how this changed (this will be further discussed below).

Another issue reported was the change in the way the company approached targets, especially if teams were unable to reach them in the agreed timeline. One senior researcher in lead optimization compared the approach of Organon and Schering-Plough; in both cases, team leaders had to be able to explain to the management why a timeline was not reached, but he felt that the two managements would respond differently:

> *'Guys we need to discuss this as we are not going to make it and this is the reason. We can solve it, but we need additional budget, more manpower or we need to discuss the criteria [e.g. levels of selectivity]. This discussion was more relaxed within Organon; with Schering-Plough it was a matter of a contract. They were talking about contracts and breaking a contract. So why are you breaking the contract? It became a lot stricter about sticking to the agreements, but it was do-able. But Schering-Plough focused on content, so with good arguments you could convince them.'* (WD, 2011)

In the case of both personal and professional targets, the interviewees reported that the focus was on reaching a set number of targets. Under Schering-Plough and even more so under MSD, target setting became more extensive. The researchers felt as if they were supposed to be competing with their colleagues to reach both personal and professional targets. This seemed to be more important to management than the contribution they were making to development. Personal targets, like elaborating on a specific topic from the literature and presenting it to colleagues, had to be met even if there was no time for such presentations. Consequently, at the end of a calendar year researchers were obliged to listen to these presentations. *'It felt compulsory, it became too much. You had to make so many compounds, so much of this and that, the numbers mattered more'* (CJ, 2011). According to the same researcher, ticking off boxes on a form seemed more important than the content, a practice borne out of the management's desire to measure research activity. He explained: *'Research is more dependent on coincidence and what pops up in your path. In my opinion, needing to hit all the numbers stops the creative process, you become a bit jerky.'* The above feelings resulted in some friction between researchers and management. The following illustrates how they jointly dealt with problems related to type and number of personal targets by transforming the latter into a team target:

'I had to test 500 compounds in half a year. And if someone did not reach the goals, it was investigated why not. There were chemists who made 100 compounds, and others 30. Is the one making 100 better than the one making 30? No, as you are comparing apples with pears. There are classes of compounds which are made easily, in a week you can make 20; and there are classes of compounds which take two weeks, even a month, to create one compound...20 or 1, it is just a number...under Schering-Plough and MSD, the numbers increased considerably. What you get is that people are not going to work on the difficult class of compounds anymore, and this is also not a good thing. So eventually, we agreed to work as a group of chemists on a fixed number of compounds, our departmental target.' (CJ, 2011)

The writing of formal individual contracts, especially at the discovery stage, is described as problematic by Gilsing & Nooteboom (2006), who cite the difficulty of capturing tacit knowledge and turning it into a formal contract. This type of knowledge is unable to predict specific outcomes, hence formalizing and monitoring it might be very difficult. Second, detailed contracts can be seen as a sign of distrust, especially where relationships are informal and coordination mechanisms depend on social agreements and reputation. As already explained, such relationships and coordination mechanisms were in place under Organon management. Researchers were also expected to continuously develop their knowledge, effectively strengthening their capacity to give and take within the team. Gilsing & Nootebom suggest that this kind of informal safeguard against free riding may provide an alternative to individual contracts.

The third indicator of change in strategic focus was the type of planning implemented after the acquisitions. The researchers felt that the way timelines and project development were dealt with changed in the transitions from Organon to Schering-Plough and then to MSD. On the whole, researchers from both phases reported similar experiences: the suspension of all unauthorized activities, strict adherence to protocols, and slow decision-making that delayed milestones and timelines, putting entire projects in jeopardy. Following the acquisition by Schering-Plough, less experimenting was done on Friday afternoons. After the merger with MSD, this practice disappeared completely:

'With MSD, it's no longer possible to experiment on Friday afternoons; the idea is supposed to be presented with all the stages that have led up to it. The pleasure and joy of experimenting have been hijacked. So everyone is working very bravely and honestly on approved projects...what happens is only what is agreed upon. They say: "We are not the University of Oss; we are not researching for the sake of researching. It is all supposed to stay here, in the team." Yes, but to even get there, to get the new ideas you need to dare and go off track...Nobody dares anymore and we do exactly what we are told.' (WD, 2011)

A similar experience was described by a clinical researcher, who spoke of the diminished influence teams had on the timeline of clinical trials. Core teams no longer had a planner, and the protocol was there to be followed strictly:

> *'With MSD the protocol is monitored, you need x number of patients, so much money we get at the end, x number of sites are used, may be ten percent more, as recruitment is an issue. That's how it goes. So a team of people, of experts as they call them, sit in judgement over your protocol.'* (WS, 2011)

Many examples were given supporting the idea that decisions about milestones delayed the overall timeline. For instance, an extended search for an alternative to Prednisolone was paused for months while MSD management decided whether or not to approve phase I of the clinical trial. At the time of the interviews, almost a year later, this decision still hadn't been made; it was the researcher's opinion that if the decision had been made when first requested, an improved compound would have by now been ready for clinical trials. In the same way, projects approved to enter full development and launch were paused even after a trial protocol had been approved. EH, a clinical researcher, commented:

> *'Especially when we were taken over, it happened a lot that projects were delayed. With some studies, approved by the committee, protocol and everything all arranged, a month later we heard, no, no budget until next year, so we just stopped everything. With Organon it was very simple, you knew a trial was to start and you knew you could invest all your energy...women's health was the most important for Organon, for Schering-Plough it felt like a sidelined area...Repeatedly, trials which were supposed to start were paused, the budget was transferred to 2010 or other studies, but not in Oss.'* (EH, 2011)

Projects were also cut off completely, with the result that 80 people were working on three projects, instead of 150 people working on 15 to 20 projects (CJ, 2011). The researchers saw this as a bad sign:

> '*We were thinking, yeah, three projects! While the academics amongst us were used to working on multiple projects, they were with five persons on one project now. This is not working, this cannot go on. We didn't know what the Americans were planning, but we had the feeling it was not going in the right direction.'* (CJ, 2011)

Other projects already approved for clinical trials, including four projects in the area of women's health, were not just delayed but scrapped completely.

The waiting for decisions to be made and cancelling of projects was reported by the interviewees as having negative consequences on overall motivation. A common topic of discussion during lunch breaks was the slowness with which things were being done. People had empty desks and felt generally unappreciated. After the announcement of MSD's plan to

close the laboratory, months and months passed by without any further details, making the situation even worse:

> *'So research and clinical will disappear, almost all positions. But they didn't know which areas they wanted to keep so there was nothing happening at that point. There was uncertainty in the department, an atmosphere of depression, the bosses not daring to say anything, maybe afraid they were to be laid off as well. Everyone was looking hard for jobs, the best ones left immediately.'* (JE, 2011)

Overall, we may conclude that the changes that occurred during the acquisitions, in terms of the organization's choice of projects, targets and planning approaches, were evidence of the change in its strategic focus. Under MSD management, the type of projects pursued reflected a strategy to be best in class; it aimed at less variation in performance and the exploitation of knowledge about existing molecular entities. The team perspective gave way to an individual perspective after the acquisitions, with the introduction of formal contracts based on individual performance. This shift in perspective is in line with the best in class strategy, which encourages predictability of behaviour. The changes in planning may also be seen as evidence of a shift in strategic perspective. Cancelling projects and not utilizing the available variation in performance may represent a desire to play safe by betting on low or no risk projects, which in general seem to be of less interest to generic companies.

6 Conclusion

The central concern in this thesis is twofold: for one it aims to understand how organizational learning processes affect the innovation ability of a pharmaceutical organization; for another it aims to understand how decisions made during the acquisition process impact these organizational learning processes and what their effect is on innovation ability.

Drawing upon March's model, nine propositions were formulated and used to structure and focus the research process. These propositions address those structural characteristics and organizational actions which have been identified as significant in the quest to strike a balance between exploration and exploitation. The first states that individuals who adapt slowly to the organizational code are associated with the raising of the level of diversity within an organization, and by extension the time spent on learning and exploration. The second posits that the combination of fast and slow learners in an organization is closely linked to the level of organizational knowledge reached in the long term. The third proposition states that new employees who adapt slowly to the organizational code are more likely to contribute to exploration, while the fourth declares that exploration is associated with modest turnover and the introduction of rules for selecting employees. The fifth proposition suggests the combination of learning types and learning processes within an organization is closely related to its ability to achieve competitive advantage, when its aim is to come out first. The sixth proposition states that less coordination and more loosely

coupled organizational parts are related to an organization's potential to make radical innovations. The seventh proposition posits that an R&D laboratory balances exploitation and exploration by allowing sub-parts to specialize in one mode, thereby contributing to long-term competitive advantage, while the eighth suggests that organizational resources and a range of mindsets contribute to the simultaneous development of both incremental and radical innovations. The ninth proposition suggests that variation in performance may be increased by taking strategic action to vary learning types and learning processes.

This case study focuses on Organon to refine the above mentioned propositions and formulate a pharmaceutical innovation prediction model. This adjusted model indicates the structural characteristics and organizational actions which are particularly applicable to the pharmaceutical industry. Diversity in learning pace, expertise and learning processes all appeared to contribute to the exploration of knowledge, particularly in the discovery and exploratory phase of product development. In the full development and launch phase, regulatory pressures from external parties rendered diversity of pace and expertise less desirable. As far as the effect of personnel turnover on the exploration ability of an organization is concerned, it appears that slow turnover actually contributes to the level of organizational knowledge reached in the long term. The ability to simultaneously recognize the functions and limitations of a molecule requires an in-depth understanding which takes years to acquire, a process which might be disturbed by new employees who have not passed the required knowledge threshold.

At the same time, the sequential character of drug discovery and development fosters the emergence of both generalists and specialists, all of whom contribute to the exploring and exploiting of knowledge in the organization. Organon appears to have been constructed of loosely coupled teams, and job hopping was more common in discovery and exploratory development than in full product development. These cross functional, multidisciplinary teams had both the responsibility and the authority to make decisions affecting the innovation ability of the firm. They preferred informal coordination and direct lines of communication with managers, most of whom had been scientists themselves. The teams balanced high and low risk projects, all sharing the common goal of discovering drugs to address unmet needs. These projects were chosen for both known and unknown therapeutic areas, allowing the company to create a mix of areas and technical expertise and to explore and exploit organizational knowledge in the long term. By allowing experimentation without obligation and collaborating intensively with external parties such as universities, the company generated the stimulation of ideas. During the exploratory and full product development phase, the organization implemented relatively straightforward planning models, which gave it the flexibility to prioritize projects and shift resources where needed. This shift in resources made both exploration and exploitation of knowledge possible within the organization. This balance was revealed in the type of projects chosen, although the premium placed on highly innovative projects reflected its strategy of coming out first.

Decisions made during the acquisition process impacted the above-mentioned structural characteristics and organizational actions; accordingly, the pharmaceutical innovation prediction model has been adapted to reflect the context of company acquisitions. Diversity in expertise can be negatively affected by company acquisitions if the acquiring company is not planning to invest in areas covered by the acquired firm or if it is investing in these but in another geographical location. The decision to downgrade job profiles negatively affected the existing variation in knowledge by forcing employees to become specialists while at the same time denying them the opportunity to use their accumulated knowledge. This was particularly evident in the full development and launch phase, where managers placed a premium on standardization and predictability of behaviour. By the same token, employees in the discovery phase became increasingly isolated from external contacts, lowering their chances of generating novel ideas. With the second acquisition, the organizational structure gradually changed, affecting the balance between exploration and exploitation of existing knowledge. While the acquired company placed a premium on being 'first in class', the acquiring one seemed to focus on being 'best in class'. This 'best in class' strategy entailed focussing on projects classified as low or no risk and outsourcing the discovery phase to other organizations for completion. MSD shifted the power from the teams to centralized authorities that were geographically distant from the employees. The company introduced vertical integration, associated with tighter control, thereby narrowing the opportunity for innovation. The division of work into simple tasks, especially in full product development, adversely affected the motivation of employees in the short term; in the long term this division limited the development of deeper knowledge and understanding. The communication lines became longer and less transparent. As a result of this strategy, decisions were delayed or not made at all, and a number of promising projects were postponed or halted altogether by the acquiring organization.

Overall, we may conclude that MSD's acquisition of the case company was part of a strategy to gain short-term market share by investing in existing and late stage products. Products further down the pipeline, including potential projects which might contribute to long-term competitive advantage, were deemed undesirable, mainly because of the high risk involved. Flexible structures were replaced by structures typical of a large bureaucratic organization. This adaptation of structural characteristics and organizational actions reflects MSD's strategy to maintain stable performance in a changing market.

A parallel can be drawn between these mechanisms and those reported by Saxenian. The single-system organizational structure of Organon is comparable with the structure of the regional network-based system found in Silicon Valley in the 80s. Flexible and dynamic, fostering experimentation and collaboration, this regional network-based system was capable of reinventing itself after Japanese firms entered the microelectronics market and changed the nature of the competition. The valley is still considered the 'incubator' of the future (Delbecq & Weiss, 2000). This parallel also highlights the importance of understanding the nature of the competition in the pharmaceutical industry – this understanding is

essential if we are to properly understand organizational learning and its relation to innovation ability in the industry. Aside from considerations of competition, the emergence of specialized pharmaceutical companies around the globe, whatever their size, has made it even more important to create and maintain networks in the industry. It reminds us that organizational learning and its effect on innovation ability cannot be understood in isolation.

The model devised by March and used as a theoretical starting point in this thesis is based on discrete event computer simulation (Dooley, 2002). Dooley finds this model strong as the results of the simulation are tied in with theoretical arguments. Computer simulation in itself answers the 'what if' question and looks into the future, in this case, of organizations. In adopting the discrete event approach, March looks at the organization as a system consisting of variables and events which set off changes in those variables. His model is valuable as its outcome indicates the probability of the mentioned events, for example the probability that an individual's code will adapt to the organizational one. This study applies March's model to analyse the data, but without the necessary empirical component it is not possible to identify findings specific to the pharmaceutical industry in the context of company acquisition. Moreover, this application contributes to the existing literature in two ways. First, it suggests that under the conditions of company acquisition, strategic actions are the overarching dimension defining the balance between exploration and exploitation. This dimension is related to the ninth proposition of the model, and the fact that we can draw such a conclusion is in itself valuable as it highlights the value of the propositions as a starting point. Second, it suggests that industry-specific characteristics such as knowledge thresholds and heavy regulation influence the process of exploration and exploitation. Evidence is also found to support the argument of Gupta et al. (Gupta, Smith & Shalley, 2006) that organizations may allocate resources to both exploration and exploitation simultaneously.

The findings also have implications for start ups and joined ventures within the biopharmaceutical industry. The costs of drug development, like pricing pressures, are growing along with our knowledge of the human cell. It is becoming extremely difficult for a vertically integrated single firm to discover drugs and bring them onto the market with the desired speed, not to mention to respond to unmet medical needs. These developments call for flexible organizational networks which foster innovation in all segments of the industry. At the same time, the complexity of the environment is increased by the shifting of power to external parties such as the Food and Drug Administration and the European Medicines Agency, forcing companies to create more centralized and formalized structures capable of coping with heavy regulation.

Finally, the findings offer an explanation of the post-2007 decline in patent applications by the case company, identifying as the main reason the delay or abandonment of projects in the discovery phase of drug development.

One of the limitations of the thesis is that its approach is purely qualitative. The relationship between organizational learning and innovation ability is associative and may not be causal. Future research might focus on quantifying the structural characteristics predicted by March, and the innovation ability of organizations. Furthermore, the findings suggest strategic actions are the overarching dimension in the balance between exploration and exploitation. Future research might investigate these strategies, for example by involving higher management and by the thorough examination of company documents. Taking the findings as a point of departure, future research might examine changes in the institutional context of organizations, specifically in the nature of the competition and the power of external parties.

7 Bibliography

Akzo Nobel. (1998 - 2003). *Annual Reports.* s.l.: s.n. Retrieved from http://www.akzonobel.com/news/annual_report/

Akzo Nobel. (2003). *Annual Report.* s.l.: s.n. Retrieved from http://www.akzonobel.com/system/images/AkzoNobel_Annual_Report_2003_tcm9-7204.pdf

Akzo Nobel. (2004). *Annual Report.* s.l.: s.n. Retrieved from http://www.akzonobel.com/system/images/AkzoNobel_Annual_Report_2004_tcm9-1162.pdf

Akzo Nobel. (2005). *Annual Report.* s.l.: s.n. Retrieved from http://www.akzonobel.com/system/images/AkzoNobel_Annual_Report_2005_tcm9-1200.pdf

Akzo Nobel. (2006). *Annual Report .* s.l.: s.n. Retrieved from http://www.akzonobel.com/system/images/AkzoNobel_Annual_Report_2006_tcm9-1232.pdf

anon. (2011, March 11). *Actualiteiten: uitspraak kort geding Organon*. Retrieved March 12, 2011, from www.rechtspraak.nl: http://www.rechtspraak.nl/Actualiteiten/Uitspraak+kort+geding+Organon.htm

anon. (2007). *Educatie, ontwikkeling van moderne geneesmiddelen*. Retrieved March 10 , 2012, from www.100jaarfarmacologie.nl: http://www.100jaarfarmacologie.nl/educatie/maken.html

anon. (2012, March 14). *Europe 2020 targets.* Retrieved April 1, 2012, from ec.europa.eu: http://ec.europa.eu/europe2020/pdf/targets_en.pdf

anon. (2012). *Feitenkaart geneesmiddelenonderzoek.* Retrieved April 1, 2012, from www.argumentenfabriek.nl: http://argumentenfabriek.nl/sites/default/files/Nefarma-Klikpdf_0.pdf

anon. (2011, March 5). Fiscus wilde Organon steunen, 15. *NRC Handelsblad*, Retrieved March 8, 2011 from www.lexisnexis.com/nl/business

anon. (2009). *Geschiedenis*. Retrieved March 10, 2011, from www.schering-plough.nl: http://www.schering-plough.nl/Over_Schering-Plough/geschiedenis.aspx

anon. (2009, March 14). Merck's manoeuvres. *The Economist, 390*(8622), 67. Retrieved from EBSCOhost. Retrieved March 10, 2011

anon. (2012, March). *Nefarma & publications.* Retrieved June 3, 2012, from www.nefarma.nl: http://www.nefarma.nl/nefarma/publicaties

anon. (2010, December 31).Tot slot...Top 5 2010, 21. *Het Financieele Dagblad,* Retrieved March 8, 2011 from www.lexisnexis.com/nl/business.

Argote, L., & Ophir, R. (2002). Chapter 8 Intraorganizational learning. In J. A. Baum (ed.), *Companion to organizations* (pp. 181 - 207). Oxford: Blackwell Publishing.

Baregheh, A., Rowley, J., & Sambrook, S. (2009). Towards a multidisciplinary definition of innovation. *Management Decision, 47*(8), 1323 - 1339.

Baum, J. (ed.). (2002). *Companion to organizations.* Oxford: Blackwell Publishing.

Bierly III, P. E., Damanpour, F., & Santoro, M. D. (2009). The application of external knowledge: organizational conditions for exploration and exploitation. *Journal Of Management Studies, 46*(3), 481 - 509.

CJ. (2011, October 5). Chemist. (M. Brinkman, Interviewer)

Cockburn, I. (2004). The changing structure of the pharmaceutical industry. *Health Affairs, 23*(1), 10 - 22. doi:10.1377/hlthaff.23.1.10

Couwenbergh, P. (2011, February 21). Hoe Organon te bevrijden van Merck. *Het Financieele Dagblad*, Retrieved March 10, 2011 from www.lexisnexis.com/nl/business

Cummings, T., & Worley, C. (2005). Chapter 14 Restructuring organizations. In *Organization development and change* (8 ed., pp. 274 - 305). Mason: Thomson - South Western.

De Weerd, P. (2010). Trends in the pharmaceutical industry and the impact on intellectual property rights. In H. Hanneman, *A century of patents in the Netherlands; Part 6 the future: renovation or innovation* (pp. 22 - 25). The Hague: SDU Uitgevers, NL Agency Ministry of Economic Affairs.

Delbecq, A., & Weiss, J. (2000). The business culture of Silicon Valley: a turn-of-the-century reflection. *Journal of Management Inquiry, 9*(1), 37 - 44. doi:10.1177/105649260091008

Devroey, P., Boostanfar, R., Koper, N., Mannaerts, B., Ijzerman-Boon, P., & Fauser, B. (2009). A double-blind, non-inferiority RCT comparing corifollitropin alfa and recombinant FSH during the first seven days of ovarian stimulation using a GnRH antagonist protocol. *Human reproduction, Oxford Journals, 24*(12), pp. 3063 -3072. doi:10.1093/humrep/dep291

Dooley, K. (2002). Chapter 36 Simulation research methods. In J. Baum (Ed.), *Companion to organizations* (pp. 823 - 848). Oxford: Blackwell Publishing.

drs. Verhagen, M. (2010, November 22). *Kamerstukken: beantwoording vragen over bezuinigingen farmasector en financiering topinstituten.* Retrieved March 12, 2011, from www.rijksoverheid.nl: http://www.rijksoverheid.nl/documenten-en-publicaties/kamerstukken/2010/11/22/beantwoording-kamervragen-over-bezuinigingen-farmasector-en-financiering-topinstituten.html

drs. Verhagen, M. (2011, February 16). *Kamerstukken: voortgangsrapportage MSD-Organon.* Retrieved March 11, 2011, from www.rijksoverheid.nl: http://www.rijksoverheid.nl/documenten-en-publicaties/kamerstukken/2011/02/17/kamerbrief-voortgangsrapportage-msd-organon.html

DZ. (2011, May 16). Director Clinical Research Anaesthesia & Analgesia. (M. Brinkman, Interviewer)

EH. (2011, May 26). Clinical Researcher. (M. Brinkman, Interviewer)

Eisenhardt, K. M., & Bhatia, M. (2002). Chapter 19 Organizational complexity and computation. In J. Baum (ed.), *Companion to organizations* (pp. 442 - 466). Oxford: Blackwell Publishing.

Engelfriet, A. (2010). Software protection, past and future trends. In H. Hanneman, *A century of patents in the Netherlands; Part 6 The future: renovation or innovation* (pp. 3-9). The Hague: SDU Uitgevers, NL Agency Ministry of Economic Affairs.

European Comission. (2012 last update, April 22). *European Commission, DG health & consumers, public health, medicinal products for human use, clinical trials*. Retrieved April 22, 2012, from ec.europa.eu: http://ec.europa.eu/health/human-use/clinical-trials/index_en.htm

Gilsing, V., & Nooteboom, B. (2006). Exploration and exploitation in innovation systems: the case of pharmaceutical biotechnology. *Research Policy, 35*, 1-23.

Gupta, A. K., Smith, K. G., & Shalley, C. E. (2006). The interplay between exploration and exploitation. *Academy of Management Journal, 49*(4), 693 - 706.

Harmancioglu, N., Droge, C., & Calantone, R. (2009). Theoretical lenses and domain definitions of innovation research. *European Journal of Marketing, 43*(1/2), 229 - 263.

HIggins, M., & Rodriguez, D. (2006). The outsourcing of R&D through acquisitions in the pharmaceutical industry. *Journal of Financial Economics 80*, 351 - 383.

Jansen, J., Van de Vrande, V., & Volberda, H. (2008). *Meer rendement uit R&D.* Rotterdam: Rotterdam School of Management, Erasmus University Rotterdam.

JE. (2011, May 24). Senior Clinical Researcher. (M. Brinkman, Interviewer)

JU. (2011, July 7). Target discovery process and molecular pharmacology researcher. (M. Brinkman, Interviewer)

Kirjavainen, P. (2009). Strategic learning in a knowledge-intensive organization. In H. W. Volberda, & T. Elfring (eds.), *Rethinking strategy* (pp. 172 - 190). London: Sage Publications Ltd.

Lehman, B. (2003). *The pharmaceutical industry and the patent system.* Retrieved April 10, 2011, from www.earth.columbia.edu: http://www.earth.columbia.edu/cgsd/documents/lehman.pdf

Levinthal, D. A., & March, J. G. (1993). The myopia of learning. *Strategic Management Journal, 14*, 95 - 112.

Levitt, B., & March, J. G. (1988). Organizational learning. *Annual Review of Sociology, 14*, 319 - 340.

Magazzini, L., Pammolli, F., & Riccaboni, M. (2009). R&D productivity, spillovers and effective patent life. *Measuring the value of IPR: theory, business practice and public policy; 4th Annual Conference of the EPIP Association.* Bologna: Measuring the value of IPR: theory, business practice and public policy 4th Annual Conference of the EPIP Association. Retrieved June 9, 2012, from http://www.epip.eu/conferences/epip04/files/MAGAZZINI_Laura.pdf

Mahoney, S., & Franco, R. (2008, Third Quarter). Good medicine for biopharmaceutical companies; how industry leaders are translating R&D efforts into innovation and growth. *Reprinted from PRTM Insight*.

Makri, M., & Geiger, S. W. (2006). Exploration and exploitation innovation processess: the role of organizational slack in R&D intensive firms. *Journal of High Technology Management Research*, 97 - 108.

March, J. (1991). Exploration and exploitation in organizational learning. *Organization Science, 2*(1), 71 - 87.

Merck & Co. (2010, July 8). *Newsroom*. Retrieved March 10, 2011, from www.merck.com: http://www.merck.com/newsroom/news-release-archive/corporate/2010_0708.html

Miller, K. D., Zhao, M., & Calantone, R. J. (2006). Adding interpersonal learning and tacit knowledge to March's exploration-exploitation model. *Academy of Management Journal, 49*(4), 709 - 722.

Mintzberg, H. (1989). Chapter 6 Deriving configurations. In *Mintzberg on management, inside our strange world of organizations* (pp. 95 - 115). New York: The Free Press.

MJvL. (2011, June 20). Researcher in Discovery Phase. (M. Brinkman, Interviewer)

Morgan, S., Lopert, R., & Greyson, D. (2008). Toward a definition of pharmaceutical innovation. *Open Medicine, 2*(1), 4 - 7.

Moroney, A. C. (2007, November). *Drugs, drug dynamics, site selectivity*. Retrieved April 3, 2012, from www.merckmedicus.com: http://www.merckmedicus.com/pp/us/hcp/framemm.jsp?pg=www.merck.com/mrkshared/mmanual_home/contents.jsp

MvdV. (2011, June 20). Researcher, Animal Testing. (M. Brinkman, Interviewer)

Nathan, C. (2007, March). Aligning pharamceutical innovation with medical need. *Nature Medicine, 13*(3), 304 - 308.

Oerlemans, L., & Kenis, P. (2007). Netwerken en innovatieve prestaties, overzicht van theorie. *Tijdschrift voor Management en Organisatie, 61*(3/4), 36 - 54. Retrieved from http://arno.uvt.nl/show.cgi?fid=67282

Orton, J. D., & Weick, K. E. (1990, April). Loosely coupled systems: a reconceptualization. *The Academy of Management Review, 15*(2), 203 - 223.

Overbeeke, S. (2011). *Innovatie door samenwerking in diversiteit, een casestudy naar de innovatieoutput van Organon Oss.* Master Thesis, Faculty of Social Sciences, Erasmus University Rotterdam.

PC. (2011, July 13). Medicinal Chemist. (M. Brinkman, Interviewer)

Pharmaceutical Research and Manufacturers of America. (n.d.). *Research and development*. Retrieved April 2, 2012, from www.phrma.org: http://www.phrma.org/research-development

Pharmaceutical Research and Manufacturers of America. (n.d.). *Drug discovery and development*. Retrieved April 2, 2012, from www.phrma.org: http://www.phrma.org/research/drug-discovery-development

PvW. (2011, June 17). Researcher and Head Patents. (M. Brinkman, Interviewer)

PwC. (2008). *Pharma 2020: virtual R&D – which path will you take?* s.l.: PricewaterhouseCoopers. Retrieved June 23, 2012, from http://www.pwc.nl/nl/publicaties/pharma-2020-virtual-rd.jhtml

PwC. (2011). *Introducing the Pharma 2020 series.* s.l.: PricewaterhouseCoopers. Retrieved June 23, 2012, from http://www.pwc.com/en_GX/gx/pharma-life-sciences/pharma-2020/introducing-the-pharma-2020-series.jhtml

Rodan, S. (2005). Exploration and exploitation revised: extending March's model of mutual learning. *Scandinavian Journal of Management, 21*, 407 - 428.

Rozendaal, S. (2010, November 27). Rampjaar 2010;tweeduizend banen weg bij Organon, vijfhonderd bij Solvay: de farmaceutische bedrijven in Nederland beleven slechte tijden. Elsevier, Retrieved March 10, 2011, from www.lexisnexis.com/nl/business .

Salomon, M. F., & Schork, J. M. (2003, July 1). Turn diversity to your advantage. *Research - Technology Management, 46*(4), 37 - 44.

Saxenian, A. (1994). *Regional advantage; culture and competition in Silicon Valley and Route 128.* Cambridge, Massachusetts, and London, England: Harvard University Press.

Saxenian, A. (1996). Inside-out: regional networks and industrial adaptation in Silicon Valley and Route 128. *Cityscape: a Journal of Policy Development and Research, 2*, 41-60.

Schering-Plough. (2008). *Investors.* Retrieved March 10, 2011, from http://www.merck.com/investors/financials/annual-reports/home.html: http://thomson.mobular.net/thomson/7/2976/3993/document_0/SGP_AR08.pdf

Schering-Plough. (2010, July 8). *MSD kondigt herstructurering van de locatie in Oss aan in het kader van wereldwijde integratie na de fusie tussen Merck en Schering-Plough*. Retrieved March 10, 2011, from http://www.schering-plough.nl/Nieuws/Persberichten/2010_07_08.aspx#0

Schulz, M. (2002). Chapter 18 Organizational learning. In J. Baum (ed.), *Companion to organizations* (pp. 415 - 441). Oxford: Blackwell Publishing.

Scott, W. R., & Davis, G. F. (2007). *Organizations and organizing.* New Jersey: Pearson Education.

Segers, J. (2002). *Methoden voor de maatschappijwetenschappen.* Assen: Koninklijke van Gorcum.

Snijders, H. (2011, March 2). Na Organon heeft Oss nu ook gezicht . *Brabants Dagblad*.

Sternberg, R. J. (2006). The nature of creativity. *Creativity Research Journal, 18*(1), 87 - 98.

Task Force Social Innovation . (2005). *Sociale innovatie, de andere dimensie.* Ministry of Economic Affairs, The Hague.

The Working Party for Implementation of Directive 2001/20/EC; Ministry of Health, Welfare and Sport. (2005, October). Instruction manual for the conduct of clinical research with medicinal products in the Netherlands. The Hague: Ministry of Health, Welfare and Sport. Retrieved April 8, 2012, from http://www.ccmo-online.nl/hipe/uploads/downloads_cati/Instruction%20manual%20versie%202.pdf

Thompson, R. (2001). Foundations for blockbuster drugs in federally sponsored research. *The Journal of the Federation of American Societies for Experimental Biology, 15*, 1671 - 1676.

Uitdehaag, J. (2010, September 6). Problemen Organon tekenend voor leegvissen farmaceutische industrie; innovatieprobleem grote bedrijven verleidt ooit stabiele sector tot roofdierkapitalisme. *Het Financiele Dagbald*.

Un, C. (2007). Managing the innovators for exploration and exploitation. *Journal of Technology Management and Innovation, 2*(3), 4 - 20.

Van der Hoeven, M. (2010, July 15). *(a) Kamerstukken: brief aan de tweede kamer over herstructurering MSD-vestiging Oss.* Retrieved March 12, 2011, from www.rijksoverheid.nl: http://www.rijksoverheid.nl/documenten-en-publicaties/kamerstukken/2010/07/15/brief-aan-de-tweede-kamer-over-herstructurering-msd-vestiging-oss.html

Van der Hoeven, M. (2010, July 20). *(b) Kamerstukken:beantwoording vragen over sluiting MSD.* Retrieved March 12, 2011, from www.rijksoverheid.nl: http://www.rijksoverheid.nl/documenten-en-publicaties/kamerstukken/2010/07/20/beantwoording-vragen-over-sluitingen-bij-msd.html

Van Wijk, L. (2010). The changing 'IP Game'. In H. Hanneman, *A century of patents in the Netherlands; Part 6 the future: renovation or innovation* (pp. 16 - 21). The Hague: SDU Uitgevers, NL Agency Ministry of Economic Affiars.

Vereniging Innovatieve Geneesmiddelen Nederland (a). (n.d.). *Feiten & cijfers; ontwikkeling van een medicijn*. Retrieved April 6, 2012, from www.nefarma.nl: http://www.nefarma.nl/feiten-en-cijfers/ontwikkeling-van-een-medicijn

Vereniging Innovatieve Geneesmiddelen Nederland (b). (n.d.). *Waarde van het geneesmiddel*. Retrieved April 2, 2012, from www.nefarma.nl: http://www.nefarma.nl/waarde-van-het-geneesmiddel/ontwikkeling

Vereniging Innovatieve Geneesmiddelen Nederland. (2011, November). *Farmafeiten 2011.* Retrieved April 1, 2012, from http://www.nefarma.nl/nefarma/publicaties

Wang, C. L., & Ahmed, P. K. (2003). Organisational learning: a critical review. *The Learning Organization, 10*(1), 8-17.

WD. (2011, June 9). Senior Researcher Lead Optimization. (M. Brinkman, Interviewer)

Weiss, J., & Delbecq, A. (1987). High-technology cultures and management: Silicon Valley and Route 128. *Group & Organization Management, 12*(39), 39 - 54. doi:10.1177/105960118701200104

Wilen, H. (2007, March 20). *R&D in pharmaceutical enterprises: the most R&D-intensive sector in Europe.* Retrieved April 16, 2011, from epp.eurostat.ec.europa.eu: http://epp.eurostat.ec.europa.eu/portal/page/portal/product_details/publication?p_product_code=KS-SF-07-039

WS. (2011, June 15). Clinical Researcher. (M. Brinkman, Interviewer)

Yin, R. K. (2009). *Case study research, design and methods* (4th ed.). Thousand Oaks: Sage .