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Doctoral Thesis

The evolution of innovation strategy: Studied in the context of medical device activities at the pharmaceutical company Novo Nordisk A/S in the period 1980-2008

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The evolution of innovation strategy

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Arne Stjernholm Madsen

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**Studied in the context of medical device activities at the
pharmaceutical company Novo Nordisk A/S in the period 1980-2008**

Arne Stjernholm Madsen

PhD thesis. Date of submission: 2012-03-16.
Supervisor: Professor Jens Frøslev Christensen,
Department of Innovation & Organizational Economics (INO).

Copenhagen Business School,
Doctoral School of Organisation and Management Studies.

Arne Stjernholm Madsen
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Preface and acknowledgements

This DBA (Doctor of Business Administration) project has been underway for six years. Although working in the field of innovation management, my background was an education as a graphic designer and I therefore had to start by writing a research proposal, in order to obtain dispensation from CBS for the lack of academic degree. Luckily, I succeeded, and thus I could begin the adventures of academic research by yearend 2006. Having my normal work to do on the side, and trying to maintain rudiments of a private life, the DBA project sometimes felt like being in a maelstrom of challenges. So much greater was the excitement, when the pieces of the puzzle began to form a picture – such peak experience makes the whole journey worth the efforts.

A number of persons and institutions have contributed to making this research project possible. I would first like to thank my employer, **Novo Nordisk A/S**, for generous financial support and for letting me use the company as a case. Furthermore, app. 50 former and present colleagues have served as my informants – these remain anonymous, in accordance with the corporate policies. However, I think it is fair explicitly to thank the three executive informants: Former CEO Mads Øvlisen, CSO Mads Krogsgaard Thomsen and CEO Lars Rebien Sørensen. Without the numerous internal informants at Novo Nordisk, there would have been no story to tell...

Several **academic researchers and educators** have supported me. First of all I wish to thank my supervisor, Professor Jens Frøslev Christensen, for believing in my project and guiding me patiently through my ups and downs. *“I can see the diamond in the coalmine”*, he persistently encouraged me. Along the way I have also received valuable input from Professor John Bessant, University of Exeter Business School, who served as external supervisor in the beginning of the project. I have received helpful advice from Professor Richard A. Bettis, The Kenan-Flagler Business School, University of North Carolina at Chapel Hill, at a PhD course at CBS in 2009. Professor Andrew Van de Ven, Carlson School of Management, University of Minnesota, opened my eyes for the principles of engaged scholarship at the EDEN doctoral seminar in 2011. For the theoretical frame, I am in debt to Professor Robert A. Burgelman, Stanford University Graduate School of Business, who has also kindly commented my diagrams of his theories. Professors Christian Knudsen and Peter Karnøe, both CBS, gave very constructive feedback at my pre-defense. Last, not least, I thank the dissertation committee for very thorough and constructive comments, which have sharpened the argumentation in the final text: Professors Christian Knudsen (Chairman) CBS; Fredrik Tell, Linköping University; Robert A. Burgelman, Stanford University. I owe all of these scholars a lot.

On the **private side**, I have been gratified by seeing both my children undertake PhD projects and thereby encourage their father: Tabita, my daughter, took her PhD from The Niels Bohr Institute, University of Copenhagen, in 2009 and Mathias, my son, currently conducts a PhD project at Institute for Logic, Language, and Computation at the University of Amsterdam. *The* one person, however, that I am most in debt to, is my wife, Kirsten, who has supported me and my project throughout the last six years, regardless how stressed or absentminded I have been.

Summary

Increased globalization in business competition makes the ability to innovate and to redefine strategy crucial to a company. An interesting question however is if a management team can control innovation and strategic renewal of the company at all; or do such changes *emerge*, driven by external events or by bottom-up processes in the organization? The present research project addresses some of these issues through the overall **research question** “*How does innovation strategy evolve?*”

The research question is examined in a **specific empirical context**. Since 2001, I have worked as an internal innovation consultant at Novo Nordisk A/S; a pharmaceutical firm founded in 1923 operating in a well established industry (insulin for diabetes treatment), characterized by intensive investments in Research and Development. I took advantage of this unique access to the internal life of an organization and consequently set up my research project as a longitudinal in-depth case study of the medical device innovation activities at Novo Nordisk A/S covering the period 1980-2008. The study specifically analyzes the relationship between the classic core product of the firm (insulin) and complementary products (medical devices, such as insulin ‘pens’), which hold the potential to either enhance the value of the core product, or to become a distinct business of its own.

Burgelman’s evolutionary theory of strategy making, especially his ‘internal ecology model’ (Burgelman 1991, 2002), has been chosen as the basic **theoretical framework** for the project. Some expansions of this framework, however, were needed. First, the present study puts greater emphasis on analyzing the external environment and its influence on internal strategy processes. Second, the analysis includes the role of management cognition, especially the notion of the corporate dominant logic (Prahalad & Bettis, 1986; Bettis & Prahalad, 1995), understood as an enduring top management worldview or mindset based on reinforcement of experiences from the past.

With regard to **results**, the present study identifies a more entrepreneurial role of the top management driven induced strategy process than traditionally described in evolutionary theory. In this case study, strategic variation and trial-and-error learning is not restricted to the autonomous initiatives in the ‘internal ecology’; on the contrary, top management cognition creates strategic visions or hypotheses, which are enacted as experiments *in the market*, for example in the form of new product categories. External feedback determines the destiny of these strategic experiments. Thereby innovation strategy (in case, for medical devices) serves as a *strategic laboratory* at corporate level, so to speak.

The device-based strategic experiments face the challenge of escaping the gravity of the dominant logic, which repeatedly pulls the strategy back towards the well-known success formula, centered on the drug itself (i.e. the insulin). Thus, the induced strategy process mediates core assets (pharmaceutical drugs) and complementary assets (medical devices), by swinging the pendulum between cycles of innovation strategy which define the devices as core or complementary

respectively. Hence, the balance between what is defined as core and what is defined as complementary in the corporate innovation strategy seems to be dynamic and negotiable.

As a consequence of the cycles of strategic experimentation, the corporate induced strategy process acts as a force of strategic entrepreneurship, seen over extended time.

The **implications for research** point towards a new paradigm of strategic research in the 'middle ground' between rational choice theory and evolutionary theory, as proposed by Gavetti & Levinthal (2004). The present research project suggests that a firm's ability for strategic adaptation depends *both* on strategic context determination of autonomous initiatives in the 'internal ecology' *and* on ability to enact induced strategic experiments with alternating innovation strategies in the market. This theory of 'inbound' and 'outbound' strategic search establishes a dynamic understanding of the corporate induced strategy process. In this understanding, innovation strategies act as *hypotheses*, which create strategic dissonance between vision and reality and thereby drive strategic learning.

The **implications for management practice** are first recognition of how fortunate it has been for Novo Nordisk to sustain the core business strategy, protected by the dominant logic. This fact relates to a background where the core market proved to hold immense growth potential, and the industry was relatively stable compared to for instance the IT industry. On the other hand, Novo Nordisk's success is partly due to cycles of strategic experiments with complementary assets for innovation, in case medical devices. Top management initiated these explorative experiments and the learning was utilized for expansion of the position within the core business. Hence, one can conclude that a company should explore and utilize the value of complementary assets, since these are perfect tools for strategic experimentation *without risking the core business*.

Resumé

I den stigende globale konkurrence har virksomheders evne til innovation og til at redefinere deres forretning fået livsvigtig betydning. Men kan man som ledelse overhovedet styre innovation og strategisk fornyelse, eller opstår fornyelsen organisk, så at sige af sig selv, drevet af ydre omstændigheder eller nedefra i organisationen? Dette forskningsprojekt indkredser en del af denne problematik gennem den overordnede **problemformulering** "*Hvordan udvikler innovationsstrategi sig?*"

Problemstillingen undersøges empirisk i en **specifik kontekst**. Siden 2001 har jeg arbejdet som intern innovationskonsulent i Novo Nordisk A/S; et firma etableret i 1923, som opererer i den forskningstunge farmaceutiske industri med insulin til diabetesbehandling som sit hovedprodukt. Jeg har valgt at udnytte min unikke tilgang til organisationens indre liv ved at udforme forskningsprojektet som et dybdegående langtids-casestudie i konteksten udvikling af medicinske devices (dvs. insulinpenne og lignende udstyr) hos Novo Nordisk A/S i perioden 1980-2008. Specielt analyseres relationen mellem devices som komplementære produkter i forhold til virksomhedens klassiske kerneprodukt (insulin): Understøtter devices salget af kerneproduktet, eller udnyttes devices til selvstændig forretningsudvikling?

Som **teoretisk ramme** er primært valgt Robert A. Burgelmans evolutionære teori om strategiudvikling kaldet strategiudviklingens *interne økologi* (Burgelman 1991, 2002). Desuden er inddraget nogle supplerende perspektiver, som Burgelmans teori gør mindre ud af: For det første er der lagt større vægt på *omverdenens* indflydelse på organisationens strategiudvikling; for det andet inddrages *ledelseskognition* i analysen, herunder begrebet *dominerende logik* (Prahalad & Bettis, 1986; Bettis & Prahalad, 1995), der betegner et relativt statisk ledelsessyn på virksomhedens succesfaktorer, som er opbygget gennem erfaring.

Som **resultat** påviser casestudiet en mere innovativ rolle for den topstyrede, inducerede strategi-proces, end man normalt ser beskrevet i evolutionær ledelsesteori. I mit studie er strategisk fornyelse og prøven-sig-frem ikke begrænset til de såkaldte autonome initiativer i den *interne økologi*; tværtimod fører topledelsens kognition til eksperimenter med strategiske visioner eller hypoteser, der prøves af *i markedet* f.eks. med introduktion af nye produktkategorier. Reaktionen fra omverdenen bestemmer disse eksperimenters skæbne. Innovationsstrategien kan altså siges at være en slags *strategisk laboratorium* for virksomheden som helhed.

De strategiske eksperimenter med devices har desuden den konstante udfordring, at den dominerende logik trækker strategien tilbage imod den velkendte formel, baseret på selve insulinen som forrettningens basis. Således balancerer strategiudviklingen mellem kerneprodukter (i dette tilfælde insulin) og komplementære produkter (devices), som på skift danner basis for vekslende innovationsstrategier. Dermed synes grænsen mellem *kerne* og *komplementær* at være dynamisk eller m.a.o. til konstant forhandling.

Som konsekvens af eksperimenterne med innovationsstrategien fremmer den inducerede strategiproces virksomhedens strategiske fornyelseskraft set over et længere tidsperspektiv.

Det **forskningsmæssige perspektiv** af nærværende projekt peger frem mod et nyt paradigme i strategiforskning midt imellem rationelle og evolutionære standpunkter, som foreslået af Gavetti & Rivkin (2004). Min forskning påviser, at strategisk fornyelse afhænger *såvel* af evnen til at udnytte de interne, autonome initiativer *som* af evnen til at udnytte topstyrede eksperimenter med alternative innovationsstrategier i markedet. Denne teori om strategisk prøven-sig-frem *indadtil som udadtil* etablerer en dynamisk forståelse af den inducerede strategiproces. I denne forståelse optræder innovationsstrategier som *hypoteser*, der etablerer et spændingsfelt mellem vision og virkelighed og dermed driver strategisk læring.

De **ledelsespraktiske perspektiver** er først anerkendelse af, hvor værdifuldt det har været for Novo Nordisk at fastholde kernestrategien båret af den dominerende logik. Dette skal ses på baggrund af et kernemarked, der viste sig at indeholde et enormt vækstpotentiale, og hvor omverdenen var relativt stabil sammenlignet f.eks. med IT-branchen. Omvendt kan en væsentlig del af Novo Nordisks succes tilskrives, at topledelsen har åbnet for en række strategiske eksperimenter med *komplementære* produkter, dvs. devices så som insulinpenne, og forstået at udnytte læringen fra disse eksperimenter til at udbygge positionen på kerneområdet. Man kan derfor konkludere, at man bør udforske og udnytte de komplementære produkters værdi, da disse er perfekte redskaber til strategiske eksperimenter, uden at man risikerer virksomhedens kerneforretning.

Content

Chapter 1: Introduction	13
Initial puzzles	13
Research questions	16
General questions	16
Specific questions	16
Definitions	17
Theoretical framework	19
Research design	23
What can we learn from a case study of Novo Nordisk?	24
Selection of one main theoretical model	24
Contribution	24
Structure of the thesis	25
 Chapter 2: Theoretical framework	27
Introduction	27
Understanding strategy – and dimensions of strategy research	29
The rational versus the behavioral paradigm	29
Basic dualities of strategy	30
Identification of a theoretical ‘middle ground’	31
Where do strategies come from?	33
Strategy making as social learning	33
Forward-looking cognitive search and backward-looking experiential learning	34
Cognitive and experience-based search in a perspective of organizational maturation	35
Conclusion on origin of strategies	36
How strategies evolve	38
The internal ecology of strategy making	38
Conclusions on strategy evolution	43
The role of management cognition for strategy	44
The impact of the initial ‘framing’ of the business – and of identity	44
Cognitive and strategic inertia	46
Dominant logic	48
How the dominant logic might be loosened up	51
Conclusions on management cognition and strategy	52
Integrative competencies	52
A synthesized model of strategy evolution	54
Scenario 1: the emergent state	54
Scenario 2: strategic lock-in	55
Scenario 3: induced strategic adaptation	56

Scenario 4: induced strategic reconfiguration	57
Chapter 3. Research design and method	60
Overall research design	60
Process study.....	60
Qualitative case study.....	61
Special research setting	62
Limitations due to business confidentiality.....	62
1. Research method for the longitudinal case study	63
Data collection	63
Definitions.....	65
Data analysis.....	65
The construction of a narrative.....	66
Validation of findings	67
2. Research method for the analysis of the device innovation project portfolio	68
Data validation.....	69
3. Research method for the mindset analysis 2007	70
Sample and data	70
Data analysis.....	71
Validation of findings	72
Chapter 4: The transformations of innovation strategy	73
Introduction	75
Diabetes and devices.....	76
Novo Nordisk in brief.....	78
The diabetes industry.....	79
Structure of the rest of the chapter	81
Part 1: The historical case study	82
Summary.....	82
Phase 0: Maturing for medical devices (1923-1980)	84
The corporate DNA	84
Industry dynamics	85
Diagnostic systems.....	85
Concluding on the period 1923-1980	86
Phase 1: Early attempts within device innovation (1980-1988)	87
Insulin industry	87
Corporate management cognition	88
Entering medical devices	89
Concluding on the evolution of the early attempts 1980-1988.....	91
Phase 2: The period around the merger (1988-1992).....	94

Insulin industry	94
Corporate management cognition	94
Medical device level.....	95
Concluding on the evolution of innovation strategy 1988-1992	98
Phase 3: The quality crisis (1992-1994)	100
Insulin industry	100
Corporate level – cognition and crisis	100
Medical device level.....	102
Concluding on the evolution of innovation strategy during the crisis 1992-1994	104
Phase 4: Harvesting (1995-2001)	106
Insulin industry	106
Corporate management cognition	107
Medical device level.....	109
Concluding on the evolution of strategy in the harvesting period (1995-2001)	110
Phase 5: The vision of closed loop (2001-2005)	112
Insulin industry	112
Corporate strategy	113
Medical device level.....	117
Concluding on the evolution of the PDS strategy (2001-2005)	118
Phase 6: Integration into the drug research area (2005-2008).....	120
Insulin industry	120
Corporate management cognition	120
Medical device level.....	121
Concluding on the formation of the DRU strategy (2005-2008).....	123
Part 2: The product innovation portfolio	124
Definitions.....	125
Expectations.....	125
Basic measurements	126
The development of the nature of the innovation project portfolio	128
Conclusion on the development of the project portfolio	135
Part 3: Close-up analysis of device level dominant logic 2007	136
Findings.....	136
Concluding on the ‘dominant innovation logic’ 2007.....	137
 Chapter 5: The “whole story” – and theory building	 139
Introduction	139
Analysis across phases – the “whole story”	140
Trends in the underlying development	140
The overall pattern in the evolution of innovation strategy	142
The drivers of change	147

Discussing theory in the light of the case study	150
The role of management cognition	150
The role of autonomous and induced strategy	152
Building new theory – in the “middle ground”	159
Strategy as a mediator between internal and external ecologies	159
Revisiting the induced strategy process: induced strategic renewal	159
Chapter 6: Conclusion	163
Introduction	163
Findings.....	164
Contribution.....	165
Implications for research	168
Implications for management practice	169
References	171
Appendix A. Research method for the mindset analysis 2007-10 in detail	176
Sample and data	176
The use of ‘cognitive maps’	178
One common ‘landscape’ model	179
The use of ‘creative questionnaires’ when interviewing	180
Identifying the dominant innovation logic.....	182
The weaknesses of the methodology	183

Chapter 1: Introduction

Content

Initial puzzles.....	13
Research questions	16
General questions	16
Specific questions.....	16
Definitions.....	17
Theoretical framework.....	19
Research design.....	23
What can we learn from a case study of Novo Nordisk?	24
Selection of one main theoretical model.....	24
Contribution.....	25
Structure of the thesis	25

Initial puzzles

Bubbles burst. When the Internet or dotcom bubble burst in 2001, I lost my job as a business developer at Ericsson Denmark. To my fortune, the Danish pharmaceutical company Novo Nordisk A/S had just established a new R&D unit for medical devices, called Protein Delivery Systems (PDS). Novo Nordisk's main business is in diabetes care, and PDS was formed out of a vision called '*closed loop*'; this referred to medical device systems, which were able to mimic the function of the human pancreas by continuously monitoring the blood sugar level and, at the same time, continuously infuse the needed amount of insulin. The healthy human body automatically registers the blood sugar level; if this gets too high, the pancreas releases insulin, which in effect lowers the blood sugar level by igniting the glucose metabolism – and if the blood sugar gets too low, the liver will release sugar from its depots. This fine-tuned mechanism is disturbed at diabetes patients, and hence they must monitor the blood sugar level manually and eventually infuse insulin with a syringe, if the blood sugar is too high, or take in extra carbohydrates, if the blood sugar is too low. The idea of 'closed loop' was to develop a feedback system of devices, which could both automatically monitor the blood sugar level and, if needed, infuse insulin, without the patient having to worry about it. Such 'closed loop' system was regarded as the *holy grail* of diabetes treatment, and being able to develop such system would mark the beginning of a new era, which also was foreseen to boost the sales of Novo Nordisk. So it was a very optimistic and entrepreneurial organization, in which I began working by yearend 2001 as an internal consultant in innovation processes.

Already in 2004, one of the two legs of the 'closed loop' vision was cut off, namely the project for developing continuous blood sugar monitoring. And in 2005, the bubble burst: PDS was terminated;

the vision had died. – Why? Didn't top management know what they were doing when they launched PDS? As employees, we got no real explanation for the turbulence in innovation strategy. I didn't expect such turbulence, since Novo Nordisk was a very mature company (founded 1923), acting in a relatively stable industry (product lifecycles of typically 20 years), based on a tradition of science and intensive R&D investments – not the kind of company, from which you expect impulsive fluctuations in the innovation strategy.

Furthermore, when I began examining the history of Novo Nordisk, I discovered that this was actually the second time that such visionary innovation strategy had bloomed and withered. At a much earlier stage in 1988, a division was established for medical devices, called Medical Systems Division (MSD), on a similar vision of full circle homecare for the patient, based on medical devices including devices for blood sugar monitoring. In 1988, the technologies were not mature for envisioning an automatic 'closed loop' system – the patient would still have to do everything manually. But the mere vision of providing the patient with *all* the drugs and devices, he/she needed for taking care of the disease at home (not at the hospital) was very progressive. However, MSD also had a lifetime of only four years, followed by a strategic turnaround in 1992: focus now should solely be on injection devices, in order to *support* the pharmaceutical drugs.

During my research, I've talked with many veteran colleagues about the evolution of the medical device activities at Novo Nordisk, and it was a great eye-opener for me, when a manager from the device area, who had been part of this venture for two decades, first described the development and then concluded: *"It's really funny to see how we started in MSD by diverging – then we converged again – then came PDS, where we went off at countless tangents – we even included our inhalable insulin project, that was really extreme – and now we have narrowed down again and have become focused again; our area must secure that the next generation prefilled [insulin pen] simply gets launched. That is our key function within Novo Nordisk today. It's quite funny – it has all happened within 20 years"* (interviewed in 2008). First, I should explain the use of the words 'divergent' and 'convergent': in this context, these concepts refer to the latitude of the device innovation activities. By "*diverging*" the manager means expanding the scope of the activities through adding new areas; by "*converging*" he means contracting the scope of activities to fewer areas. The point, however, is that this manager sees the MSD period from 1988 to 1992 as similar to the PDS period from 2001 to 2005: both periods were "divergent". In contrast, the period between MSD and PDS (1992-2001) is likened with the period after 2005: in these periods the activities "converged".

When I dug more into the history of the medical device activities at Novo Nordisk, it struck me that the fluctuations in strategy, as outlined in the quotation above, contrasted the actual development in the market. Until 1985, insulin was sold in vials, to be injected with traditional syringes. Novo Nordisk introduced the first injection device, the NovoPen®, in 1985. The NovoPen® was well received by the market and was followed by the introduction of several other 'insulin pens', as these devices were called (because they imitated the look of a fountain pen). The insulin pens contained the insulin in a customized insulin cartridge, and therefore the market penetration of the devices can be measured by the volume of insulin sold in these cartridges compared to the total volume of insulin

sold. Since 1985, insulin sold in cartridges customized for devices has steadily increased market share, compared to insulin sold in traditional vials, and today (2012) accounts for nearly two thirds of *all* insulin sold globally (source: internal Novo Nordisk statistics). This development has been initiated and driven by Novo Nordisk. In other words, the introduction of insulin devices ('insulin pens') has *gradually* changed the market towards the new systems, displaying a steady growth. Metaphorically, the market impact of the new insulin devices since 1985 has slowly increased like a train, which mile for mile crosses the landscape, following the laid down track. In contrast to this *steady* increase in market impact, the explicit innovation strategy of Novo Nordisk has unfolded two very "divergent" waves, as described in the above quotation from a veteran device manager. The two epochs which he labeled "divergent" (Medical Systems Division, MSD, 1988-92; Protein Delivery Systems, PDS, 2001-05), held ambitious visions about how Novo Nordisk could create large revenue streams based on medical device systems, beyond the revenue from the insulin itself; in other words making medical devices a business of its own. Outside these two 'waves' were periods, in which the explicit strategy defined the insulin drug as the sole revenue generator, and the role of the medical devices was seen more or less as "advanced packaging" for the drug (as it was called by several informants from the device area). One can say that there have been two waves of visionary ideas about revolutionizing diabetes care through the means of medical devices – and in between, the role of medical devices in the explicit strategies has been almost understated, if we consider the actual market success. Metaphorically spoken, the strategy twice has attempted to lift off from the laid down track in a helicopter.

As a consequence of the above observations and reflections, I asked myself about the reasons for these fluctuations in explicit innovation strategy, which seemed to contrast the actual development in market impact. To what extent were the fluctuations planned and deliberate or, alternatively, emerging 'by themselves', either driven by external trends and events or by bottom-up organizational processes? "*How does innovation strategy evolve?*" became the overall research question, which guided my longitudinal case study of the medical device innovation activities at Novo Nordisk. First, I mapped and analyzed each transformation of innovation strategy, which had occurred. From the concrete understanding of each transformation, the next level of reflection arose: Is there a *pattern* in the changes of innovation strategy? Can we, in other words, extract a generalized understanding, i.e. a theory?

These puzzles resulted in the formulation of the research questions outlined in the next section.

Research questions

General questions

The topic of this research project is the evolution of innovation strategy, stated in the overarching question **“How does innovation strategy evolve?”**

For examining the topic, evolutionary theory on strategy-making forms a theoretical basis (see next section, and Chapter 2, about the theoretical framework), especially Robert A. Burgelman’s (1991; 2002) theory on the ‘internal ecology’ of induced and autonomous strategies. Consequently, the topic is addressed with a general research question based on the ‘internal ecology’ model:

- **What is the role of induced and autonomous strategy processes for the evolution of innovation strategy?**

Specific questions

To study the general questions empirically, I focus on the evolution of the innovation strategy for a specific area in a specific organization; namely, the medical device innovation activities at the pharmaceutical company Novo Nordisk A/S in the period 1980-2008. Following a logic of lifecycles (see Definitions below) the evolution of innovation strategy can be split into sub-questions about the creation, the growth and the eventual change of a strategy. Consequently, the following specific research questions are stated:

1. **How did the innovation strategy for medical devices at Novo Nordisk come into being?**
2. **Through which processes was the device innovation strategy substantiated or retained, once established?**
3. **Through which processes was the device innovation strategy altered or reconfigured?**
 - a. **Phase by phase, transformation by transformation**
 - b. **Patterns of change across the individual phases and transformations.**

Inspired by literature (see next section and Chapter 2) some underlying themes will be examined. One important theme is the role of *management cognition* for the evolution of innovation strategy. An element hereof is the perception of the medical devices as either *core assets* for innovation, i.e. seen as means of creating a business of its own – or as *complementary assets* for innovation, i.e. seen as enhancers of the sales of pharmaceutical drugs. Another theme is the already mentioned relationship between induced and autonomous strategy-making processes, which overlaps with the question of deliberateness versus emergence in the evolution of strategy. And a third theme is the interplay between internal and external ‘ecologies’ in the evolution of innovation strategy.

Definitions

The following definitions of the concepts used in the research questions are applied (mentioned in alphabetic order):

Autonomous and induced strategies: Burgelman (1991) contrasts two sorts of strategy making processes: *“The induced process concerns initiatives that are within the scope of the organization’s current strategy and build on existing organizational learning; the autonomous process concerns initiatives that emerge outside of it and provide the potential for new organizational learning”* (p. 241). This definition, as can be seen, links to the *content* or scope of the strategy process and resembles the two modes of organizational learning described by March (1991): exploitation and exploration. However, Burgelman (1991) also links the concepts to the organizational *hierarchies*: in the normal case, he claims that autonomous strategies work their way up from beneath the organization, whereas induced strategies are exactly ‘induced’ from the top. And further, Burgelman analyzes the *process*: Does the strategy develop out of local experiments, i.e. vision ‘ex post’, or does it develop out of cognition, i.e. vision ‘ex ante’? The normal distribution of these three parameters in Burgelman (1991, 2002) is shown in Table I-1.

	Autonomous strategy	Induced strategy
<i>Content (per definition)</i>	Explores opportunities outside current strategy	Expands within current strategy
<i>Actor</i>	Lower or middle managers	Top management
<i>Process</i>	Action-based: learning from experiments (vision ex post)	Cognition-based: plan before action (vision ex ante)

Table I-1. The normal distribution of parameters in Burgelman (1991, 2002) for characterizing respectively autonomous and induced strategy.

Cognition: thinking. *“The mental action or process of acquiring knowledge and understanding through thought, experience, and the senses”*¹. In the context of this research, cognition is seen as part of the mental aspect of strategy making, e.g. formulation of visions and strategies in words and models, as opposed to the physical aspect, e.g. trial-and-error experiments or other action in the ‘real world’.

Core and complementary assets: builds on Teece (1986), who describes innovation as comprising core technical knowledge, needed for the invention itself, and complementary assets, needed for the successful commercialization of the invention. Teece mentions processes such as marketing,

¹ <http://oxforddictionaries.com/definition/cognition>, accessed 2011-07-16

manufacturing and after-sales support as examples of complementary assets. For this research project, however, it is essential that he also mentions: *“when the innovation is systemic, the complementary assets may be other parts of the system. For instance; computer hardware typically requires specialized software”* (ibid, p. 288). In this understanding, the medical devices may be seen as complementary assets, being part of the pharmaceutical product offering as a whole – but also potentially being seen as core technical knowledge, needed for innovation on par with the other components, such as knowledge about the insulin.

Evolution: *“the gradual development of something”*². The term is here used to label changes of an organization (or its environment) over time, unfolding as cycles of variation-selection-retention. Van de Ven (2007) defines evolution by stating: *“An evolutionary model explains change as a recurrent, cumulative, and probabilistic progression of variation, selection, and retention among entities in a designated population”* (p. 204). The present research project studies only at one entity, namely Novo Nordisk – however, such organization can in itself be seen as a population or an ecosystem of initiatives (as in Burgelman, 1991) or of multiple cognitive frames (as in Kaplan, 2008).

Innovation: the invention and market introduction of new products. Hence, compared to literature on management of innovation in general (example: *“Innovation is about knowledge – creating new possibilities through combining different knowledge sets”*, in the textbook by Tidd, Bessant & Pavitt 2005), the definition of innovation is here narrowed down to product innovation only, since that is the focus of the present study.

Innovation strategy: the strategy for the individual innovation activities with the objective to create product or business innovations (strategy understood as a plan for the future or a storyline of the past).

Life cycles: *“the series of changes in the life of an organism including reproduction”*³; i.e. the sequence of birth, growth and decline which an organization, a technology or a new product follows. In this context meaning that also strategies are born (i.e. formulated), grow (i.e. are implemented and substantiated) and decline (i.e. lose momentum and eventually are formally cancelled, to be replaced by new strategies). However, social phenomena like strategies do not evolve in predefined phases, as we often observe in nature; ‘evolution’ in social science is not deterministic.

Strategy: the pattern of activities of a company over time, before action (strategy as plan) or after action (strategy as pattern). This definition builds on Mintzberg (2007), who identifies the two meanings of the word, the forward-looking plan or commitment to action, or the backward-looking

² <http://oxforddictionaries.com/definition/evolution>, meaning 2, accessed 2011-07-16

³ <http://oxforddictionaries.com/definition/life+cycle>, accessed 2011-07-16

“*pattern in a stream of decisions*” (p. 2). In general, whenever the word ‘strategy’ in this thesis is *not* attached to ‘innovation’, the word refers to *business strategy*; i.e. it is the corporate storyline about the company’s product-markets – it’s customers, offerings, value proposition, profit model etc.

Theoretical framework

The present research project belongs to the research field of *strategic management* and explores the topic of ‘strategy making’. Concepts from the field of *management of innovation* have been included as well, because of the specific focus on innovation strategy. As the overall research question is “*How does innovation strategy evolve?*”, we need a basic understanding of what strategies are, how they come into existence and how they evolve. This basic understanding is taken from general strategic management literature, from research on strategy making and, since strategies both exist in observable reality and in managers’ minds, from literature on strategic cognition.

The literature on strategic management unfolds several schools of thought (see for example Gavetti & Levinthal, 2004, for a review). In broad terms, these can be placed in a continuum between rational choice theory and behavioral decision theory:

- a) **Rational choice theory** builds on a premise of the organization or the management team as a rational agent, where the actor is supposed to make informed and deliberate decisions based on analysis of the consequences of alternative options. This rational premise is consistent with mainstream (neo-classic) economics. Examples within strategic management comprise both the early, operational approach to strategy as for instance in Ansoff (1965), as well as the later **positioning school** with Porter (1980) as the principal representative.
- b) In opposition to the rational premise in economic and management theory, a paradigm of **behavioral decision theory** evolved based on the research of H. Simon (e.g. 1955), who analyzed the limitations of rationality in actual decision behavior. These limitations became known as ‘*bounded rationality*’. Bounded rationality implies that even if managers are “intendedly” rational, they don’t have full access to information and they only have limited resources and capabilities for processing information. In alignment with the notion of bounded rationality, several schools of thought developed. These schools of thought shared their focus on *actual organizational behavior*, in contrast to the ideal of rational choice. One such school is the stream of research in management cognition (see Walsh, 1995, and Kaplan, 2011, for reviews), which provides evidence for the constraints and biases of the cognitive representations used in decision making. Another school consists of evolutionary economic theory (Nelson & Winter, 1982), which analyzes how knowledge and experience become embedded in enduring organizational routines. Within strategic management theory, models of emergent strategy and evolutionary strategy making were developed by researchers such as Mintzberg (1994) and Burgelman (1991).

If we turn towards the topic ‘*evolution of strategy*’, one should notice that the **rational choice models**, such as the positioning school, mainly are concerned with explaining the causes of superior

business performance as reflected in the competitive landscape (the *outcome* of strategy), and less with analyzing the underlying process of strategy formation. The main question for rational choice theory on strategy can be stated as: ‘what kind of strategy should we build?’

Conversely, the **evolutionary theories** are more focused on the actual behavior in the *process* of strategy making. The main question of such theories could be stated as: ‘where do strategies come from?’ Thus, Gavetti & Rivkin (2007) summarize the two research strands as “*the content-oriented rational-choice class and the process-centered learning class*” (p. 422). For the present research project, behavioral theories (or learning models) of strategy-making provide the best foundation for understanding the evolution of innovation strategy.

The theoretical framework will be analyzed in detail in Chapter 2. However, some core elements should be presented here.

First, the word strategy (see Definitions) has two meanings or two dimensions: Strategy can be a forward-looking plan or vision or it can be a backward-looking “*pattern in a stream of decisions*” (Mintzberg, 2007). This dualism comprises a time-bound dimension: strategy as perceived before or after action.

Furthermore, strategies exist as concepts or theories in the minds of managers (in the form of forward-looking visions and plans; or backward-looking rationalization of experience) and they also manifest as patterns in actual organizational behavior or practice. This dualism comprises a space-bound dimension spanning the two realms, in which strategies exist: the mental and the physical (Gavetti & Rivkin, 2007).

These two basic dualisms (time-bound: before/after action and space-bound: mental/physical realms) can be synthesized into a simple model of a learning cycle, see figure I-1, inspired by similar learning cycles in literature on strategic search and managerial cognition (Burgelman, 1988, Figure 2; Gavetti & Levinthal, 2000, Figure 1; Walsh, 1995, Figure 1; Prahalad & Bettis, 1986, Figure 1). The model shows how strategy making unfolds in a learning cycle of theory application into practice, from which experiences fuel further theorizing. This basic learning cycle synthesizes the dualism between the *mental and the physical realms* in the *vertical axis* (between Theory and Practice) and the dualism between the *forward-looking and backward-looking search processes* in the *horizontal axis*. Going from theory to practice is normally associated with forward-looking and *deliberate* strategy making, because it springs out of a strategic intent or vision. Going from practical experience to theory is normally seen as the basis of backward-looking and *emergent* strategy making, because the strategy is formed via trial-and-error, where the understanding develops en route (Mintzberg, 1994), or even backwards, as rationalization of experience (Burgelman, 1988).

(The theoretical foundation for this simplified model is presented in detail in Chapter 2).



Figure I-1. Strategy making shown as a learning cycle between theory and practice, inspired by similar learning cycles in literature on strategic search and managerial cognition – see Chapter 2. Even the learning cycle is here depicted as one loop, the learning process of course is recursive and in principle endless; loop after loop unfolds.

The interplay between deliberate or theory-driven strategy making on the one side and emergent or experience-based strategy making on the other has been very thoroughly analyzed in Burgelman’s evolutionary theory on the ‘*internal ecology of strategy making*’ (Burgelman 1991, 2002). He basically models how long-term adaptation of the corporate, *induced* strategy is achieved via continuous integration of local, *autonomous* initiatives from the ‘internal ecology’ of the organization. The learning cycle in figure I-1 integrates the *mental* and the *physical* aspects of strategies in the Theory-Practice dimension. The ‘theory’ part includes strategy formulation, visioning and reasoning in general. Research on managerial cognition informs about the pervasive influence of *cognitive representations* (or, mental models) of reality. For the present research project, I especially apply the concept of *dominant logic* (Prahalad & Bettis, 1986; Bettis & Prahalad, 1995), which terms a set of mental models, which have settled as a top management worldview or mindset, created via reinforcement of experiences from the past. Such dominant logic, once established, is difficult to change but has strong effect on the strategy making of a firm.

Since the present research project addresses the evolution of **innovation strategy**, we need a basic characterization of this concept as compared to 'strategy' in general.

First, what is innovation? – *"The word innovation derives from the Latin word **innovatus**, which is the noun form of **innovare** "to renew or change," stemming from **in**—"into" + **novus**—"new".*"⁴. In a business context, *"newness can refer to anything that affects customers, manufacturing, sales or service"* (Foster & Kaplan, 2001, p. 24). Literature on innovation distinguishes innovation from invention: *"Invention is the first occurrence of an idea for a new product or process, while innovation is the first attempt to carry it out into practice"* (Fagerberg et al, 2005, p. 4); *"Innovation is invention that has produced economic value. Without economic value there can be no innovation. Invention **precedes** innovation"* (Foster & Kaplan, 2001, p. 24). For the present research project, the concept of innovation is narrowed down to the introduction of new products (and the concurrent new business).

What is then innovation strategy? – Strategies in general are seen as overall patterns in a company's activities, either in form of forward-looking plans or backward-looking storylines. Corporate strategy as a forward-looking plan may (but must not) envision the creation of new product-markets. In such case, the corporate strategy comprises a strategy for innovation. However, innovation can be organized as a distinct set of activities within a company. Thus, Christensen (2002) defines: *"Management of innovation signifies the management and organization of the individual innovation processes with the objective to produce product or process innovations"* (p. 1318). Accordingly, I define innovation strategy as such:

- **Innovation strategy** is the strategy for the individual innovation activities with the objective to create product or business innovations (strategy understood as a plan for the future or a storyline of the past).

Clearly, the innovation strategy may be overlapping with the general business strategy – often, the overarching corporate strategy comprises an underlying specific innovation strategy. In large organizations, where innovation is organized as a distinct set of activities, the strategy levels will be equal to organizational levels; the innovation strategy will be the responsibility of the organizational unit for product innovation.

⁴ <http://en.wikipedia.org/wiki/Innovation>, accessed 26-05-2012

Research design

For understanding the *evolution* of innovation strategy we need a **process research model** rather than a *variance* research model (Van de Ven, 2007): “*In general terms, a variance model explains change in terms of relationships among independent variables and dependent variables, while a process model explains **how a sequence of event leads to some outcome***” (p. 148; my emphasis). The fundamental difference between the two approaches is shown in figure I-2. The process study approach does not exclude the search of causality; but the way to causality goes through “*a narrative describing how things develop and change*” (ibid, p. 148).

To establish such narrative, I chose the format of a longitudinal case study of the medical device area at the pharmaceutical company Novo Nordisk A/S, analyzing the medical device innovation activities since the beginning of these activities around 1980 to year-end 2008. The study also includes a combined qualitative and quantitative tracking of the portfolio of product innovation projects within the studied timeframe. Such case study design opens for a ‘*thick description*’ of the events, contexts and interpretations (Stake, 2000, p. 437). The ‘thickness’ is achieved both via in-depth interviews and studies of archival data resulting in:

- *Analysis at **multiple levels***: external industry dynamics; corporate events and top management cognition; local device level events (cognition, strategy and structure); and concrete innovation activities (innovation projects and product launches).
- *Mapping **long term** evolution* – across more lifecycles of strategy; this opens for seeing generic patterns.

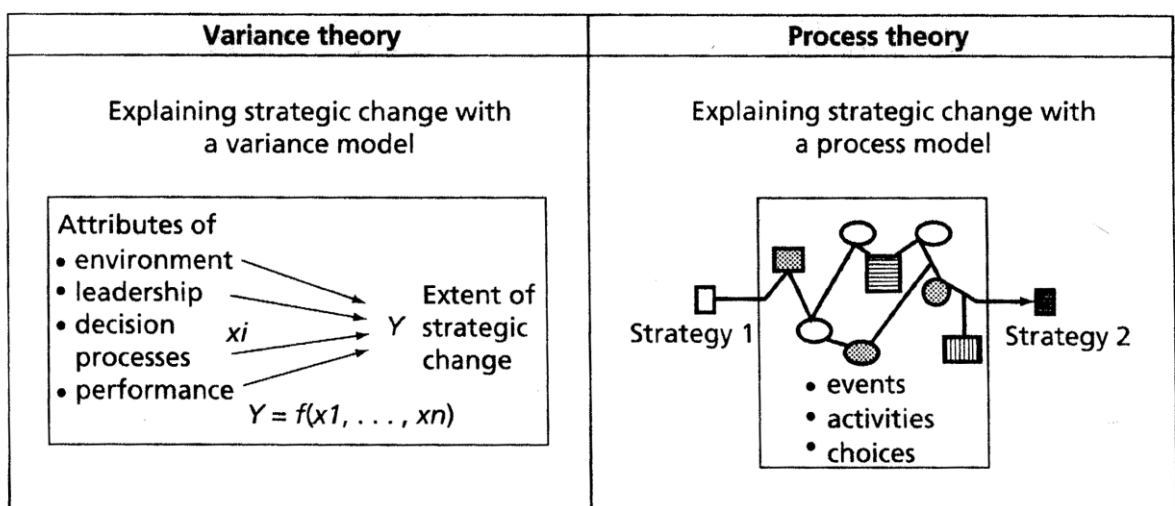


Figure I-2. “Two approaches to explaining strategic change” - from Van de Ven, 2007 (p. 149).

What can we learn from a case study of Novo Nordisk?

When scholars study how strategies evolve, they often select empirical contexts which amplify the change processes, since these contexts provide clearer input for analysis of the drivers and processes of strategic transformations. Thus, periods of 'ferment' (Anderson & Tushman, 1990), displaying technological discontinuities, have been popular research contexts (examples include Barr et al, 1992; Christensen & Bower, 1996; Noda & Bower, 1996; Tripsas & Gavetti, 2000; Tripsas, 2009). Also, young companies or immature industries, characterized by highly dynamic environments, have served as 'test tubes' of strategy making (examples include Burgelman, 1988, 1991; Gavetti & Rivkin, 2007; Kaplan, 2008). These research contexts are well suited for analyzing strategy evolution, because discontinuities and high industry velocity make the change processes more visible (for the researcher) and more challenging (for the firm). However, the challenges of strategic renewal reach beyond these dynamic environments. In fact, strategic change is often more challenging either for mature companies, due to settled routines and capabilities, or in relatively stable industries, where the signals from the environment are more subtle and hence more difficult to make sense of. Where 'radical innovation' may seem natural for a young company or in the case of technological discontinuities, then the management of such innovation implies complex challenges to mature organizations (Leifer et al, 2000). Yet, in terms of research of strategic change, large and mature companies comprise complex organizational structures and often very dim decision processes. Novo Nordisk A/S was founded 1923, employs 32,800 employees (March 2012) and is, as these lines are written, the most valuable company at the Scandinavian stock markets (spring 2012). Moreover, the company has been in the same main business (insulin for diabetes treatment) throughout the company's entire lifetime. To get an inside research perspective on the strategy evolution of this company is a unique opportunity for examining whether the strategy evolvement in such context resembles the mechanisms described in the studies of more dynamic contexts. Perhaps the mature and stable empirical context will provide other results, which again can feed back to the existing theories on strategy evolution?

Selection of one main theoretical model

In the beginning of my research, many theoretical perspectives were examined and often applied for analyzing the empirical case story. These perspectives include (in chronological order):

- Organizational learning models, going back to Argyris & Schön (1978)
- Abernathy & Clark's (1985) theory about architectural innovation
- Strategy-structure incongruities (Chandler, 1990, 1992; Christensen, 2002 a & b)
- Weick's (1993) concept of sensemaking
- Nonaka's (1994) theory on organizational knowledge creation
- Dynamic capabilities (Teece, Pisano & Shuen, 1997; Teece, 2007; Eisenhardt & Martin, 2000)
- Theories on ambidexterity (O'Reilly III & Tushman, 2004, 2008; O'Reilly, C. J. et al, 2009)
- Mintzberg's (2007) taxonomy of organizational archetypes

- Discovery vs. creation of entrepreneurial action (Alvarez & Barney, 2007).

All of these theoretical perspectives opened interesting views of the empirical case. However, my attempt has been to build a coherent storyline in the case analysis; this is best achieved using one (or two) overarching theoretical models. My choice ended by Burgelman's evolutionary model on strategy making, complemented with a perspective on management cognition, for two reasons:

1. Burgelman's model is the most direct answer to my research question, "*How does innovation strategy evolve?*", apart from the focus on broader business strategy rather than specific innovation strategy. Burgelman (1991, 2002) goes deeply into the *transformation processes* of strategy and the *evolution* from an emergent state to an institutionalized state of strategy making.
2. This framework had the best resonance with the story I was creating in the case narrative (see also Chapter 3 on research method), about two modes of innovation strategy: these modes resembled Burgelman's concept of autonomous and induced strategy (measured by the content of the strategies).

Contribution

The present case study's in-depth analysis of innovation strategy at multiple levels of one corporation over a period of 30 years is in itself seldom.

The case study identifies a more entrepreneurial role of the top management driven induced strategy process than traditionally described in evolutionary theory. In the present case study, strategic variation and trial-and-error learning is not restricted to the autonomous initiatives in the 'internal ecology'; top management enacts induced strategic experiments *in the market*, for example in the form of new product categories. External feedback determines the destiny of these strategic experiments. Thereby, the innovation strategy (in case, for medical devices) serves as a 'strategic laboratory' at corporate level and, in effect, the induced strategy process acts as a force of strategic entrepreneurship.

A specific finding in the present case study is that the induced process mediates innovation logics of core assets (pharmaceutical drugs) versus complementary assets (medical devices), by swinging the pendulum between cycles of innovation strategy. Thus, the balance between what is defined as core and what is defined as complementary in the corporate innovation strategy seems to be dynamic and negotiable.

Structure of the thesis

Chapter 2 describes the theoretical framework of the thesis in more detail, comprising literature on strategy making as well as literature on strategic cognition. Further, the theoretical framework is synthesized by applying the model of strategic learning shown in figure I-1. **Chapter 3** outlines the

overall research design and the concrete research methods. **Chapter 4** holds the in-depth case study, including the empirical evidence and analysis of the strategic transformations, phase by phase.

Chapter 5 analyzes the *pattern* of evolution across the entire period (the “whole story”). Further, Chapter 5 also discusses the theoretical framework in the light of the case study and builds theory.

Chapter 6 summarizes the conclusions.

Appendix A provides a detailed description of the research method for the management cognition analysis, which were conducted at the device area of Novo Nordisk in 2007 and again 2010 (the findings from the 2010 analysis have not been included in the thesis, due to business confidentiality issues).

Chapter 2: Theoretical framework

Content

Introduction	27
Understanding strategy – and dimensions of strategy research	29
The rational versus the behavioral paradigm.....	29
Basic dualities of strategy.....	30
Identification of a theoretical ‘middle ground’	31
Where do strategies come from?.....	33
Strategy making as social learning	33
Forward-looking cognitive search and backward-looking experiential learning.....	34
Cognitive and experience-based search in a perspective of organizational maturation	35
Conclusion on origin of strategies.....	36
How strategies evolve	38
The internal ecology of strategy making.....	38
Conclusions on strategy evolution.....	43
The role of management cognition for strategy	44
The impact of the initial ‘framing’ of the business – and of identity.....	44
Cognitive and strategic inertia	46
Dominant logic	48
How the dominant logic might be loosened up.....	51
Conclusions on management cognition and strategy	52
Integrative competencies	52
A synthesized model of strategy evolution.....	54
Scenario 1: the emergent state.....	54
Scenario 2: strategic lock-in	55
Scenario 3: induced strategic adaptation.....	56
Scenario 4: induced strategic reconfiguration.....	57

Introduction

This research project seeks to understand how an innovation strategy comes into being, how it is retained and how it eventually is changed or substituted by another innovation strategy.

Evolutionary literature on strategy making is concerned exactly with these questions, just regarding business strategies in general, and therefore these theories are applied as the main theoretical instrument for the present case study. It will then be examined if the specific context of innovation strategy opens for new perspectives of the evolutionary theories on strategy making.

The presentation of the theoretical framework is laid out as follows:

First, a basic understanding of the nature of business strategies and of the paradigms underlying general strategic management research is established. Based on this foundation, selected evolutionary models of strategy making are presented. Thereafter, specific literature on strategic cognition is analyzed, because this literature holds important keys for understanding strategic evolution. Furthermore, some theoretical perspectives from the field *management of innovation* are presented. A specific topic from this literature concerns integration of complementary assets for innovation, which is an underlying theme in my whole case study of medical device innovation at the pharmaceutical company Novo Nordisk.

Following the presentation of the theoretical framework, the concepts are synthesized into a model of strategic learning.

Understanding strategy – and dimensions of strategy research

As described in Chapter 1, research on strategic management can be seen in a continuum between rational choice theory and behavioral decision theory. In a rational choice perspective, the organization or the management team acts as a rational agent, who makes deliberate decisions based on analysis of alternatives. This rational premise is underlying all mainstream neo-classic economic theory, and was adopted in management research. The term “rational”, however, has two meanings, as described by Kahneman (2011). In everyday language, it is associated with calculation and reasoning. In economic theory, “rational” means internally consistent: *“The only test of rationality is not whether a person’s beliefs and preferences are reasonable, but whether they are internally consistent. A rational person can believe in ghosts so long as all her other beliefs are consistent with the existence of ghosts...Rationality is logical coherence – reasonable or not”* (p. 411 – my emphasis). In the strategic management literature applied in the current project, the term “rational” seems rather to be used in the everyday meaning, associated with reasoning (e.g. Nelson, 2008, p. 78), and hence the term “rational” is here used as “based on reasoning”.

The rational versus the behavioral paradigm

The premise of rationality was underlying the early instrumental or ‘engineering’ approaches to strategic management, e.g. in Ansoff (1965), which aimed for solving the problem of how to design a corporate strategy. One element in the rational choice paradigm is the presumption that the actor is free to choose the best alternative and implement this option. Such premise to a large extent also underlies the positioning school of strategic management (Porter, 1980). Consequently, the positioning school has been criticized by the behavioral oriented schools, because of the path dependent bonds that in reality limit the available options. This debate and the standpoint of the positioning school are illustrated in the following quotations from Porter (1991): *“Firms inherit positions that constrain and shape their choices, but do not determine them. They have considerable latitude in reconfiguring the value chain with which they compete, expanding or contracting their competitive scope, and influencing important dimensions of their industry environment”* (p. 104). *“The cross-sectional frameworks address the choice of strategy given whatever array of capabilities the firm and its rivals possess at a point in time and can feasibly develop in the future”* (ibid, p. 105). *“The firm cannot be seen only as optimizing within tight constraints, but as having the ability to shift the constraints through creative strategic choices, other innovative activity, and the assembly of skills and other needed capabilities. There are alternative strategies open”* (ibid, p. 110).

The belief in free rational decisions was criticized with Herbert Simon’s analysis of the limitations of rationality, which later has been noted in the concept of *bounded rationality*. Thus, Simon (1955) identified the constraints evolving from path dependency as well as the limitations of available information, resources and analytical capabilities, which are presumed to be unlimited in an ideal or

'global' rationality. *"Broadly stated, the task is to replace the global rationality of economic man with a kind of rational behavior that is compatible with the access to information and the computational capacities that are actually possessed by organisms, including man, in the kinds of environments in which such organisms exist"* and *"we are interested in models of "limited" rationality rather than models of relatively "global" rationality"* (Simon 1955, p. 99 and 113). Simon called his theory a 'behavioral model' and several schools of research in strategic management subscribed to the behavior oriented paradigm erected by the Carnegie School, which besides Herbert Simon included researchers such as R. Cyert and J. March. Their interest in *actual* decision behavior as opposed to the ideal or 'global' rationality also opened for studying strategic management in a *process theory* perspective (Van de Ven, 2007 – see Introduction), where the interest moved from studying conditions and variables behind different strategic outcomes to studying the *processes* leading to the formation and change of a strategy.

Basic dualities of strategy

One of the researchers to build on Herbert Simon and the Carnegie School was Henry Mintzberg, who has researched within the field of strategy making since the 1960's (e.g. "The Science of Strategy-Making", in Sloan Management Review 1967). Mintzberg noted that Simon saw the concept of strategy as a ***pattern***: *consistency in behavior over time*" (Mintzberg, 2007, p. 1). This led Mintzberg to pursue the question: *"because there is a pattern, must there necessarily be a plan? In other words, must strategies always be deliberate? Or can they emerge: that is, can patterns just form out of individual actions?"* (Mintzberg, 2007, p. 4 – the emphasized words are italics in the original). Mintzberg's strong orientation towards a behavioral or learning oriented model is clearly expressed in the following statement: *"If deliberate strategy is about control, then emergent strategy is about learning. It suggests that anyone, so-called formulators and implementers alike, can learn their way into strategies – action by action, perhaps also decision by decision. Indeed, strategies can form without people even realizing it, although they may recognize these strategies once they have formed"* (Mintzberg, 2007, p. 5). This quotation perfectly contrasts the rational choice theory, and Mintzberg's concept of 'emergent strategy' opens for new perspectives on strategy making, which has been further explored by other researchers, such as Burgelman (1991).

The dualism between *deliberate* and *emergent* strategy is one aspect of strategy making. Another aspect – where Mintzberg's work similarly can illuminate the understanding – is the dualism between the *mental* and the *physical* realms of strategy making. Corporate strategies can be seen as managers' way of making sense of the world and conceptualizing a storyline about the organization in the form of a perceived pattern in the activities over time – looking backward, as a rationalization of past behavior, or forward, as a plan or vision. Strategies are top managers' tools for understanding the corporate situation – they give language to complex matters, such as dynamics in the internal and external environment. In this sense, strategies belong to the mental realm of perception, reasoning, theory and cognition. This mental aspect of strategies has been well expressed by Mintzberg (1994): *"No one has ever seen or touched a strategy. Strategies, in other words, do not exist as tangible entities."*

*They are abstract concepts, in the minds of people. And the best of them seem to be **gestalt** in nature, tightly integrated, whether intended strategies as synthesized patterns of preferences prior to the taking of actions or realized strategies as synthesized patterns already formed among actions. Thus, serious change in strategy generally means shift in gestalt – the **conception** of a new worldview, generally based on a permanent change in conditions, or at least the **perception** of such a change”* (p. 240 – the emphasized words are italics in the original).

Aligned with the above thinking, Burgelman (1983) states: “*the **concept of corporate strategy** represents the more or less explicit articulation of the firm's theory about its past concrete achievements. This theory defines the identity of the firm at any moment in time. It provides a basis for the maintenance of this identity and for the continuity in strategic activity. It induces further strategic initiative in line with it*” (p. 66). Thus, the emphasis in the understanding is here on strategy as a ‘theory’; and this theory is both backward-looking (building on past achievements) and forward-looking (inducing further initiatives).

However, even if strategies are abstract concepts in the minds of people, or theories, they also often manifest in action – for example launch of new products in new markets etc. Thus, strategies have a dual nature, both belonging to the intangible sphere of thinking and to the physical and observable sphere of behavior or action.

Identification of a theoretical ‘middle ground’

Gavetti & Levinthal (2004) analyze the first nearly 50 years of research on business strategy. They map the strands of research according to two dimensions: a) the view on choice processes (rational choice models versus behavioral models) and b) the level of analysis. This second dimension in their map concerns whether researchers describe context and *situation* specific events, or rather seek for general and more permanent *structural* factors. When applying this map, Gavetti & Levinthal (2004) place the positioning school (e.g. Porter, 1980) in a so-called ‘*structure-conduct-performance*’ paradigm, which is characterized as being both highly rational and structural. Researchers like Henry Mintzberg and Robert Burgelman are placed in a cluster of ‘emergent views’ on strategy, which are behavioral rather than rational and situational rather than structural: “*These authors argued that a firm's articulated strategy was often an ex post construction, occurring subsequent to the emergence of patterns of behavior that had, de facto, already configured the firm's strategy*” (Gavetti & Levinthal, 2004, p. 1312).

Gavetti & Levinthal (2004) propose a ‘middle ground’ between rational and behavioral views and between situational and structural levels of analysis. They suggest the new paradigm ‘in the middle’ to build on *evolutionary economics*, going back to Nelson & Winter (1982). However, they identify some limitations in the evolutionary theory which should be overcome in order to serve as a broader paradigm. One such basic limitation is the evolutionary theory's focus on **organizational routines** as the holder of the “DNA” of the company: “*...our general term for all regular and predictable behavioral patterns of firms is “routine” ...In our evolutionary theory, these routines play the role that genes play in biological evolutionary theory. They are a persistent feature of the organism and determine its possible*

behavior” (Nelson & Winter, 1982, p. 14). Such premise nearly excludes elements of deliberation and reasoning. Thus, the evolutionary theory is mostly behavioral: organizations learn through their activities, and this learning becomes imbedded in the organizational routines, displaying large degree of tacit knowledge. If a new ‘middle ground paradigm’ should be able to embrace the rational perspective, then “*the current challenge is to identify other genetic traits [than organizational routines], as well as search mechanisms operating on those traits, consistent with more deliberate forms of thinking*” (Gavetti & Levinthal, 2004, p. 1314). The dilemma is between remaining faithful to the evolutionary logic, implying that “*the property of **firm-level behavioral continuity** must be maintained*” (ibid, p. 1314, my emphasis), and at the same time embracing deliberation and reasoning. “*The question then arises as to what extent the evolutionary framework can incorporate elements of deliberation and cognition*” (ibid, p. 1314). As an example of ‘middle ground’ research, they mention amongst others Tripsas & Gavetti’s (2000) case study of Polaroid, because it “*illustrates the power of cognitive representations as carriers of behavioral continuity, thus giving them a similar status as routines as part of the organization’s genetic material*” (Gavetti & Levinthal, 2004, p. 1314). In accordance herewith, research on strategic cognition has been included in the theoretical framework of the current research (see later section).

Besides the focus on *organizational routines* as the holder of the ‘corporate DNA’, traditional evolutionary theory also is biased towards seeing the routines and capabilities as developing “from below” in the organization, and Gavetti & Levinthal (2004) therefore suggest to “*pay more attention to the linkages across actors within the organizational hierarchy*” (ibid, p. 1315). This perspective is salient in the research of Robert A. Burgelman, which I shall present in the next sections.

Where do strategies come from?

Mintzberg (1994) defines three sources of strategy:

- Intended strategies, which are plans formulated ahead of time (some of which are never realized)
- Deliberate strategies, which are intended strategies realized via use of formal control systems
- Emerging strategies, which are formed (not formulated) 'en route', as adaptation to the real world: "where a realized pattern was not expressly intended" (p. 25).

Together, these sources result in the realized strategy. See figure II-1, which shows two strategy processes, respectively Deliberate and Emergent Strategy Process (taken from Mintzberg, 2007).

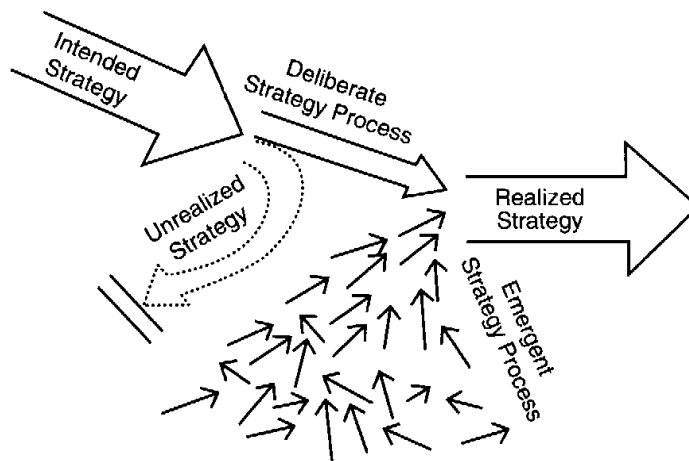


Figure II-1. The sources of strategy, as described by Mintzberg (1994, 2007) (here from Mintzberg, 2007, p. 6).

Strategy making as social learning

Burgelman's (1988) case study on Internal Corporate Venture units in large firms analyzes the emergent strategy process in detail. Burgelman (1988) describes strategy making as a social learning process of interplay between an *action realm* (in the form of entrepreneurial activities) and a *cognitive realm* (in the form of strategy formulation). Strategic renewal is seen as a result of gradual development, where each step depends on emerging activities in previous phases. Burgelman suggests that in the beginning of a new business, action and strategy are narrowly based and grow together (learning by doing). Gradually, a strategic (cognitive) framework can be abstracted. In the end, strategy can be separated from action – as it becomes *institutionalized*. Burgelman (1988) describes this institutionalizing of a strategy as a shift from 'doing well is basis for planning well', to 'planning is basis for doing' (p. 81). Thus, Burgelman differentiates the two phases, respectively before and after the institutionalization (ibid, p. 83):

- **The emergent state:** Planning is retro-active rationalization of autonomous strategic activities.

- **The steady state:** A strategy is distilled from experiences to induce further strategic activities through a planning process.

What starts as “*opportunistic search in the stream of ongoing work*” at operational level, manifested in local experiments, can – in case of success – gradually gain impact at yet higher management levels, ultimately to be recognized at corporate management level and thereby change the firm’s ‘*concept of strategy*’. Hereafter, the institutionalization of the new strategy begins.

Figure II-2 synthesizes Burgelman’s (1988) theory of interplay between the two aspects of strategy making: the physical aspect (experiments and implementation in the ‘realm of action’) and the mental aspect (strategy formulation in the ‘realm of cognition’).

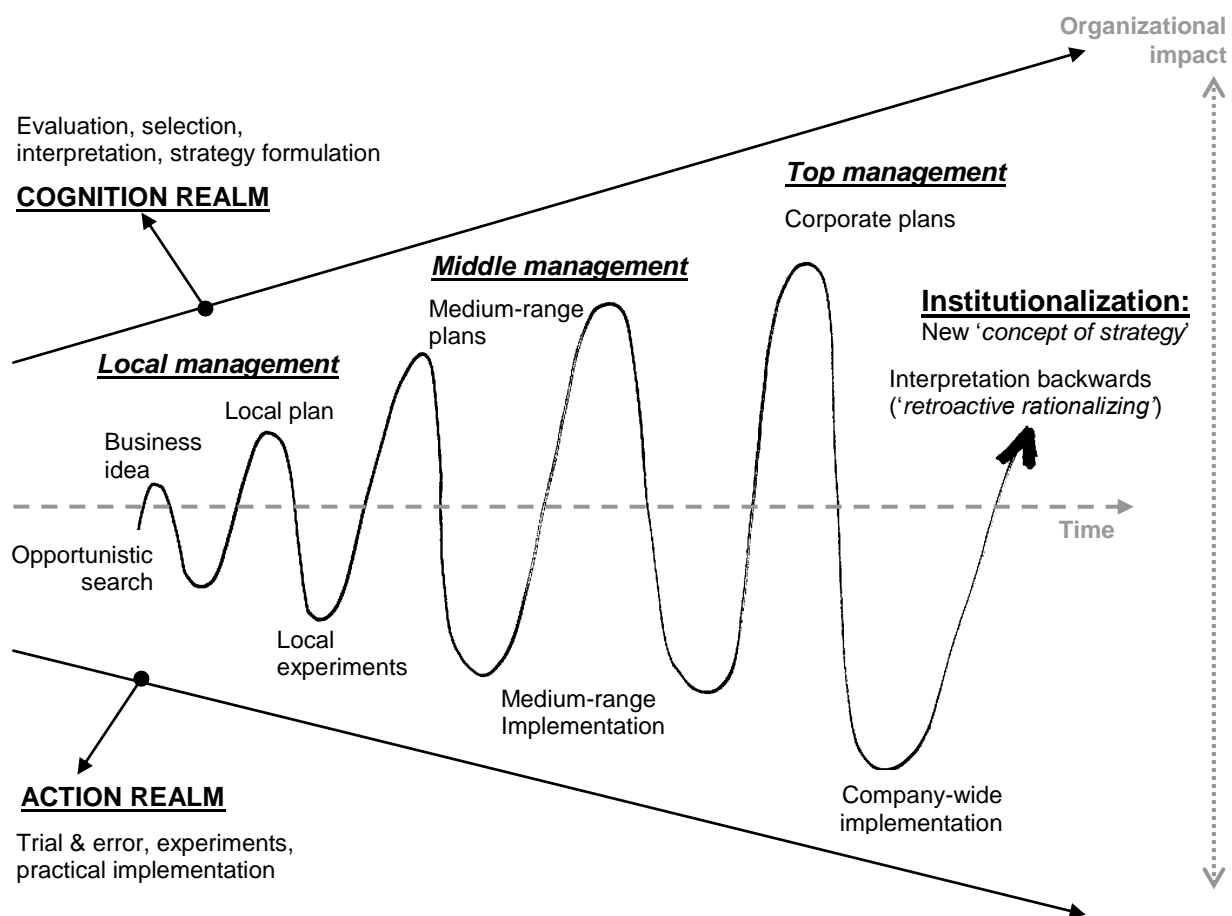


Figure II-2. Strategy making as a social learning process, based on Burgelman (1988). The process is here depicted as a ‘sound wave’ swinging in the polarity between the realms of cognition and action, gradually gaining resonance at yet higher organizational levels.

Forward-looking cognitive search and backward-looking experiential learning

Similarly to Burgelman (1988), Gavetti & Levinthal (2000) analyze how organizational search processes can either be *forward-looking*, based on cognition, or *backward-looking*, based on experience: “*Cognition is a forward-looking form of intelligence that is premised on an actor’s beliefs*

about the linkage between the choice of actions and the subsequent impact of those actions on outcomes. Such beliefs derive from the actor's mental model of the world (Holland et al., 1986)" (p. 113). "In contrast, experiential wisdom accumulates as a result of positive and negative reinforcement of prior choices (Levitt and March, 1988). Choices that have led to what are encoded as positive outcomes are reinforced, while the propensity to engage in actions that have led to negative outcomes is diminished. In this sense, experiential learning offers a form of backward-looking wisdom" (ibid, p. 114). They summarize this understanding in a learning or reinforcement cycle – see figure II-3.

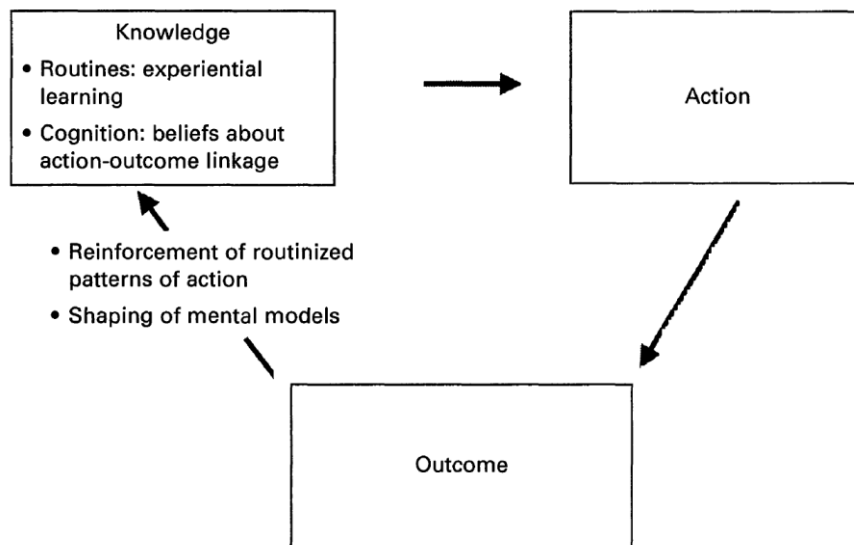


Figure II-3. Gavetti & Levinthal's (2000) model of "intelligence of action" as a learning or reinforcement cycle comprising forward-looking cognitive search and backward-looking experiential search.

Gavetti & Levinthal (2000) state that the forward- and backward-looking search processes are complementary, because experience-based search is limited to the number of experiments you can actually engage in, and cognitive search is constrained by the incompleteness of the mental models in use. Their theory is not focused on strategic search; however, their theory can be directly applied to strategy making.

Cognitive and experience-based search in a perspective of organizational maturation

In a more recent study, Gavetti & Rivkin (2007) develop a time-bound theory on action and cognition in strategy making. Their research question is: "Where do strategies come from?", and the title of the paper addresses the dualism between the mental and the physical aspect of strategy: "On the Origin of Strategy: Action and Cognition over Time". They conduct a longitudinal case study of the Internet portal company Lycos and its search for strategies. For building their theory, they contrast two strategy models: "The **positioning model** portrays strategic search as cerebral and top-down; the core search mechanism is deductive application of economic logic to a firm's activities—the central elements that are searched. It assumes firms are highly plastic, conforming readily to the shape desired by the

management team. The **evolutionary model** posits that managers are intendedly but boundedly rational (Simon 1957a, p. xxiv). As a result of cognitive bounds, much behavior in organizations is based on semiautomatic rules and routines (Nelson and Winter 1982). The core search mechanism is local search: Actors seek solutions that entail incremental change to existing routines—the key elements searched—often through trial and error (Cyert and March 1963) and with limited deliberation. Managers rely on local search because they are cognitively limited and know their firms are not fully plastic” (p. 421, my emphasis).

Based on their longitudinal case study, Gavetti & Rivkin (2007) suggest that positioning and evolution models have different plausibility or likelihood depending on the maturity of both the company and the industry: For young companies in immature industries, local search and experiments is most plausible. This corresponds to the evolution model; action comes before cognition. Conversely, rationality gains plausibility especially as the industry matures. This corresponds to the positioning model; cognition and planning comes before action. Gavetti & Rivkin (2007) conclude: “*The world of action, the world of cognition, and their interplay are sensitive to time, and our models need to incorporate this sensitivity*” (p. 436). They summarize their contribution such:

- “*Over time, the cognitive and physical elements that make up a strategy become less plastic, while mechanisms to search rationally for a strategy become more available. This generates a fundamental tension in the origin of strategy: Managers struggle to understand their environment well enough to search rationally for an effective strategy before their firms lose the plasticity [plasticity: see quotation above] necessary to exploit that understanding. A focus on time allows us to synthesize and extend the evolutionary and positioning models of strategic search*” (ibid, p. 420).

Gavetti & Rivkin (2007) thus propose that the plasticity (“*conforming readily to the shape desired by the management team*”, p. 421) of the firm decreases as result of the maturation of the company – the organization settles in its competencies, routines etc. By contrast, the possibilities for rationality in strategic search increase with the maturation of the industry. This theory integrates the evolutionary and positioning models of strategy as depending on the stage of maturation of the company and its industry.

Conclusion on origin of strategies

Based on the presented research, there seems to be strong evidence showing that the strategy processes evolve in phases. Just as we all learn our ways through the childhood via endless trial-and-error processes, so does strategy making seem to begin with local experimentation leading to retroactive rationalizing, based on which top management can induce further strategic activities through a planning process (Burgelman, 1988). Similarly, strategic search in a young organization seems more likely to be based on action or behavior (the evolutionary model), where cognition and rationality (the positioning model) increases likelihood as the organization and especially its industry matures (Gavetti & Rivkin, 2007). Put differently:

- In the emergent state (a strategy before institutionalization; or an immature organization) strategy making is dominated by experience-based learning (trial-and-error practice and backward-looking search).
- In the steady state (a strategy after institutionalization; or a mature organization) strategy making is dominated by cognition-based planning (beliefs and forward-looking search).

From the understanding of strategy making as a learning process, I build on previous approaches in literature on strategic search and managerial cognition to model strategy making as a learning or reinforcement cycle. Burgelman (1998) does so in his Figure 2, p. 84. Gavetti & Levinthal (2000) do it in their Figure 1 (shown above as Figure II-3). Prahalad & Bettis (1986) similarly show the dominant logic as being created in a reinforcement cycle in their Figure 1 (shown below as Figure II-9). Walsh (1995) summarizes the body of literature on managerial cognition in a recursive learning cycle in his Figure 1 (p. 282), displaying respectively the *development* and the *use* of knowledge structures. ‘Knowledge structures’ are cognitive representations of the information environment, built up from past experience (“*mental templates*” for interpretation of the environment; *ibid* p. 281 – i.e. *theories* about the world). The use of the cognitive representations leads to consequences in practice; which again feed back to further development of the mental templates (the theories). Applying this thinking, my Figure I-1, shown again here as figure II-4, synthesizes theory-based and experience-based processes of strategy making into a basic, recursive learning cycle. The conclusion from this section is that the two processes (respectively the right and the left side of the learning cycle) have different emphasis respectively before and after the institutionalization of strategy.



Figure II-4. The basic learning cycle of strategy making, repeated from figure I-1, inspired from Walsh (1995) and others. The experience-based process seems dominant before strategic institutionalization; while the theory-based process gains importance after institutionalization of strategy.

How strategies evolve

The internal ecology of strategy making

The basic idea that strategy processes are not all planned by top management, but also emerge from lower levels in the organization, is central in the theoretical framework developed by R.A. Burgelman (1991, 1996, 2002). Central here are the concepts of **induced** and **autonomous** strategy. “*Induced strategy exploits initiatives that are within the scope of a company’s current strategy and that extend it further in its current product-market environment. Autonomous strategy exploits initiatives that emerge through exploration outside of the scope of the current strategy and that provide the basis for entering into new product-market environments*” (Burgelman, 2002 - p. 327). This definition clearly reflects the two modes of organizational learning proposed by March (1991), exploitation and exploration: induced strategy as exploitation of existing capabilities and positions; autonomous strategy as exploration outside existing capabilities and positions.

According to Burgelman (2002), induced and autonomous strategy should be balanced, since induced strategy reduces variation whereas autonomous strategy increases variation (p. 354). In

other words: the strategic renewal (variation) comes from emerging autonomous strategies, whereas selection and retention are obtained via the induced strategy. This interplay between induced and autonomous strategy is framed as the '*internal ecology of strategy making*'.

Burgelman's theory is depicted in a simplified form in figure II-5.

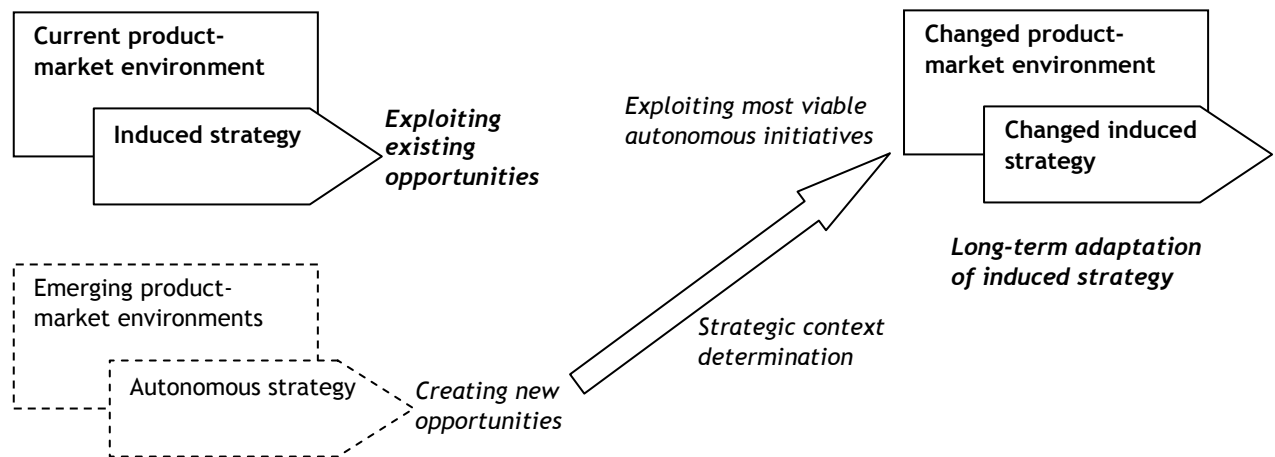


Figure II-5. A simplified image of Burgelman's model of '*internal ecology of strategy making*' (based on Burgelman, 2002). The concept '*strategic context determination*' is the process by which corporate management recognizes a legitimate role of an autonomous initiative in the induced strategy.

Burgelman's theory comprises in-depth analysis of the evolution of strategy and provides many keys to answering my research questions, although the theory concerns business strategy in general – therefore we shall go into more detail with this framework.

Burgelman (1991) builds his theory on a longitudinal case study of Intel Corporation. He notes that when Intel in 1985 made the strategic decision to exit the DRAM (memory) business and devote its main activities to the microprocessor business, this seemingly dramatic decision was a formal articulation of a de facto development in Intel's activities over more than 10 years. In fact, at the time of decision, the memory business accounted for less than 25% of Intel's revenue, whereas the microprocessor business had gradually climbed to app. 75%. How can such development take place, even though Intel's formal strategy still saw Intel as a "memory company"?

To explain the development, Burgelman (1991) contrasts the two sorts of strategy making processes within an evolutionary framework of variation-selection-retention:

The induced strategy process is driven by top management's intent within the established domain. Even if this might result in planned variation (Burgelman 1991, p. 246), the induced process generally has "*a variation-reduction effect on the set of strategic initiatives*" (ibid, p. 245). *Variation* (i.e. alternative and novel opportunities) in the induced process implies that top management, based on its ex ante vision, proposes initiatives (projects) and then seeks resources for establishing them. The main parts of the induced process, however, concern the selection and retention. For the *selection*, top management applies administrative procedures (such as strategic planning) to define

the place of new initiatives within the organizational structure (so-called *structural context determination*). The potential fit to the organizational structure must be defined for any new project, in order to allocate resources. In the *retention* part, a process of organizational learning identifies the basis of success, the distinctive competencies and the field of activities of the organization, and integrates these elements into the top management vision.

In the **autonomous strategy process**, however, *variation* is created by operational-level managers' local experiments, "*seeking to use their skills in new combinations with [the] organization's distinctive competencies*" (Burgelman 1991, p. 254). The survival of such initiatives depends on the ability of the lower-level managers to mobilize top management for a so-called *strategic context determination* process – that is, identifying the strategic value of the various experiments in order to assess their business potential for the corporation. This *selection* process requires that top management makes sense of the experiments and defines a strategic space for the new initiatives within the overall corporate strategy. Hereby top management must be able to rationalize and justify the new initiatives based on a corporate strategic intent. Eventually top management will "*recognize that a major change in strategy is necessary and feasible*", which again will "*lead to a new, ex post vision*" (ibid, p. 254). In other words: based on the interpretation of the autonomous experiments, top management concludes a new strategic intent. "*Once formally ratified, [the] new vision becomes part of the basis for the induced process*" – that is the *retention* part of the autonomous process (ibid, p. 254).

Linked to the induced and autonomous strategy processes, Burgelman (1991) defines four modes of **organizational adaptation**, three of which are linked to the induced strategy process:

1. **Relative inertia**, which is characterized "*reluctance to change organizational strategy*" (ibid, p. 254)
2. **Adjustments**, which are characterized by "*relatively minor changes to strategy*" (ibid)
3. **Reorientation**, which is characterized by "*major changes in strategy as response to major environmental change*" (ibid)
4. **Strategic renewal**, characterized by "*major changes in organizational strategy preceded by internal experimentation*" (ibid).

The 'strategic renewal' is, as the only of these, linked to the autonomous strategy process. Since the present research project identifies strategic transformations linked to the induced strategy process, it is worthwhile to look closer at Burgelman's (1991, p. 253) description of the most radical induced adaptation, which is here quoted in its entirety (my emphasis, except for the word 'reorientation'):

- "**Reorientation.** *Major changes in the strategy seem likely to upset the induced strategic process in fundamental ways. The necessity for a major strategic change suggests that **selective pressures from environmental variations** have made the organization's capacity for relatively modest adjustments largely irrelevant. At first, threat-rigidity (Staw, Sandelands and Dutton 1981) may lead top management to reaffirm familiar approaches. For instance, Cooper and Schendel (1976) found that established firms, **confronted with the threat** of radically new*

technologies, were likely to increase their efforts to improve the existing technology rather than switch to the new technology, even after the latter had passed the threshold of viability. Eventually, however, **confronted with chronic low performance**, top management is more likely to take major risks (March 1981b, Singh 1986) by making extreme and vacillating changes in the strategy, potentially involving a complete change of domain (Hambrick and D'Aveni 1988). **When an organization finds itself in a precarious situation, reorientation may be perceived by top management as necessary to maintain or regain viability** (Miles and Cameron 1982), and may be better than doing nothing. However, as March (1981b) has observed, organizations **facing bad times**, and therefore following riskier and riskier strategies, may simultaneously increase their chances of survival through **the present crisis**, but also reduce their life expectancy: "for those organizations that do not survive, efforts to survive will have speeded the process of failure." (1981b, p. 567)".

From this description, as well as the overall characterization "major changes in strategy as response to major environmental change" (ibid, p. 254), I understand 'reorientation' as a **reactive or even defensive response** to external pressure or internal crisis (the well-known 'burning platform'). Such reorientations took place twice at Novo Nordisk, as can be seen in the case story. Burgelman's (1991) model lacks an *induced* process for major strategic changes, driven by **proactive** visions about future possibilities. 'Strategic renewal' solely belongs to the autonomous process. This limitation has made it necessary to expand the model for the present research project.

Burgelman (1991) calls his framework the "*intraorganizational ecology of strategy making*", and this evolutionary model is used to explain how the microprocessor business at Intel grew autonomously from the bottom until, ex post, to be recognized as the new corporate strategy for Intel.

In a later paper, Burgelman (2002) continues the longitudinal case study of Intel. He describes how CEO Andy Grove, after reformulation of the corporate strategy in 1985, focused the activities around the highly successful core business of microprocessors to a degree where nearly everything else was abandoned. "*Grove began to consider non-core business development as a distraction.strategic planning was almost exclusively focused on the core business... Resource allocation favored the core business*" (ibid, p. 351). Burgelman (2002) terms such kind of strategic inertia 'co-evolutionary lock-in'. He explains the phenomenon by comparing his evolutionary model of strategy making with the rational actor model: "*Intel's strategy making before Grove became CEO resembled an internal-ecology model in which induced (memory-related) and autonomous (microprocessor-related) initiatives competed for the company's scarce resources based on their success in the external competitive environment. This paper documents how Grove's successful strategy vector created a highly focused induced-strategy process, which moved Intel's strategy making away from the internal-ecology model and closer to the rational-actor model*" (ibid, p. 327).

Burgelman (2002) further comments that the backside of the success of the microprocessor strategy was a blockage of the strategic context determination process described above. "*In spite of Grove's efforts to vectorize everybody in the same direction, numerous autonomous strategic initiatives continued to emerge, indicating continued attempts at exploration. **The decrease in Intel's capacity to***

activate strategic context determination processes, however, prevented the company from exploiting the more viable autonomous initiatives" (ibid, p. 355 – my emphasis). Thereby the so-called 'co-evolutionary lock-in' destroyed what Burgelman considers a sound balance between autonomous and induced strategy processes. *"The capacity to activate and successfully complete such processes [autonomous initiatives and strategic context determination] can be viewed as a measure of the intelligence of the company's internal selection environment and may be at the very heart of strategy making as an adaptive organizational capability"* (ibid, p. 355).

One should notice that Burgelman (1991) does not restrict the validity of the 'internal ecology' model to the case of Intel. On the contrary, he states that *"The perspective [internal ecology model] serves to illuminate data from a field study of the evolution of Intel Corporation's corporate strategy. The data, in turn, are used to refine and deepen the conceptual framework"* (ibid, p. 239) and he makes generalized proposals such as *"consistently successful organizations are characterized by top managements who spend efforts on building the induced and autonomous strategic processes"* (ibid, Abstract). Thus, Burgelman's (1991) model is not an intrinsic case study (Stake, 2000), but a generalized theory. The theory on internal ecology of strategy making (Burgelman 1991; 2002) is shown graphically in figure II-6.

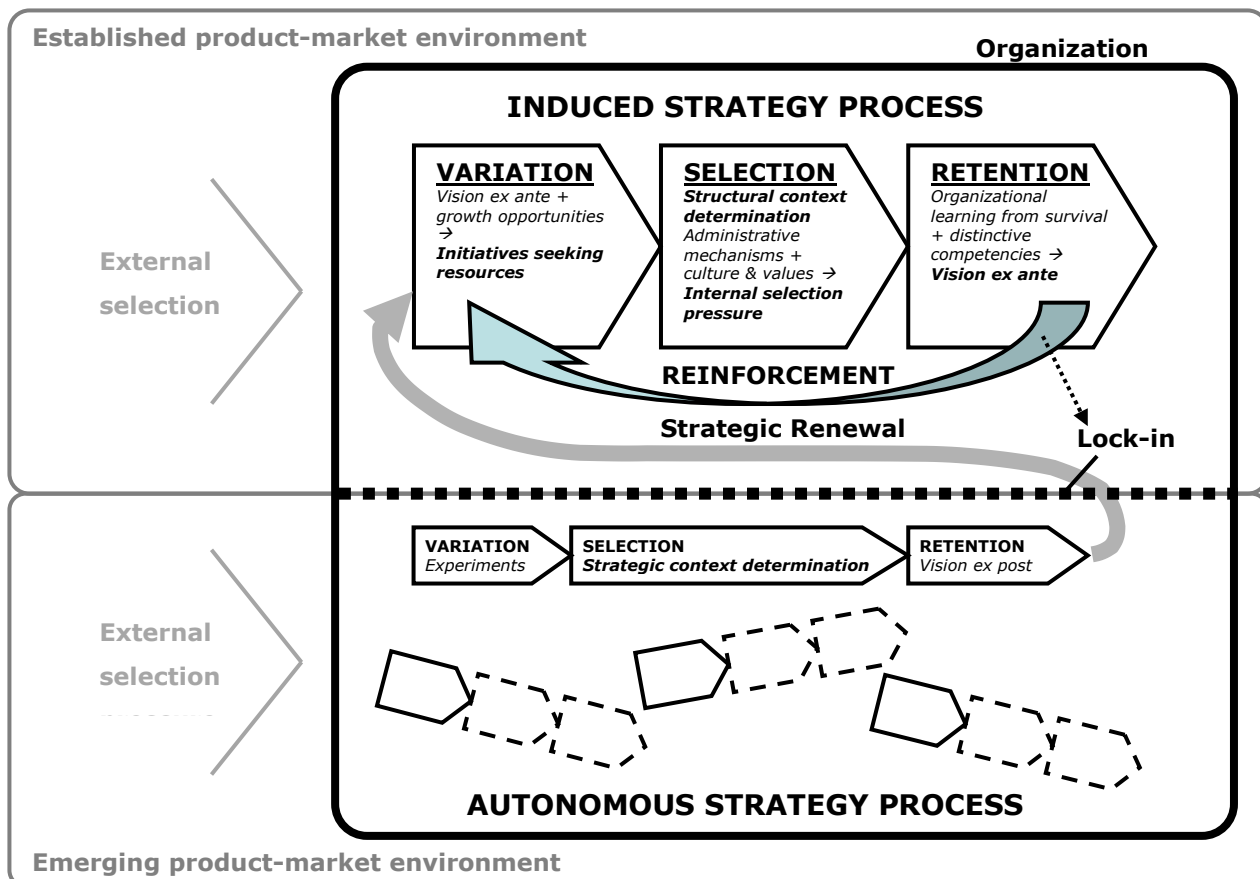


Figure II-6. A model of the theory on internal ecology of strategy making in Burgelman (1991; 2002). Only some of the many autonomous initiatives succeed in mobilizing top management for the strategic context determination process, eventually leading to strategic renewal. Reinforcement in the induced process may result in co-evolutionary lock-in, which again may impede strategic renewal. The external environment establishes a permanent 'background pressure' on the internal selection processes.

Conclusions on strategy evolution

The evolutionary theories of strategy-making subscribe to the behavioral paradigm within strategic literature. These theories are centered on emergent, experience- or learning-based strategy processes. Burgelman's theory remains one of the most comprehensive evolutionary models of strategy making, and Burgelman thoroughly analyses how *business* strategies evolve. The essence of Burgelman's theory is that long term renewal of induced strategy is mediated by autonomous initiatives.

However, related to the present empirical case study, some gaps remain:

- It remains open, whether the theory can explain the evolution of **innovation** strategy, defined as '*the strategy for the individual innovation activities with the objective to **create** product or business innovations*'. In the Intel case study, the autonomous microprocessor strategy obviously built on previous innovation activities, but Burgelman (1991) does not as such analyze the emergence of this innovation strategy, i.e. *before* the establishment of microprocessors as a business. Rather, he analyses how the microprocessor business gradually (over a period of nearly 15 years) takes over as the main business and as the official corporate strategy; at the time of the formal change in strategy (1985), the microprocessors already accounted for 75% of Intel's turnover (Burgelman, 1991). This internal competition between the induced memory business strategy and the autonomous microprocessor business strategy is different than an (earlier) competition about which new product categories to develop and launch – microprocessors and memory products both existed in the market at the period, which Burgelman (1991) analyses.
- Burgelman's 'internal ecology model' to large extent disregards the influence of external dynamics (e.g. competitor moves): an intra-organizational perspective is *deliberately* chosen in order to arrive at new understanding of strategy processes (Burgelman 1991, p. 240).
- According to Burgelman (2002), induced strategy reduces variation, whereas autonomous strategy increases variation (p. 354). Strategic renewal is described as tied to the autonomous process only; major strategic changes in the induced process are termed 'reorientation', and these are described as reactive or defensive responses to a 'burning platform'. A vision-based or proactive major change of strategy within the induced process is not described in the model.
- Managerial cognition is mentioned, but has no central role in the internal ecology model.

In conclusion, Burgelman's 'internal ecology model' seems the most direct theoretical response to my research question "*How does innovation strategy evolve?*"; however, it is interesting to examine the significance of the different research contexts: business strategy in general versus innovation strategy, and a relatively young company in a dynamic industry (Intel) versus a mature company in a relatively stable industry (Novo Nordisk).

The role of management cognition for strategy

Departing amongst others from Herbert Simon's analysis of the limited rationality in actual decision making (e.g. Simon, 1955), a large stream of research on management cognition evolved – see Walsh (1995) and Kaplan (2011) for reviews. Walsh (1995) summarizes the general landscape of this research as such: *“The basic idea is that individuals can approach information processing in two dominant ways. They can use a “top-down” (Abelson and Black 1986) or “theory-driven” (Nisbett and Ross 1980) approach, whereby their past experiences in similar circumstances guide present information processing, or they can let the current information context guide information processing in a “bottom-up” or “data driven” approach. In the former case, the cognitive structures generated from experience affect individuals' abilities to attend to, encode, and make inferences about new information; in the latter case, the information itself shapes individuals' response to it”* (p. 281). This understanding is the basis of the model of strategy making as a learning cycle between theory and practice (figure II-4).

A part of the research on management cognition focuses specifically on strategic cognition – see Narayanan et al (2011) for a review. This literature (according to Narayanan et al, 2011) analyzes the strong influence of the cognitive structures on decision making, hereunder *‘strategy frames’*, which filter the information and direct managers' attention via a sort of *‘cognitive template’* for how to understand the environment. The literature also identifies how such strategy frames *“often lag behind changes in the internal or external environment, making strategic change problematic”* (ibid, p. 336); in other words: cognitive inertia may result in strategic inertia.

We shall now look into the concepts of strategy frames, cognitive inertia, dominant logic and framing contests, since these concepts haven proven to be valuable for analyzing the empirical case.

The impact of the initial ‘framing’ of the business – and of identity

Noda & Bower (1996) conduct a dual case study of the strategic development of respectively BellSouth and US West (two regional US telecom operators established by the breakup of the Bell system in 1984), during the period of breakthrough for cellular/mobile telephony (1983-1994). The case study clearly illustrates the importance of how top management defines the business and phrases the strategic direction:

- BellSouth defined itself as a telecommunication company (ibid, p. 173) and saw the new cellular business as complementary; as a growth vehicle (ibid, p. 174). Consequently, top management set modest goals for profit and cash flow from the new business and invested for the long term profitability. The modest expectations were met; the new business had gradual success, and therefore top management invested more – a positive reinforcement cycle, which ended with a strong, official corporate commitment to the cellular business (ibid, p. 176, 177, 186).
- US West saw itself as a *diversified* firm in the *“information industry”* (ibid, p. 173); they even started up real estate investments and financial service business. Top management expected

cellular business to be profitable on a short term basis, since they perceived it on equal terms with the many other businesses (ibid, p. 174). This led them to a 'cream-skimming' strategy with less emphasis on long term investments. Their high, short term expectations could not be met and hence a negative self-fulfilling prophecy cycle was started (ibid, p. 176, 177, 179, 186). This led top management to reduce its investments even further (ibid, p. 176) and they missed the opportunity of the cellular business.

In conclusion, this case study clearly states how the initial framing of corporate strategy (or '*phrasing*', see ibid p. 188) sets the stage for the activities and for evaluation of the results. Via the learning from the early experiences, a *dominant logic* (see later part) about the new business was built, which became self-reinforcing and difficult to change. In other words, there's a direct link between initial strategic framing and the later performance.

Tripsas (2009) studies the concept of an organization's **identity** and how it might hinder a company from adopting new technologies, in the case where these technologies do not fit to the *internal identity* of the firm. She defines internal identity as "*a shared understanding by organizational members regarding what is central, distinctive, and enduring about an organization*" (ibid, p. 441). She conducts a longitudinal case study of a disguised digital photography company on the effect of 'identity threats' from new technologies. She finds that "*First, identity serves as a lens that filters a firm's technical choices...Second, the self-reinforcing dynamics among identity, organizational action, and the industry and technological context create a strong impediment to change*" (ibid, p. 454). In this analysis, the concept of identity in many ways resembles Prahalad & Bettis' (1986) and Bettis & Prahalad's (1995) analysis of the *dominant logic* of a firm as a filter mechanism, built up via reinforcement cycles, which result in strategic inertia (see the section on dominant logic). The two concepts are closely related – dominant logic, even if not being explicit, consists of cognitive models and is therefore closer to the sphere of deliberate cognition, where identity seems more emotional, based on tacit experience. Both concepts label shared mental structures within an organization, which have an *enduring* function with regards to the worldview of the management team and in effect on the corporate strategy. Thus, Tripsas (2009) states: "*When faced with uncertainty or a challenging issue, managers view the issue through the lens of the firm's internal identity, which guides interpretation and action*" (p. 441). Metaphorically, the identity of a firm can perhaps be compared to the internalized value systems of the parents, which guide a child or a young person through his/her life. Staying in the metaphor, the dominant logic would then be cognitive schemas for problem solving, which are created through the person's own successful problem solving experiences. To conclude this part on framing and identity: The initial framing of a strategy has a long lasting effect, because the framing process scopes the subsequent learning or reinforcement cycles and defines the metrics of success. Similarly, the internal identity of a company provides enduring guidance for the decision making in the organization, and thereby offers an alternative to organizational routines as part of the 'corporate DNA' (Gavetti & Rivkin, 2007).

Cognitive and strategic inertia

Barr, Stimpert & Huff (1992) analyze longitudinal data from a matched pair of U.S. railroad companies during the decades after World War II, in which the entire U.S. railroad industry was undergoing a significant decline – private cars, and trucks for transportation of goods, were taking over the transportation market. These external dynamics of course hit both companies, which displayed a number of similarities from the outset, such as geographical area, size of company etc. Still, the two companies responded very differently to the changes in the external environment, and their different courses of action led them to different destinies – the one (Rock Island) sought bankruptcy in the mid 1970s and ceased to exist. The other (C&NW) was viable as the article was published in 1992. Based on archival data (annual reports) the authors thoroughly identify and analyze the *mental models* of the top management of the two corporations. They link the different courses of action to differences in the development of top management’s mental models: “...the leaders of the C&NW not only recognize changes in their environment, they also gradually change their mental models...” - “At the Rock Island, in contrast, changes in beliefs and action are not undertaken until the railroad is near bankruptcy.” In other words, C&NW successfully adapted their mental models to changes in the market conditions, whereas this learning did not take place at Rock Island, which therefore ended with having a business understanding out of sync with market reality. Using vector symbols, this analysis is illustrated in figure II-7.

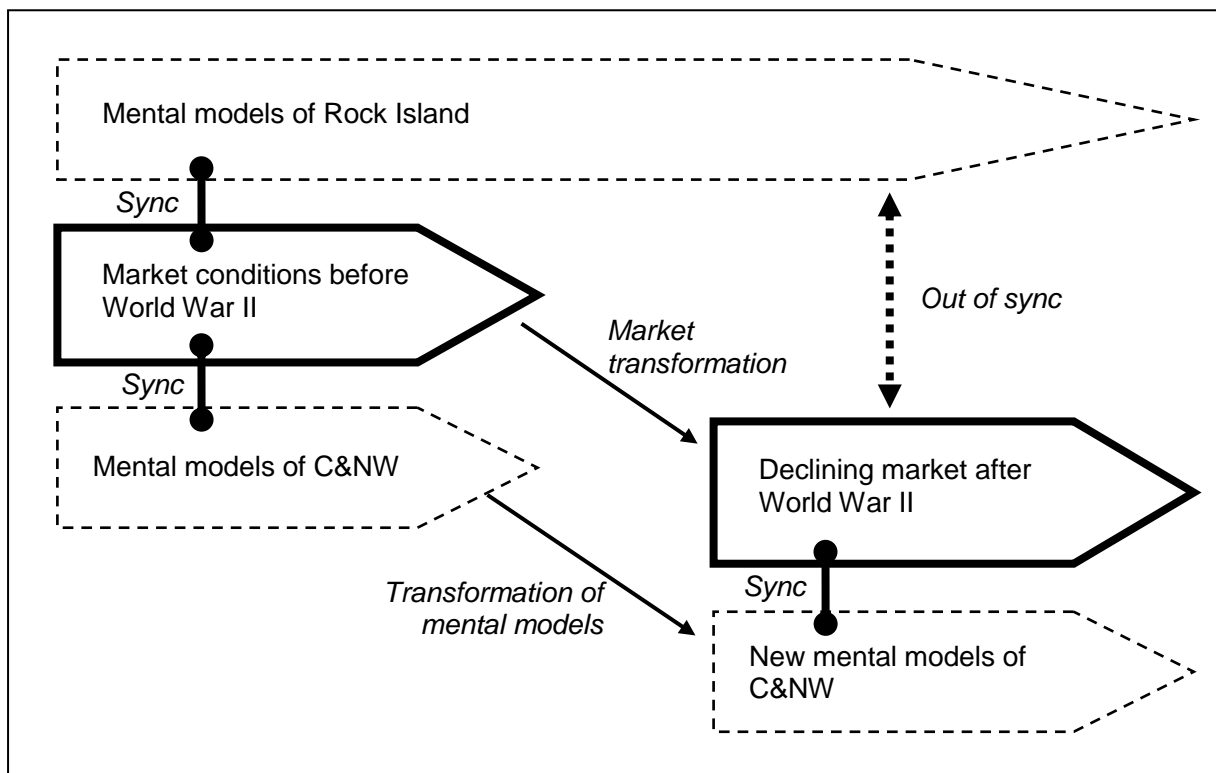


Figure II-7. A graphical model of the railroad case by Barr, Stimpert & Huff (1992).

Tripsas & Gavetti's (2000) case study of Polaroid's struggle with the challenges of digital photography similarly deals with the problem of adapting the top management cognition to changes in the external environment – in case, the new technology of digital imaging. The new technology per se was not a challenge for Polaroid – their digital cameras got top scores in comparative product evaluations. Polaroid's challenge mimicked the one of Rock Island – they did not realize that the changes in external reality required them to rethink their business. Polaroid had built their success on a business model, which they themselves compared to Gillette's razor-blade model: They sold high quality cameras at relative low prize to retain the profits from the consumer goods needed for making pictures (i.e. the films). They wrongly believed that digital cameras would not change the consumers' wish for paper prints of the images; so top management stuck to the same business model, which had paved the way for Polaroid's historical success. This cognitive inertia led to the decline of Polaroid.

Another example of cognitive inertia and resulting strategic inertia is found in Christensen & Bower's (1996) study of the disk-drive industry, which presents the dilemma of incumbent firms between serving existing customers with sustaining innovation versus addressing new markets associated with innovations based on disruptive technologies. Disruptive technologies are defined as:

"Technologies which disrupt an established trajectory of performance improvement, or redefine what performance means" (ibid, page 202). These technologies tend to be valued more in remote or emerging markets than in established markets (ibid, p. 203). Thus, the managerial challenge is

caused by external factors (new technologies) – however, I am here more interested in the internal dimension of the challenge. The dilemma lies in the resource allocation for innovation – in the end, the well-known existing customers will be prioritized over the uncertain emerging new customers segments, resulting in lack of ability to change the innovation strategy. Interestingly, Christensen & Bower (1996) describe how the incumbent firms often experiment with the disruptive technologies internally in the form of technical prototypes etc., but top management disregards these projects in their selection for the innovation strategy, because the existing customers respond negatively to the prototypes. In Burgelman's (2002) wording, the strategic context determination is blocked by a co-evolutionary lock-in, which makes the companies unable to exploit the potential of the autonomous initiatives. Christensen & Bower (1996) state that when the incumbent firms later are forced to take the disruptive technologies up again for product development, it is often too late – consequently, entrant firms are more successful in building businesses based on the disruptive technologies.

Christensen & Bower's theory is modeled in figure II-8. The model shows how the cognitive inertia of top management, by bonds to the existing customer needs, hinders the exploitation of the new technologies. First when entrant companies have success in establishing product-markets based on the new technologies, this external change will force a shift in the cognition at top management level, who will now open for utilization of the new prototypes, which had been put on shelf.

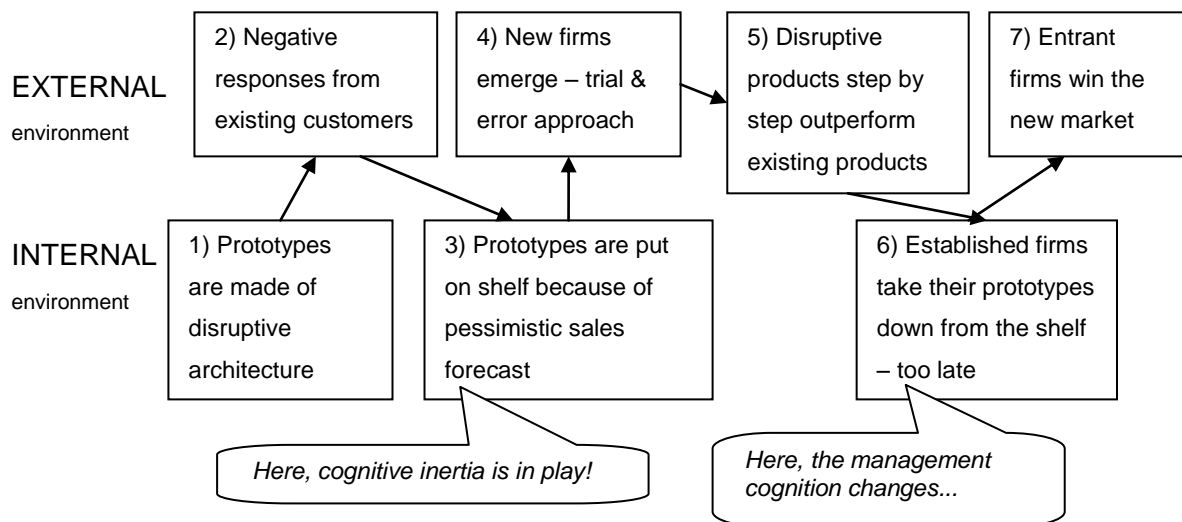


Figure II-8. A model of Christensen & Bower's (1996) theory on incumbent firms' failure with regards to integrating disruptive technologies in their innovation strategies.

Dominant logic

Prahalad & Bettis (1986) analyze the mechanisms which lock top management in their thinking, as illustrated in the previous case studies. They describe how managers develop a *dominant general management logic* based on experiences from the main business of the firm. "A *dominant general management logic* is defined as the way in which managers conceptualize the business and make critical resource allocation decisions" (ibid, p. 490). "Dominant logic, as we have defined it here, is a mind set or a world view or conceptualization of the business and the administrative tools to accomplish goals and make decisions in that business" (ibid, p. 491). This 'dominant logic' summarizes the 'success formula' of the dominant management coalition and causes managers to perceive problems and solutions as framed by past experiences. Prahalad & Bettis (1986) refer to the concept of *operant conditioning*; meaning that behavior, which is reinforced, will occur more frequently in the future. Thus, the dominant logic evolves in a positive cycle of reinforcement of 'doing the right things' in the past. "This reinforcement results in their [managers'] focusing effort on behaviors that led to success" (ibid, p. 491-492). The learning cycle which leads to establishment of the dominant logic is shown in figure II-9.

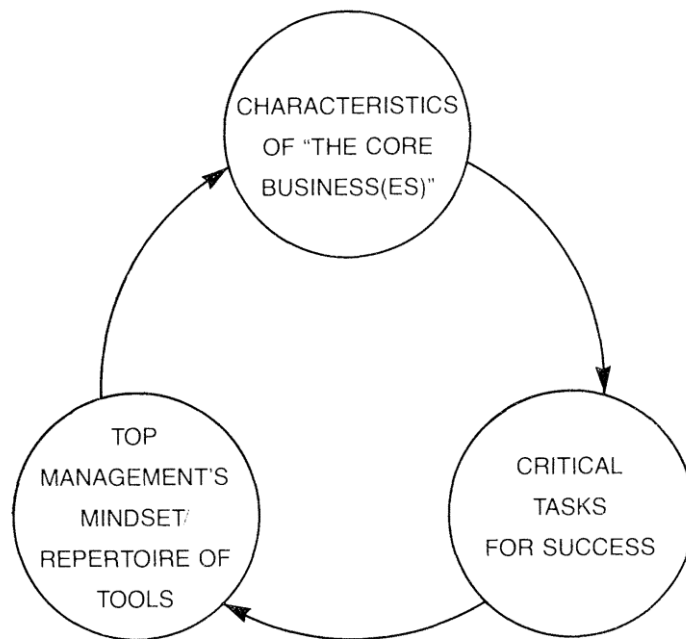


Figure II-9, from Prahalad & Bettis (1986), p. 491, showing the learning cycle behind the establishment of the dominant logic of a firm.

Bettis and Prahalad (1995) elaborate the concept of dominant logic. *"We have come to view the dominant logic as an information filter...Organizational attention is focused on data deemed relevant by the dominant logic. Other data are largely ignored"* (p. 7). The direction of organizational attention towards certain issues (deselecting other) is a central element in a behavioral analysis of strategy, cf. Ocasio (1997). Thus, Bettis & Prahalad (1995) place the dominant logic *"as a fundamental aspect of organizational intelligence"* (p. 7). Their key point is that dominant logic is crucial for an organization's adaptability. *"Interestingly, it [dominant logic] provides a set of heuristics that simplify and speed decision making. This inherently results in 'adaptive ability', so long as changes in the underlying logic are not necessary"* (ibid, p. 11, my emphasis). As indicated by the previous studies, the bond to past experiences has a 'toxic side effect', if the management team wrongly applies the established dominant logic to situations, where changes in the environment have made the learned behaviors inappropriate.

Since the dominant logic is shaped via positive reinforcement of successful actions, it can be difficult to alter or unlearn the logic, once established: *"Interestingly, the more successful organizations have been, the more difficult unlearning becomes"* (Prahalad & Bettis, 1986, p. 498). Therefore, the dominant logic can cement as a 'deep structure' (Gersick, 1991), like the scientific paradigm in Kuhn's (1964) analysis of scientific revolutions. This understanding of the role of dominant logic is reflected in Bettis & Prahalad (1995). They describe the dominant logic as a 'local optimum' or equilibrium, which it requires substantial efforts to escape (Bettis & Prahalad, 1995, p. 12-13). Small fluctuations from the dominant logic will end by returning to the original equilibrium – it takes a far move to allow a firm to establish a new equilibrium = a new logic. See figure II-10.

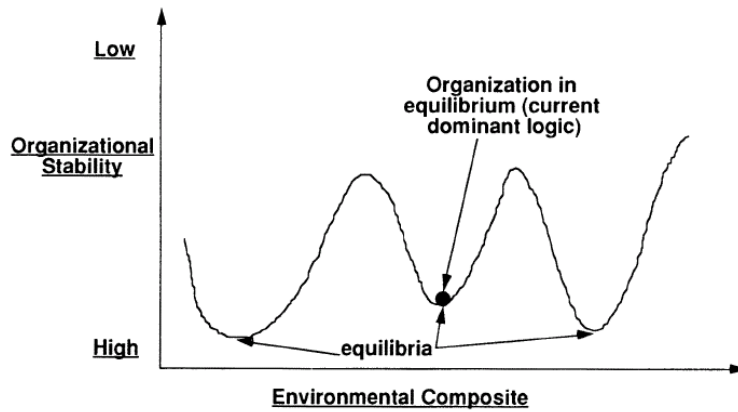


Figure 2a. Organizational stability

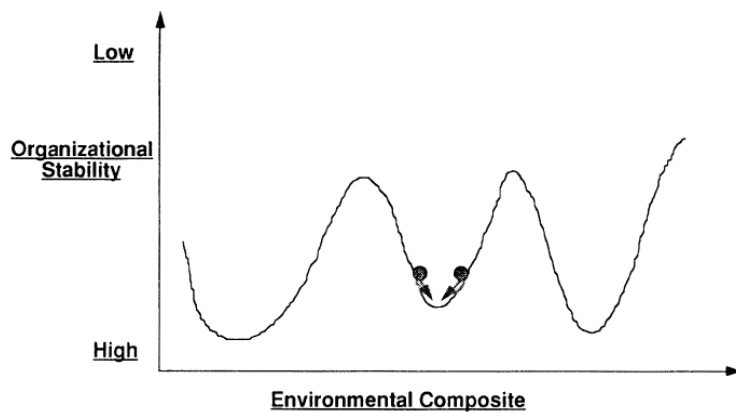


Figure 2b. Small fluctuations return to original equilibrium

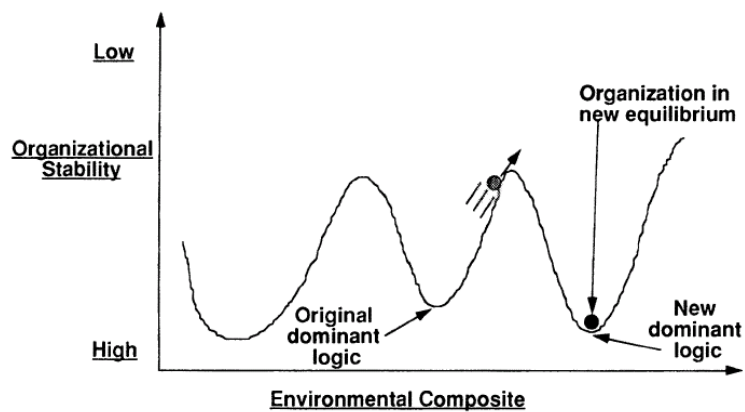


Figure 2c. Moving far from equilibrium allows firm to establish new equilibrium

Figure II-10 – taken from Bettis & Prahalad, 1995. It takes a far move to escape the established equilibrium of the current dominant logic. Hence, dominant logic may hinder strategic renewal.

Burgelman (1983, 1988) uses the term ‘*concept of strategy*’ in a way that resembles the concept of dominant logic (Burgelman 1983, p. 68 – my emphasis):

- *“The concept of strategy provides a more or less explicit, and more or less shared, frame of reference or “paradigm” (Duncan & Weiss, 1979; Jelinek, 1979) concerning the bases of the firm’s past success. Not unlike the sociological notion of a paradigm (Kuhn, 1970; Masterman, 1970), it provides guidance for further strategic action in line with it. At the same time, it **crystallizes the attitudinal and social factors that were selected together with the cognitive, substantive factors underlying the past success.** As such, it also is likely to prescribe, often **implicitly and tacitly, attitudes and managerial styles and an ideology** deemed necessary for the prolongation of the firm’s success. Autonomous strategic behavior, identified here as the major source of strategic renewal, thus is likely to encounter nonrational obstacles in its efforts to convince top management that changes in corporate strategy are necessary”.*

As can be seen, the overlap to the concept of ‘dominant logic’ is huge, and even the ‘gravity’ (Figure II-10) is described. If I should point to differences, then the dominant logic is a purely cognitive phenomenon; an information filter for making sense of the whole environment of the business; whereas Burgelman’s ‘concept of strategy’ is more closely linked to the strategy. Furthermore, in Burgelman (1988) the change in a firm’s ‘concept of strategy’ is the result of the initial strategy making process, concluding the emergent state. The establishment of a dominant logic would require longer reinforcement cycles within the induced strategy process, perhaps even linked to the eventual stage of ‘co-evolutionary lock-in’ of the strategy (Burgelman, 2002).

I have here chosen to apply the concept of dominant logic, both because of the opening towards the literature on management cognition, and because it not always is crystal clear, when Burgelman’s (1983, 1988) ‘concept of strategy’ refers to a deep cognitive structure underlying the firm’s strategy making (the ‘paradigm’) or to the ‘strategy concept’ (the strategy as the individual theory or plan, building on the underlying paradigm). The concept of ‘dominant logic’ is here easier to decode; it always terms the underlying ‘mental models’, the ‘paradigm’ beneath the strategy making.

How the dominant logic might be loosened up

Based on a recent case study, Kaplan (2008) links cognitive frames and strategy making under conditions of uncertainty into a theory of ‘framing contests’. Kaplan (2008) defines **frames** as “*the means by which managers make sense of ambiguous information from their environments*” (p. 729). She describes strategy making as a ‘framing contest’ between different groups within the organization, each promoting their cognitive frame “*to make their frame resonate and mobilize action in their favor*” (ibid, p. 730). In her ethnographic case study of a single company (a disguised manufacturer of communication technologies), she observed such ‘**framing practices**’: “*By attempting to establish the legitimacy of a frame or of themselves as claimsmakers or by realigning the frames in play, actors sought to push the strategic choice in the direction of their own frames and*

interests... *If framing practices were successful, this process produced a predominant frame*" (ibid, p. 736). By proposing this concept of **framing contests**, the view on management cognition is lifted above the perspective of cognitive inertia – the contest between different cognitive frames becomes a driver of strategic renewal. *"I find that frames influence strategic choices, not in a deterministic fashion, but rather in one mediated by organizational framing contests. This model opens up the black boxes of politics in cognitive models and of cognition in political models of strategy making by showing that frames are both constraints and resources for actors acting purposefully to shape strategic choices"* (ibid, p. 745, my emphasis). Kaplan (2008) herself makes the link to Prahalad & Bettis (1986) by stating *"The framing contests model sheds light on the organizational processes by which dominant logics emerge and change"* (p. 746).

To conclude: where dominant logic is formed through reinforcement cycles, starting from the initial framing of strategy, the dominant logic may change as result of framing contests between managers – at least, under conditions of uncertainty.

Conclusions on management cognition and strategy

In conclusion, some key findings from the theories on management cognition could be:

- The link between top management's cognitive structures and strategic inertia is well documented. However, most of the underlying case studies are on technological discontinuities and environmental changes not controlled by the focal firm, setting top management in a reactive role (Barr, Stimpert & Huff, 1992; Christensen & Bower, 1996; Tripsas & Gavetti, 2000). The *entrepreneurial* role of top management cognition is underresearched.
- The initial identity and framing of strategy form the basis of organizational learning cycles, which have an enduring effect via establishment of the dominant logic. One study analyzed how the dominant logic might undergo change processes: Kaplan (2008) analyses 'framing contests' as an ecosystem of cognitive frames, which compete for becoming dominant. This theory therefore points towards a more dynamic model of managerial cognition.

Integrative competencies

The evolution of innovation strategy at Novo Nordisk to large extent is a case of integration of complementary products (medical devices) in a drug-based, pharmaceutical company. Some theoretical concepts could facilitate the understanding of this perspective.

In a context of *Open Innovation*, Christensen (2006) describes two trends in today's business environment:

- Growing technological complexity, which makes deep technical competencies less important than so-called 'background competencies' for utilizing emerging areas of knowledge

- Increasing vertical disintegration of the industries, where nobody can have full control and ownership of the entire value chain of their business.

These trends force large companies into a role as system integrators or ‘innovation architects’, and this role again requires *integrative competencies* for synthesizing various knowledge resources into applications.

The foundation of integrative competencies are the *complementary assets* (Teece, 1986), which typically characterize larger, established companies as compared to technology-specialized startup companies. Complementary assets include customer linkages, established distribution channels, production know-how for economies of scale etc. The role of complementary assets is to amplify the value of the core assets. Teece (1986) describes the core of an innovation as the “*technical knowledge about how to do things better than the existing state of the art*” (p. 288). Around the core technological know-how, a range of complementary assets are needed for commercializing the basic technical invention. Interestingly, Teece states: “*In some cases, as when the innovation is systemic, the complementary assets may be other parts of the system. For instance; computer hardware typically requires specialized software, both for the operating system, as well as for the applications*” (ibid, p. 288).

Going back to Christensen (2006): integrative competencies, which utilize complementary assets, enable large firms to orchestrate a portfolio of technologies and transform these into product offerings.

This whole perspective of complementary assets and system integration is very relevant for the case study of the medical device activities at Novo Nordisk, where the medical devices most of the time have been perceived as complementary products compared to the pharmaceutical drugs in the product innovation strategy. Still, in the present form, the theories lack the *longitudinal* perspective of the dynamics between core and complementary assets for innovation strategy in a single company – i.e. what happens with the balance between core and complementary over time?

A synthesized model of strategy evolution

This section provides a synthesized theoretical model of how a strategy comes into being, is sustained and eventually changed, based on the research presented earlier in this chapter.

Mintzberg (2007) describes combined deliberate and emergent processes of strategy formation: "*If deliberate strategy is about control, then emergent strategy is about learning ...almost every sensible real-life strategy process combines emergent learning with deliberate control*" (p. 5; my emphasis). This quotation underpins that the conceptual dichotomy between deliberate and emergent strategy is exactly *conceptual*; in real life, these processes are closely interrelated. Mintzberg's graphical model (see figure II-1) may therefore be misleading, since it shows the deliberate and emergent processes as two separate sources of strategy. In reality they develop together, as analyzed in Burgelman (1988). In fact, the dichotomy may simply consist of different hierarchical standpoints: what is deliberate seen from one hierarchical level is emergent seen from the next level (cf. figure II-2).

However, there is empirical evidence for varying levels of significance of respectively emergent and deliberate processes:

- In Burgelman's case studies of internal corporate venture units (1988) and of Intel (1991) – and in Gavetti & Rivkin's (2007) case study of the internet portal Lycos – the emergent (experience-based) learning seems to dominate the strategy making when it comes to strategic renewal.
- However, in Noda & Bower's (1996) case study of two telecom operators' different approaches to the upcoming mobile telephony, the initial strategic framing (deliberate strategy formulation) seemed to determine both the scope and the outcome of succeeding experiences in the market.

Based on the above reflections on the conceptual dichotomy, the learning or reinforcement cycle (figure II-4) has been applied as the basic model of strategy formation over Mintzberg's two separate streams (figure II-1); because the *interrelatedness* of deliberate and emergent processes is visible. Still, it should be noted that the two sides of the learning cycle might have shifting emphasis in different stages of development. In the following, different evolutions of strategy are applied by applying the generic model of strategic learning (figure II-4), laid out in four scenarios: 1) the emergent state; 2) strategic lock-in; 3) induced strategic adaptation; 4) induced strategic reconfiguration.

Scenario 1: the emergent state

In the emergent state, the 'theory' is most often established via retroactive rationalization of emergent experiments (Burgelman 1988). Figure II-11 models this initial formation of a strategy – i.e. strategy making before *institutionalization*, referring to Burgelman (1988).

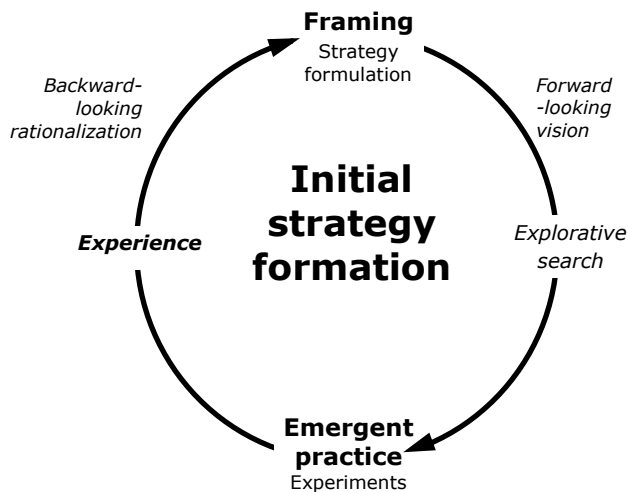


Figure II-11. The initial formation of strategy as a learning cycle between deliberate (forward-looking) and emergent (backward-looking) processes. The depicted learning cycle represents strategy making *before* institutionalization; i.e. in the emergent state (cf. Burgelman 1988). In this phase, the experience-based learning seems to dominate, according to the presented literature. As an empirical example, Burgelman (1988) builds his theory on an investigation of strategy making in internal corporate venture units.

When a strategy first has been institutionalized, the strategy making changes character and becomes an induced process: planning before action (Burgelman, 1988). However, strategic learning still takes place. In that sense, Mintzberg's (2007) statement "*If deliberate strategy is about control, then emergent strategy is about learning*" is unfortunate; it's not an either-or between deliberate strategy and learning. Burgelman & Grove (1996) state: "*The fact is, corporate strategy is realized by performing a series of such strategic actions, and not via strategic planning. Strategic plans are abstract, far away, and give managers a lot of chances to reconsider as they go along*" (p. 21). This implies that when the induced strategy is implemented, practical experiences provide feedback to the strategy making process in the form of *positive* or *negative* reinforcement.

Scenario 2: strategic lock-in

Let's look at the scenario of *positive reinforcement*. This occurs, when the central strategic actions are successful. Consequently, the core of the strategy is sustained, although it will continuously be adjusted based on feedback from practice. Such feedback includes the perceived distinctive competencies (Burgelman, 1991) and the perceived critical tasks for success (Prahalad & Bettis, 1986). Following Prahalad & Bettis (1986), repetitive positive reinforcement can eventually result in the establishment of a dominant logic, which becomes hard to change. The dominant logic is the cognitive aspect of '*co-evolutionary lock-in*' of strategy, using Burgelman's (2002) terminology. In case of lock-in, strategic renewal is suppressed, and the strategic activities are focused on exploitation of established capabilities and positions. The dominant logic retains the lock-in by directing management attention narrowly towards the core business – everything else is perceived as distraction (cf. Burgelman, 2002). See figure II-12. An empirical example of this learning cycle is

described in Burgelman's (2002) analysis of Intel Corporation after the institutionalization of the microprocessor strategy in 1985.

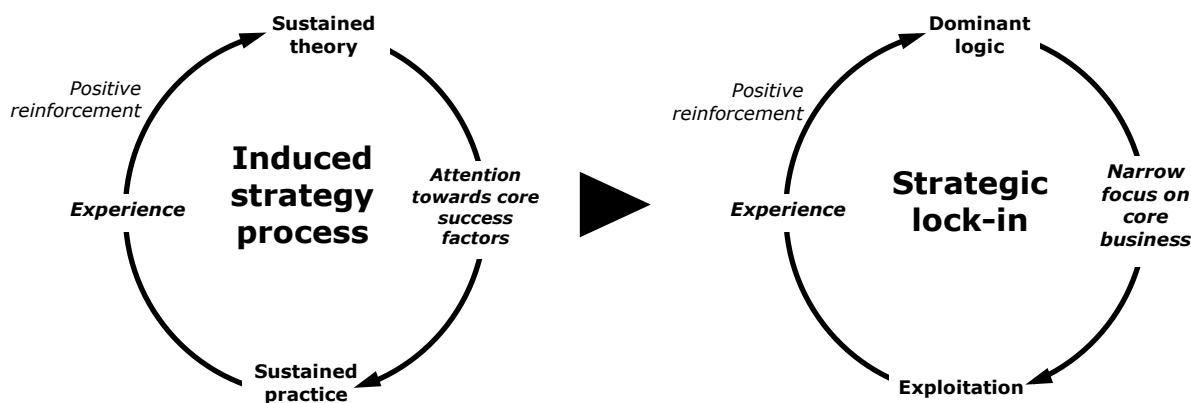


Figure II-12. Strategic learning after institutionalization of strategy, i.e. in the 'steady state' (Burgelman, 1988), displaying the scenario of positive reinforcement. Continuous positive reinforcement of the initial theory (strategy) may lead the induced strategy process towards a strategic lock-in, supported by a dominant logic, which impedes strategic renewal and focuses the activities on exploitation. The case study of Intel after 1985 in Burgelman (2002) provides an empirical example of this scenario.

Scenario 3: induced strategic adaptation

Let's now look at the case of *negative reinforcement* of the induced strategy. After the institutionalization of a strategy, the starting signal for strategic change could be negative reinforcement of the current strategy in the form of negative results (Prahalad & Bettis, 1986) or so-called strategic dissonance (Burgelman & Grove, 1996). The latter refers to misalignment between the strategic intent and the reality of action – the primary example is Intel, where the *de facto* strategy had changed years before the explicit strategy was reformulated in 1985. Burgelman & Grove (1996) propose the concept of a "*strategic inflection point*": a moment, where industry changes, technological developments or *de facto* changes in strategic actions require reformulation of the corporate strategy. As result of such negative reinforcement, an explorative search process seeks for alternative strategic options, in theory and practice. The most successful theories (strategy frames) and strategic initiatives (emergent practices) are selected, as they gain resonance within the corporate management team. Thereafter, new cycles of induced strategy making processes begin. In the case of Intel Corporation in the 1980's (cf. Burgelman, 1991), the negative reinforcement came from the fact that Japanese companies were taking over the DRAM (memory) business. The emerging business of microprocessors won the framing contest as the most convincing alternative strategy, due to successful results. Hence, the microprocessor business became institutionalized as the new induced strategy in 1985. See figure II-13. Burgelman (1991) reversely focuses on the emergence of the microprocessors as an autonomous strategy, resulting in 'strategic renewal'. In my opinion, one

can either analyze the transition as autonomous ‘renewal’ or as a ‘reorientation’ of strategy in response to continuous bad performance of the memory business.

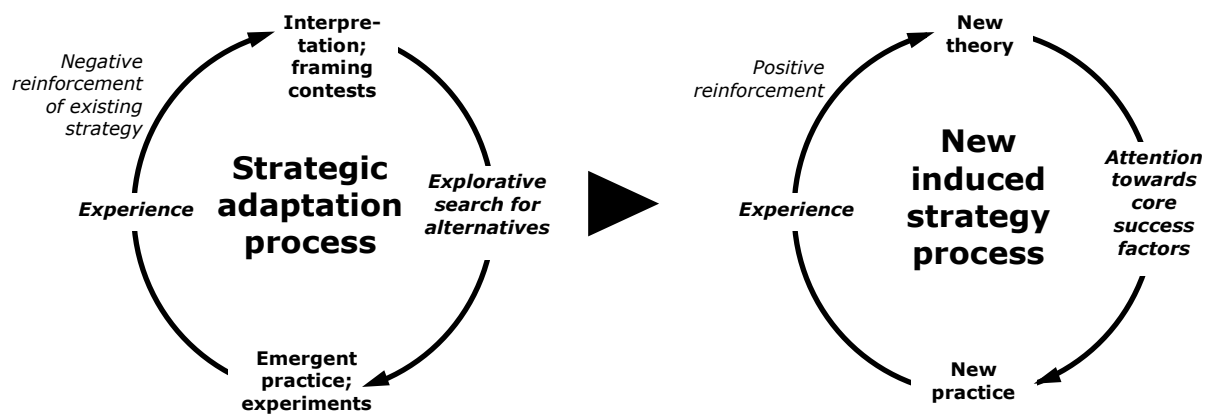


Figure II-13. Strategic learning after the initial institutionalization of strategy, displaying the scenario of negative reinforcement. The starting point is negative reinforcement of the existing strategy, which triggers search for strategic alternatives. Emergent practice unfolds a variety of experiments; and framing contests offer interpretations of reality, formulated as alternative strategies (Kaplan, 2008). Via selection a process, a new induced strategy is chosen, which is then continuously refined via new induced learning cycles. An empirical example of this scenario is the Intel Corporation in the 1980's (Burgelman, 1991), where the memory business declined and the microprocessor business emerged and eventually was institutionalized in 1985 as the new corporate strategy.

Scenario 4: induced strategic reconfiguration

When posing a dichotomy such as autonomous and induced strategy (or emergent and deliberate strategy), the induced strategy process will tend to be perceived as a ‘conservative’ force as opposed to the ‘creative’ autonomous strategy. However, we should not forget that strategy per definition is a conservative aspect of organizational life: it’s the *enduring* pattern of an organization’s activity. As stated by Michael Porter (1991): “*Strategy, in modern language, is a solution to the agency problem that arises because senior management cannot participate in or monitor all decisions and directly ensure the consistency of the myriad of individual actions and choices that make up a firm’s ongoing activities*” – “*Strategy is seen as a way of integrating the activities*” – “*An explicit and mutually reinforcing set of goals and functional policies is needed to counter the centrifugal forces*” (p. 96). Porter is here of course colored by the rational choice paradigm, seeing strategy as a deliberate and explicit construct. However, the analysis of strategy as an aligning force, which creates consistency, is valid also in an evolutionary perspective. Furthermore, Porter (1991) states, “*Strategy is the act of aligning a company and its environment. That environment, as well as the firm’s own capabilities, are subject to change. Thus, **the task of strategy is to maintain a dynamic, not a static balance***” (p. 97 – my emphasis). The emphasized part is central, exactly because an evolutionary perspective might

result in a deterministic view on the induced strategy process as purely static; where strategic renewal is seen as only coming from emergent processes.

Even though the deliberate (induced) strategy process is constrained by 'bounded rationality', there still is rationality (reasoning) in place – and a lot can be learned and changed based on reasoning. The coin called 'bounded rationality' has two sides: the constraints of cognition make the one side; the ability to learn and adapt makes the other. This point was made in the analysis of bounded rationality by Nelson (2008): *"I use the term "bounded rationality" to connote the reasoning and learning abilities of an actor who has a goal to achieve and, on the one hand, an at least partially formed theory about how to achieve it (this is the "rationality" part of the concept), and on the other hand, that the actor's theory is likely somewhat crude and perhaps even a bad guide for action, and that success is far from assured (this is the meaning of the "bounded" qualification to rationality)"* (p. 78). Further, Nelson analyzes how learning can take place, departing from the (imperfect) theory: *"at any time search for a satisfactory or a better way of doing something is strongly oriented, but also limited, by a theory held by the actor at that time. Empirical exploration of alternatives at any time is treated as like going down a path, which current theory suggests is promising, finding out where it in fact leads, and then perhaps trying another path. However, the actor is not locked into his present theory. As a result of what is learned in exploration, theory may be revised...my approach here puts special emphasis on the role of trial and error learning in potentially leading to improvements in the theory held by the actor"* (ibid p. 79 – my emphasis). In terms of strategy making: the starting point is an 'ex ante' vision or strategy; from here, explorative search unfolds trial-and-error; this process eventually leads to improvement or change of the strategy. – Since this cyclic process is based on 'ex ante' vision or theory, such strategic change takes place within the induced strategy process.

Based on the above understanding, negative reinforcement is not the only scenario of strategic change within the induced strategy process. We need a model of theory-driven strategic change – see figure II-14. The initial vision (or, 'crude' theory; Nelson, 2008) drives an explorative search, which via trial-and-error and interpretation of experiences results in improvement or revision of the 'theory', i.e. reconfiguration of the strategy, which again drives further strategic learning. Thus, such scenario (based on Nelson, 2008) implies strategic change initiated out of positive vision rather than negative reinforcement. An empirical example of this scenario could be the case of BellSouth exploring the mobile telephony, as analyzed in Noda & Bower (1996). However, the present case study provides further empirical evidence.

To distinguish the two scenarios of strategic change in the 'steady state' (Burgelman, 1988), the change process starting with negative reinforcement is here labeled 'induced strategic *adaptation*' (since it adapts the strategy based on negative feedback); whereas the vision-driven process is labeled 'induced strategic *reconfiguration*' (or 'strategic *renewal*'), since it changes the strategy going out from a positive vision.

It is here necessary to point to the differences in my terminology compared to Burgelman's (1991) terminology. Burgelman (1991) links the induced and autonomous strategy processes to four modes of organizational adaptation (inertia; adjustment; reorientation; renewal). 'Reorientation' in his

terminology is an induced process response to negative reinforcement. ‘Renewal’ labels the autonomous process, which creates novel opportunities based on positive reinforcement of previous experiments – described in my Scenario 1 of the initial strategy formation. The case of theory-based strategic renewal within the induced process is not present in Burgelman’s (1991) four modes of organizational adaptability.

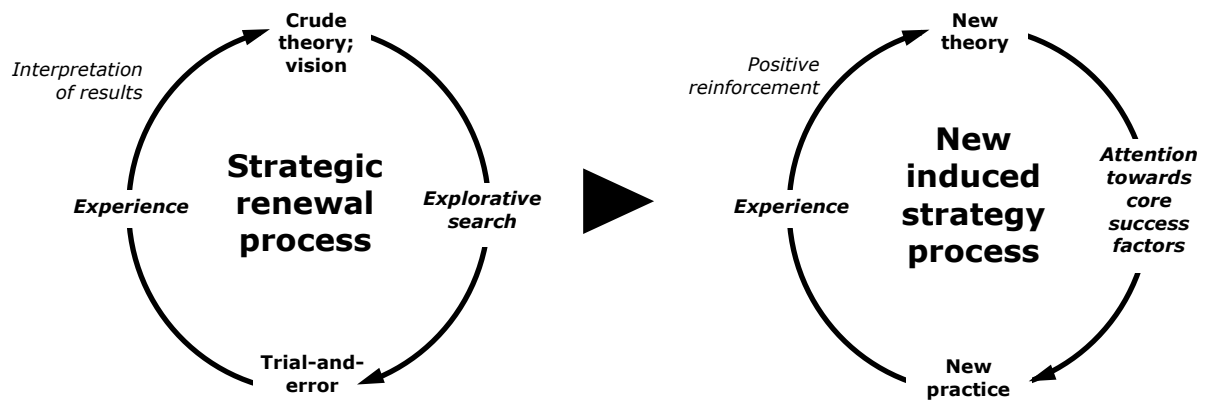


Figure II-14. Strategic learning in the ‘steady state’, displaying the scenario of ‘theory’-based strategic change, based on Nelson (2008). The induced strategy process defines a ‘crude theory’ or vision, which via trial-and-error and interpretation ‘en route’ results in a revised theory, i.e. a reconfigured strategy. An empirical example of this scenario is found in Noda & Bower’s (1996) analysis of BellSouth’s exploration of mobile telephony. The present case study provides further empirical evidence.

Chapter 3. Research design and method

Content

Overall research design.....	60
Process study	60
Qualitative case study	61
Special research setting.....	62
Limitations due to business confidentiality.....	62
1. Research method for the longitudinal case study.....	63
Data collection	63
Definitions.....	65
Data analysis	65
The construction of a narrative.....	66
Validation of findings.....	67
2. Research method for the analysis of the device innovation project portfolio	68
Data validation	69
3. Research method for the mindset analysis 2007	70
Sample and data.....	70
Data analysis	71
Validation of findings.....	72

Overall research design

Process study

The present research projects aims for understanding the processes of change in innovation strategy.

This calls for a *process research* study rather than a variance research study (Van de Ven, 2007):

“Variance and process models are used to empirically examine two different types of research questions that are often asked about an issue being studied:

- **What** are the antecedents or consequences of the issue?
- **How** does the issue emerge, develop, grow, or terminate over time?” (p. 145).

Important is that both models can lead to understanding causality; the process model just takes another road:

*“From a variance perspective, events represent changes in variables, and these changes are the building blocks of process in an input-process-output model. But since a process question is not whether, but **how**, a change occurred, we first need a story that narrates the sequence of events that unfolded as the innovation emerged from concept to implementation. Once the sequence or pattern of events in a*

developmental process is found, then one can turn to the 'what' questions about the causes or consequences of the event sequence" (Van de Ven, 2007, p. 146).

To follow a process study model has implications for data collection and analysis. Concerning the data needed: *"Process questions of how things change and develop over time require longitudinal data that can be obtained either from historical archival files or from a real-time field study of a change process"* (Van de Ven, 2007, p. 195). Concerning the data analysis: *"Analysis of process data requires methods that (1) can identify and test temporal linkages between events and also overall temporal patterns (Poole et al, 2000); and (2) can cope with the multiple time scales that often occur in processes (where some events extend for years, other events embedded in them run for shorter periods, and others embedded within these run for even shorter periods) (Langley 1999)"* (Van de Ven, 2007, p. 159).

With regards to data collection, the case study at hand builds both on archival data and a five-year real-time field study. With regards to the data analysis, I thoroughly mapped events and overall trends at several levels of analysis, from the trends in the industry over corporate management events all the way to concrete innovation projects of the case organization. I here had great benefit from utilizing the method for data analysis prescribed by Mintzberg (2007), because it describes concrete techniques for working at multiple levels of analysis and multiple timeframes – see the section on the methods of the historical case study.

Qualitative case study

This research project aims for an in-depth understanding of the processes of change in the innovation strategy at a particular context. Again, this points not towards a quantitative, cross-sample study of variables and their interdependencies. I have chosen an inductive approach to qualitative research, going deep into the events in one organization. This empirical research has the format of a longitudinal case study of the medical device area at the pharmaceutical company Novo Nordisk A/S, describing the medical device innovation activities since the beginning of these activities around 1980 to year-end 2010. Such case study design opens for a *thick description* of the events, contexts and interpretations (Stake, 2000, p. 437). According to Stake (2000), case studies can be either *intrinsic*, where the interest is on the idiosyncratic case itself – or *instrumental*, where the case *"facilitates our understanding of something else"* (ibid, p. 437), often at more generalized level. The present case study holds an intrinsic part, driven by the curiosity of understanding the fluctuations in strategy at the organization where I worked, presented in Chapter 4. However, the present case study also holds an instrumental part, driven by my theoretical studies, presented in Chapter 5. The inclusion of both intrinsic and instrumental dimensions is consistent with the methodological framework in Mintzberg (2007): his prescribed method of analysis works from understanding concrete events up to synthesizing overall patterns, thereby building theory in the form of more generalized explanations – see the part on data analysis for the historical case study. The case study also includes a combined qualitative and quantitative tracking of the portfolio of product innovation projects at the case organization within the studied timeframe. Furthermore, I made two rounds of interviews in respectively 2007 and 2010 with managers at the device R&D

organization of Novo Nordisk, in order to analyze the local management cognition. Together, there are thus three empirical investigations and three data sets: 1) the historical development of the medical devices activities 1980-2010, which forms the overarching narrative; 2) the development in device innovation project portfolio 1980-2010; 3) the two interview rounds 2007 and 2010 amongst device R&D managers. The specific research methods for each of these investigations are described in separate sections below.

Special research setting

Since I am myself employed at the case organization, the research method includes participant observation and can be characterized as 'self-ethnography' (Alveson, 2003) and 'engaged scholarship' (Van de Ven, 2007). 'Self-ethnography' is defined by Alveson (2003) as *"a study and a text in which the researcher-author describes a cultural setting to which s/he has a 'natural access', is an active participant, more or less on equal terms with other participants"* (p. 174). Where a conventional researcher has the challenge to 'break in' to experience the focal organization from the inside, in self-ethnography the challenge is the opposite; the researcher *"struggles in order to create sufficient distance in order to get perspective on lived reality"* (ibid, p. 176). In the present case, the struggle especially was about seeing the corporate perspective of the history. In the beginning, I found myself again and again taking a standpoint from a pure device area perspective. The corporate perspective and the understanding of the external environment were then built up gradually.

Limitations due to business confidentiality

As a consequence of the specific research setting, Novo Nordisk A/S had to approve the case study before publication, in order to avoid disclosure of confidential information. As result, all information about the years 2009 and 2010 has been left out from the findings.

A further consequence of the confidentiality issue is that names and roles of individual managers are not disclosed – apart from some of the early founders. For the same reason, the names of external consultants are not disclosed. Similarly, the names of specific organizational departments are not disclosed – since these names often label the concrete projects, which the departments host.

1. Research method for the longitudinal case study

This research project takes a *historical* perspective to gain insight into the evolution of the strategy, and has the overall format of a longitudinal case study.

Qualitative data were used to identify and describe the *strategic phases* which the Novo Nordisk medical device innovation activities undertook from the start around 1980 until yearend 2010.

Quantitative data were then included for analyzing the evolution in *product innovation activities*, described in the next section. Data collection, data analysis and conceptualization have interacted in an iterative process of interviewing, mapping data along a time axis, comparing with archival documents, categorizing and analyzing data, describing the historical phases and the development of the product innovation portfolio, addressing open questions in conversations with managers (informal interviews), new formal interviews to validate the findings, adapting the analysis etc. A retrospective graph of the overall research process is shown in figure III-1.

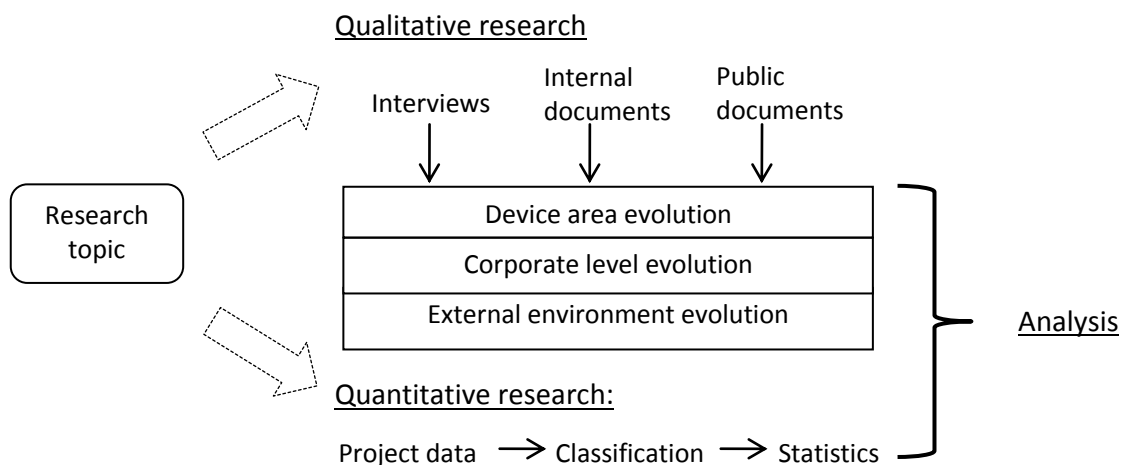


Figure III-1. Diagram of the overall research process.

Data collection

The data consist of public annual reports; a design case study published in 1993 (Freeze, 1993); internal documents especially on strategy; internal project portfolio lists and project documentation; a comprehensive internal report of the entire history of the Novo Nordisk device activities, made by a former device production manager in 2006; 43 semi-structured, recorded interviews with current and previous managers from the device area as well as at corporate level; and hundreds of informal day-to-day conversations with current managers and employees with historical experience from the device area. This daily access to data was enabled by the fact that the author since yearend 2001 has been employed at the case organization, serving as an internal consultant within innovation management and innovation processes.

The prioritization of data has been, in order of significance: interviews – internal documents – public documents. The interviews were semi-structured and lasted from 10 to 123 minutes each (mean 58

min.). They were conducted in Danish language from June 2007 through August 2011. All interviews but one were recorded and 26 were transcribed. Detailed notes were taken in all cases but two. See a list of the interviews in table III-1.

Date	Position	Duration	Recorded	Notes	Transcribed	Interview used for:
2007.06.28	Department manager	2:03	Yes	Yes	Yes	Mindset analysis 2007 + historical case study
2007.06.29	Department manager	1:36	Yes	Yes	Yes	Mindset analysis 2007 + historical case study
2007.07.02	Department manager	1:19	Yes	Yes	Yes	Mindset analysis 2007 + historical case study
2007.07.03	Device VP	1:21	Yes	Yes	Yes	Mindset analysis 2007 + historical case study
2007.07.04	Device VP	0:54	Yes	Yes	Yes	Mindset analysis 2007 + historical case study
2007.07.05	Senior project manager	0:49	Yes	Yes	Yes	Mindset analysis 2007 + historical case study
2007.07.11	Department manager	1:15	Yes	Yes	Yes	Mindset analysis 2007 + historical case study
2007.07.12	Department manager	0:52	Yes	Yes	Yes	Mindset analysis 2007 + historical case study
2007.07.16	Project director	1:08	Yes	Yes	Yes	Mindset analysis 2007 + historical case study
2007.08.08	Device SVP	0:59	Yes	Yes	Yes	Mindset analysis 2007 + historical case study
2008.04.15	Strategy manager	1:00	No	Yes	No	Historical case study
2008.05.05	Former device manager	1:13	Yes	Yes	No	Historical case study
2008.05.09	Device VP	1:06	Yes	Yes	Yes	Historical case study
2008.05.26	Device manager	1:13	Yes	Yes	No	Historical case study
2008.06.23	Project director	1:01	Yes	Yes	No	Historical case study
2008.07.01	Device VP	1:16	Yes	No	No	Historical case study
2008.08.11	Production manager	1:02	Yes	Yes	Yes	Historical case study
2008.08.26	Department manager	0:42	Yes	Yes	No	Historical case study
2009.01.23	Device manager	0:45	Yes	No	No	Historical case study
2009.01.27	Quality manager	1:01	Yes	Yes	Yes	Historical case study
2009.03.23	Device SVP	0:32	Partly	Yes	Yes	Historical case study
2009.03.30	Device VP	0:10	No	Yes	Only notes	Historical case study
2009.08.14	Quality engineer	0:53	Yes	Yes	No	Historical case study
2009.09.18	Development engineer	1:12	Yes	Yes	No	Historical case study
2009.10.22	Strategy manager	0:46	Yes	Yes	No	Historical case study
2009.11.18	Former executive	0:51	Yes	Yes	No	Historical case study
2009.12.03	CSO	0:35	Yes	Yes	No	Historical case study
2009.12.08	Former device manager	1:34	Yes	Yes	No	Historical case study
2009.12.17	Former device manager	1:37	Yes	Yes	No	Historical case study
2010.06.30	Strategy manager	0:27	Yes	Yes	No	Historical case study
2010.07.07	Strategy manager	0:34	Yes	Yes	No	Historical case study
2010.08.06	Device VP	0:57	Yes	Yes	Yes	Mindset analysis 2010
2010.09.09	Department manager	0:48	Yes	Yes	Yes	Mindset analysis 2010
2010.08.11	Device VP	0:46	Yes	Yes	Yes	Mindset analysis 2010
2010.08.12	Department manager	0:55	Yes	Yes	Yes	Mindset analysis 2010
2010.08.20	Department manager	0:45	Yes	Yes	Yes	Mindset analysis 2010
2010.08.23	Department manager	0:46	Yes	Yes	Yes	Mindset analysis 2010
2010.08.25	Department manager	0:44	Yes	Yes	Yes	Mindset analysis 2010
2010.09.08	Device VP	0:42	Yes	Yes	Yes	Mindset analysis 2010
2010.09.09	Device VP	0:35	Yes	Yes	Yes	Mindset analysis 2010
2010.09.15	Senior project manager	0:44	Yes	Yes	Yes	Mindset analysis 2010
2011.04.07	Former CEO	1:11	Yes	Yes	Yes	Historical case study
2011.08.17	CEO	1:00	Yes	Yes	Yes	Historical case study
TOTAL / average	43 interviews 29 informants	0:58	All but one	All but two	26	

Table III-1. List of interviews. (The 20 shorter follow-up interviews for the mindset analysis 2007-10 have not been included in the list). 3 informants were executives. 4 were at the next level (SVPs).

Definitions

In order to identify the strategic phases and the linked transitions, two indicators were defined:

- *Strategic changes* are defined as changes in: 1) overall vision for or purpose of the device area; 2) targeted customer segments and value proposition; 3) field of activities; 4) source of revenue. Changes in these parameters are identified via statements in interviews and archival data.
- *Structural changes* are defined as organizational restructurings, in which the *entire* device innovation area at Novo Nordisk is moved around within the Novo Nordisk organization; internal restructurings within the device area are disregarded. Structural changes are identified via the organizational charts.

Data analysis

For the analysis of the historical data, I followed the “*steps in research on strategy formation*” as described by Mintzberg (2007, p. 380-390).

The main steps are (based on Mintzberg, 2007):

1. **Basic data:** collect data to develop chronologies of decisions and actions, trends and events, and results – across all key strategy areas as well as aspects of the environment.
2. **Determination of strategy patterns:** map each track of events on a common timescale, if possible as visualized graphs under each other. Determine vertically the concurrent changes and identify and label the strategic periods. – See a list of the mapped tracks below.
3. **Analysis of each major period:** investigate intensively each period of the strategy, including drivers that shaped it, the underlying causes of changes in strategy and interrelationships. Conduct systematic theoretical analysis of each period of change in strategy by use of the chosen theoretical framework. – The outcome of this step forms the basis of Chapter 4.
4. **Theory building:** Extract the core of each period and its drivers. Interpret, brainstorm, make hypotheses and extract conceptual insights, for each period and for *the overall pattern in the whole study*. – The outcome of this step forms the basis of Chapter 5.

In step 2, I mapped in total 13 tracks distributed at 3 main levels – see table III-2 below.

1. External environment:

- Management dogmas (i.e. the prevailing concepts of management practice)
- Pharma industry trends
- Medical device inventions for diabetes
- Impact of Type 2 diabetes
- Insulin inventions
- Pressure from competitors

2. Novo Nordisk corporate level:

- Corporate management cognition and identity
- Corporate strategy and events
- Product tracks (drugs)

3. Novo Nordisk medical device level:

- Product tracks (devices)
 - Device strategy
 - Device R&D organization
 - Portfolio of ongoing device innovation projects
-

Table III-2. The tracks mapped for the “Determination of strategy patterns” – step 2 in Mintzberg’s (2007) methodology (p. 381-383).

The construction of a narrative

In the method described by Mintzberg (2007), the phases of the historical development are set via identification of concurrent events at the different tracks in the map of patterns (see Table III-2): “in scanning vertically for concurrent changes in a number of important strategies, delineate overall periods for the whole study and label them” (p. 381). Even it sounds straightforward, it is not. The determination of phases totally depends on the perspective of interpretation. It took me a couple of years to arrive at the phase model applied here; and I have seen many other classifications of the historical epochs of Novo Nordisk’s device activities. Van de Ven (2007) writes:

- “Thus, as we move from surface observations towards a process theory, we move from description to explanation. Explanation requires a **story**, and stories can be understood as process theories (Pentland 1999). In narrative theory the story is an abstract conceptual model; it identifies the generative mechanisms at work. At a minimum this story must describe a progression or sequence of events. In narrative theory, however, the ‘story’ includes a great deal more than just event sequence. In particular, a process theory should hold the following features in the story...” (p. 223)

Van de Ven then continues by describing five elements, respectively: 1) sequence in time; 2) focal actors; 3) narrative voice; 4) frame of reference; and 5) other indicators. Especially element 4 deserves to be illuminated here. Van de Ven states: “*Narratives carry meaning and cultural value because they encode, implicitly or explicitly, standards against which actions of the characters can be judged*” (p. 224). He concludes the description by saying “*These five steps in theory building are easier said than done*” (p. 224).

My frame of reference was the **content** and **nature** of the innovation strategy for the device activities at Novo Nordisk A/S. Key questions were which sort of product-markets the innovations were targeting (e.g. was glucose monitoring products included in the strategy?); the degree of systemic and patient-centered approach to the innovation activities; and the definition of either the pharmaceutical drugs or the medical devices as most central. Only through such story, the narrative provides meaning and explanation. A concrete example could be the phase division around the merger of Novo and Nordisk in 1989. I have seen narratives setting the discriminating year as 1989 (the merger was announced in the beginning of 1989 and the implementation started later that year) or 1990 (where the organization was in place). I have chosen 1988, since the visionary strategy about patient-centered homecare was launched in the beginning of 1988, organized in the new Medical Systems Division within Nordisk – although this was one year *before* the merger. The reason for my choice is that the strategic intent and the organizational setup was continued after the merger – the much smaller device activities of Novo were integrated into the strategy and organization of MSD. Thus, data in itself does not provide the narrative; you need an underlying story.

It is also clear from this description that only a qualitative in-depth study can provide the data needed for establishing such narrative. It is the voice of many different informants, inside and outside the case organization, which accumulates not only into a sequence of events, but into an explanation of the change processes at the case organization.

Validation of findings

My mapping and interpretation of data was continuously, from 2008 on, validated in the way that I presented my findings to different audiences at the device area of Novo Nordisk at many occasions – such as large seminars for employees, management team meetings etc. This gave me the opportunity to capture comments from many sources, which helped the further data capture and interpretation. Based on this iterative validation, I am absolutely sure that my findings are robust, concerning the overall case narrative.

2. Research method for the analysis of the device innovation project portfolio

The current research project builds on the understanding that strategies belongs to a mental realm of theory or reasoning as well as to a physical realm of action; and that strategy making evolves in learning or reinforcement cycles between these two realms. Accordingly, I investigated whether this relationship between strategy in theory and strategy in practice was traceable in empirical reality: are changes in innovation strategy and changes in the actual innovation projects linked? Or do these realms live their own, separate lives?

The *product innovation activities* were mapped, quantitatively and qualitatively. This was established by a combination of 1) objective data from internal documents regarding year of project start-up, project closure or product launch, and 2) inter-subjective assessments of the nature of each project. For the latter, each project was classified with regards to Burgelman's (1991; 2002) concepts of induced and autonomous strategic initiatives. The inter-subjective assessment was established via interviews with managers and employees, as well as by the author himself; in the latter case based on project documents, informal conversations with project managers or firsthand experience. See the qualitative categories and empirical definitions in Chapter 4, in the section about the project portfolio.

A good starting point was an overview of the historical device development pipeline, made by two device managers in 2003. These data were compared to two internal lists of previous and current development projects, the one including one-page descriptions of each project. The information was then matched with a comprehensive historical report about the Novo Nordisk device activities, made by a former device production manager in 2006. The remaining 'holes' in corporate memory were partly solved by visits in the archives and conversations with former project managers. To validate the findings, all device 'veterans' were invited to a meeting, where they were confronted with the results. This meeting resulted in even more details and identification of several historical development projects, which had not been discovered yet. All data were compiled in a spreadsheet for statistics.

The research resulted in the identification of 233 official development projects. These were first classified to sort out a) product development projects, e.g. injection devices; b) explorative research projects regarding technologies and materials, internally called 'technology projects'; c) development

of accessories and packaging material, e.g. new generations of needles for the insulin pens; and d) process improvement projects like lean management initiatives etc. As result, 102 product development projects were registered; 95 could be classified and analyzed (with regards to the data sample for 1980-2008; not including data from 2009 and 2010). Only these 95 projects were included in the further quantitative analysis⁵. The analysis was made by use of a traditional spreadsheet, compiling objective data (year of project start-up, duration, launch/closure) and the subjective classification of each project.

Statistics on the *product innovation portfolio* were made for the *number per year* of: product development projects initiated; development projects in parallel; new product launches; project closures; in all cases distributed per category.

Data validation

The qualitative findings were continuously presented to informants and verified through their comments. Also the project data behind the quantitative research were tested by presenting these to knowledgeable project managers. Their comments and additional information brought the analysis further and filled out many gaps, as for example identification of not yet registered projects or classification of projects, which had not been classified until then.

⁵ The restriction to the 95 product development projects was made because it showed to be very difficult to gather detailed information about the historical projects; in many cases the only information left was the name of the project. Therefore, it would have been impossible to establish the basic information about all 233 projects.

3. Research method for the mindset analysis 2007

The purpose of this empirical investigation was to identify and analyze the 'dominant logic' (Prahalad & Bettis, 1986) of the device innovation area with regards to the management mindset on innovation – here termed '*dominant innovation logic*'.

Prahalad & Bettis (1986) in their implications for further research request 'rigor approaches' for identifying the dominant logic of a firm, beyond simple conversations with managers. The current empirical investigation builds such method for identifying the dominant logic of an organizational unit. Therefore, the research method in itself can be said to hold a novel research contribution at methodological level. Consequently, I have included a detailed description of the entire method in Appendix A. For reasons of business confidentiality, all information after 2008 had to be excluded. Hence, the comparative analysis of the two investigations in 2007 and 2010 could not be included. In this section, I therefore only describe the overall research method for the mindset analysis in 2007 (for details, see Appendix A). The findings from the 2007 analysis are presented in a separate section of Chapter 4.

Sample and data

The unit of analysis was the device innovation area of Novo Nordisk A/S. A sample of 10 managers was selected as informants. These 10 were chosen in order to represent the organizational functions as broadly as possible. First of all, the VPs of the three functional areas were chosen, plus a VP from a governance unit, who was a former VP from the device area. The other 6 were department managers. The interviews were conducted as qualitative, semi-structured in-depth interviews throughout the summer of 2007. See total list of interviews, table III-1. – All interviews were recorded and transcribed.

The interviews were based on lists of questions, which mainly included the themes

- a) industry identification; b) value proposition; c) core capabilities; d) product innovation portfolio;
- e) innovation barriers and enhancers. See table III-3 for the lists of core questions.

- What is the value, we produce for our customers? (we = device R&D)
- Which are our most essential capabilities?
- Could we be an independent company?
- Which industry would we then become a part of?
- What are the drivers of this industry?
- Who are the jokers within this industry?
- Could you mention 3 highlights from the history of device innovation at NN?
- Are we still creating history?
- What would it take to ensure that we have success in 2015?
- What is holding back and what is advancing our device innovation?
- Our current development projects: How innovative are they?
- Which are the most crucial factors, when deciding if an idea or a project is either supported or stopped?
- What are the external blocks and dilutors? – and the internal?
- What are our fears/concerns/doubts that prevent us from giving our best?
- Do we tend to stick to what we already know? – Why (not)? (Where have we settled in our comfort zones?)
- What's the biggest learning we have made at device R&D?
- If time: Actant modeling (subject, goal, provider, receiver, supporter, opponent)
- If we were a car, which car would it be?

Table III-3. The list of key questions for the interviews in 2007.

Summaries of the interviews were made in a format resembling 'cognitive maps' (Eden, 1988; Fiol & Huff, 1992; Barr, Stimpert & Huff, 1992; Bougon, 1992), containing *condensed statements* clustered in themes. Short follow-up interviews were conducted to get approval from the informants of the summaries. The follow-up interviews were not recorded, but the corrections by the informants were noted and approved at the interviews. These follow-up interviews typically lasted 15-30 minutes. Thereafter, the data analysis was based on the summaries as data input. The summaries contained 680 condensed statements in total, corresponding to 0.9 condensed statement per interview minute.

Data analysis

The condensed statements were taken from the individual cognitive maps into a spreadsheet, reformulated in 107 yet more generic terms, termed '*constructs*', so that each reformulated construct could cover several informants' condensed statements. At the same time, the language was changed from Danish to English.

For the analysis, the constructs were clustered in three main spheres, Foundation-Innovation-Future (FIF), which basically formed a timeline of past, present and future. The FIF structure emerged out of the data analysis. Within each sphere, the constructs were clustered in groups. See table III-4 with the generic FIF structure.

FOUNDATION

Value Proposition

Strategy - Business Drivers - Business Model

Competition

Core Capabilities – strengths and weaknesses

Organization – Structure, governance

Identity - Culture

INNOVATION

Innovation enhancers

Innovation barriers

Portfolio management

The current portfolio – balance radical/incremental

FUTURE

Opportunities and threats

Future competencies

Future organization

Table III-4. The generic FIF structure which emerged out of the data analysis.

The FIF structure was applied for the data analysis in the spreadsheet of the total constructs. The spreadsheet was used as an instrument for quantification; each construct was correlated with the data to determine exactly which of the informants who supported the construct in question in their individual statements. This way I could quantify how widespread each of the constructs was amongst the 10 informants. For traceability, the exact timestamps from the interview transcriptions of the statements in support of each construct were also noted.

The ‘dominant logic’ is a worldview shared across the management team. Arguably, idiosyncratic individual viewpoints cannot belong to the ‘dominant’ logic. Therefore, to get a clearer picture of the management thinking, all constructs with less than 5 supporters (of 10 possible) were deleted. As references for this criterion, Tyler & Gnyawali (2002) similarly assess the concept of ‘shared cognition’ in a management team such that 50% must agree in a small group; 40% in a large group (where 30 managers make a large group).

The relatively few constructs left (28 of 107) were then ‘translated’ into full sentence narratives, which concluded the *dominant innovation logic* of the device management team. See the result in the specific section of Chapter 4.

Validation of findings

The only validation – after the informants’ approval of the condensed statements – were two workshops for the entire device management team held in 2008, where they were presented for the results from the 2007 interviews, including the ‘dominant logic’. The research findings served as input for discussions on the identity and strategy of the device area.

Chapter 4: The transformations of innovation strategy

Introduction	75
Diabetes and devices	76
Novo Nordisk in brief	78
The diabetes industry.....	79
Structure of the rest of the chapter	81
Part 1: The historical case study	82
Summary.....	82
Phase 0: Maturing for medical devices (1923-1980)	84
The corporate DNA.....	84
Industry dynamics	85
Diagnostic systems	85
Concluding on the period 1923-1980	86
Phase 1: Early attempts within device innovation (1980-1988)	87
Insulin industry.....	87
Corporate management cognition	88
Entering medical devices	89
Concluding on the evolution of the early attempts 1980-1988	91
Phase 2: The period around the merger (1988-1992)	94
Insulin industry.....	94
Corporate management cognition	94
Medical device level	95
Concluding on the evolution of innovation strategy 1988-1992.....	98
Phase 3: The quality crisis (1992-1994).....	100
Insulin industry.....	100
Corporate level – cognition and crisis.....	100
Medical device level	102
Concluding on the evolution of innovation strategy during the crisis 1992-1994.....	104
Phase 4: Harvesting (1995-2001).....	106
Insulin industry.....	106
Corporate management cognition	107
Medical device level	109
Concluding on the evolution of strategy in the harvesting period (1995-2001).....	110

Phase 5: The vision of closed loop (2001-2005)	112
Insulin industry	112
Corporate strategy	113
Medical device level	117
Concluding on the evolution of the PDS strategy (2001-2005)	118
Phase 6: Integration into the drug research area (2005-2008)	120
Insulin industry	120
Corporate management cognition	120
Medical device level	121
Concluding on the formation of the DRU strategy (2005-2008)	123
Part 2: The product innovation portfolio	124
Definitions	125
Expectations	125
Basic measurements	126
The development of the nature of the innovation project portfolio	128
Conclusion on the development of the project portfolio	135
Part 3: Close-up analysis of device level dominant logic 2007	136
Findings	136
Concluding on the 'dominant innovation logic' 2007	137

Introduction

In the current longitudinal case study of the medical device innovation at the pharmaceutical company Novo Nordisk A/S, the main focus has been on:

- The most defining events at three levels: external environment (insulin industry); corporate level, with emphasis on top management cognition and corporate strategy; and local device area events.
- The integration of medical devices as a complementary product innovation area, compared to the core product (insulin).

The analysis is structured in three parts, as result of three empirical investigations:

1. The overall historical case study, providing the basic narrative
2. The evolution of the portfolio of medical device innovation projects
3. A close-up portrait of the management cognition in the device innovation area in 2007.

The first investigation about the historical development has been divided into phases. Ideally these phases should reflect changes in innovation strategy. However, as will be clear from the data, the exact beginning and end of a strategy is not always easy to determine. Changes in organizational structure, in contrast, are made explicit via organizational charts. Furthermore, changes in structure are often connected to changes in strategy (cf. Chandler, 1992). Therefore, as a pragmatic empirical solution, the phases of the historical case description in the narrative have been separated by the years of major organizational changes at the medical device innovation area, with two exceptions:

- The start has been chosen to 1980. Organizational changes did not occur until 1984, with establishment of the first Medico-Technical Department in Nordisk Gentofte. However, since the first insulin pump was launched already in 1983, the development activities must have started around 1980.
- In 1988, Nordisk Gentofte established Medical Systems Division for the device activities. In 1989, Nordisk Gentofte and Novo merged. However, since Medical Systems Division was continued in the joined company, only the year 1988 has been chosen for phase separation, even though the merger in 1989 of course also implied organizational changes.

Before we turn to the case study, some background information about diabetes, Novo Nordisk and the diabetes industry should be provided.

Diabetes and devices

Diabetes is defined as having too high blood sugar levels, and is caused by disturbances of the metabolism due to malfunction of the pancreas, which produces the hormone insulin. Insulin is a protein, which acts like a key, opening the cell pores for glucose molecules, thereby triggering the glucose metabolism. Type 1 diabetes patients have no insulin secretion from the pancreas at all, whereas Type 2 diabetes patients have reduced insulin secretion, often combined with reduced insulin sensitivity of the cells. Type 1 diabetes is also called juvenile diabetes or insulin-dependent diabetes, since the patients typically get the disease in a young age; within few months, the pancreas totally stops producing insulin, making insulin treatment a necessity. Until Canadian researchers in 1921 discovered the function of insulin, Type 1 diabetes patients simply died. Type 2 diabetes previously was referred to with terms like 'old-men's diabetes' or 'non-insulin dependent diabetes'; however, these terms are misleading. The patients truly are older in average when diagnosed, but Type 2 diabetes is partly a lifestyle dependent disease, and some patients get Type 2 diabetes already as teenagers. Type 2 diabetes does not imply a sudden malfunction of the pancreas; rather, the insulin secretion decreases over a couple of decades, combined with a decreasing ability of the cells to response to the insulin. The symptoms gradually get worse and many Type 2 patients end by having to treat themselves with insulin injections, just like Type 1 patients.

Both Type 1 and 2 diabetes patients must try to compensate for the bodily dysfunction by taking in carbohydrates, if the blood sugar gets too low, or taking in medicine, if the blood sugar gets too high. Insulin injection has an immediate lowering effect on the blood sugar level, but besides insulin a range of less intrusive treatments exist, such as tablets (so-called OAD's, Oral Anti Diabetics). The tablets either support the insulin secretion of the pancreas or the insulin sensitivity of the cells. In less serious cases of diabetes (i.e. Type 2 in an early stage), diet and exercise can be enough to lower the blood sugar levels.

To control the blood sugar and perform self-treatment, the patient has to monitor the blood sugar level by use of technical devices (blood glucose meters, BGM) and, in the case of insulin treatment, also has to inject insulin manually by the use of syringes or insulin 'pen' systems, or eventually by using a so-called insulin pump, which infuses insulin to the body continuously. See figure IV-1, IV-2, IV-3.



Figure IV-1. Left: Insulin in vial (Levemir® from Novo Nordisk). Middle: For each injection, the insulin dose must be taken from the vial to a disposable syringe. Right: insulin pens (NovoPen® 3), containing insulin for several injections in a cartridge.



Figure IV-2. An insulin pump (here the Nordisk Infuser from Nordisk Gentofte). The pump, containing the insulin in a cartridge, is carried in the patient's pocket. Via a tube ending in a needle, the insulin is continuously infused into the body.



Figure IV-3. A blood glucose meter (OneTouch Ultra2 from LifeScan; a company in the Johnson & Johnson group). A drop of blood is transferred to a test strip, which has been inserted in the device.

Novo Nordisk in brief

Novo Nordisk A/S came to existence in 1989 as a merger of two former rivals, Novo Industry and Nordisk Gentofte, both Danish insulin manufacturers established in respectively 1925 and 1923. Novo Nordisk today defines itself as a leader in the diabetes care market, mainly active within the insulin business, producing the insulin drugs as well as the injection systems for the drug delivery. Novo Nordisk also offers an OAD (Oral Anti Diabetics) product for tablet treatment, NovoNorm®⁶, but this product holds a minor share of both the total tablet market and of Novo Nordisk's revenue. By yearend 2010⁷, Novo Nordisk had a global market share of the insulin market of 51% (measured in volume) and was by far the world's largest insulin manufacturer. The company employed 30.000 people worldwide by yearend 2010. Medicine for diabetes accounted for 75% of Novo Nordisk's turnover; the other business areas being growth disorder, hemophilia and menopause treatment. Headquarters are in Denmark.

Key figures from the 2010 account are inserted below.

Profit and loss (Amounts below in DKK million)	2010	2009	2008	2007	2006	% change 2010 vs. 2009
Sales	60,776	51,078	45,553	41,831	38,743	19%
Gross profit	49,096	40,640	35,444	32,038	29,158	21%
<i>Gross margin</i>	<i>80.8%</i>	<i>79.6%</i>	<i>77.8%</i>	<i>76.6%</i>	<i>75.3%</i>	
Sales and distribution costs	18,195	15,420	12,866	12,371	11,608	18%
<i>Percent of sales</i>	<i>29.9%</i>	<i>30.2%</i>	<i>28.2%</i>	<i>29.6%</i>	<i>30.0%</i>	
Research and development costs	9,602	7,864	7,856	8,538	6,316	22%
<i>Percent of sales</i>	<i>15.8%</i>	<i>15.4%</i>	<i>17.2%</i>	<i>20.4%</i>	<i>16.3%</i>	
Administrative expenses	3,065	2,764	2,635	2,508	2,387	11%
<i>Percent of sales</i>	<i>5.0%</i>	<i>5.4%</i>	<i>5.8%</i>	<i>6.0%</i>	<i>6.2%</i>	
Licence fees and other operating income	657	341	286	321	272	93%
Operating profit	18,891	14,933	12,373	8,942	9,119	27%
<i>Operating margin</i>	<i>31.1%</i>	<i>29.2%</i>	<i>27.2%</i>	<i>21.4%</i>	<i>23.5%</i>	
Net financials	(605)	(945)	322	2,029	45	(36%)
Profit before income taxes	18,286	13,988	12,695	10,971	9,164	31%
Income taxes	3,883	3,220	3,050	2,449	2,712	21%
<i>Effective tax rate</i>	<i>21.2%</i>	<i>23.0%</i>	<i>24.0%</i>	<i>22.3%</i>	<i>29.6%</i>	
Net profit	14,403	10,768	9,645	8,522	6,452	34%
<i>Net profit margin</i>	<i>23.7%</i>	<i>21.1%</i>	<i>21.2%</i>	<i>20.4%</i>	<i>16.7%</i>	

⁶ Prandin in the U.S.

⁷ 2010 has been chosen, because it is the last year of my empirical research. However, due to confidentiality issues, the findings presented in the rest of Chapter 4 end by yearend 2008.

	Sales 2010 DKK million	Growth as reported	Growth in local currencies	Share of growth in local currencies
The diabetes care segment				
Modern insulins	26,601	24%	18%	57%
– NovoRapid®	11,900	22%	16%	23%
– NovoMix®	7,821	20%	14%	14%
– Levemir®	6,880	32%	26%	20%
Human insulins	11,827	5%	(1%)	(2%)
Protein-related products	2,214	12%	5%	2%
Victoza®	2,317	-	-	32%
Oral antidiabetic products	2,751	4%	(1%)	0%
Diabetes care total	45,710	22%	16%	89%
The biopharmaceuticals segment				
NovoSeven®	8,030	14%	8%	9%
Norditropin®	4,803	9%	4%	2%
Other products	2,233	6%	(1%)	0%
Biopharmaceuticals total	15,066	11%	5%	11%
Total sales	60,776	19%	13%	100%

Other key numbers	2010	2009	2008	2007	2006	% change 2010 vs. 2009
(Amounts below in DKK million except earnings per share, dividend per share and number of employees)						
Depreciation, amortisation, etc	2,467	2,551	2,442	3,007	2,142	(3%)
Capital expenditure	3,308	2,631	1,754	2,268	2,787	26%
Free cash flow	17,013	12,332	11,015	9,012	4,707	38%
Total assets	61,402	54,742	50,603	47,731	44,692	12%
Equity	36,965	35,734	32,979	32,182	30,122	3%
Equity ratio	60.2%	65.3%	65.2%	67.4%	67.4%	
Diluted earnings per share (in DKK)	24.60	17.82	15.54	13.39	10.00	38%
Dividend per share (in DKK) ¹⁾	10.00	7.50	6.00	4.50	3.50	33%
Payout ratio ²⁾	39.6%	40.9%	37.8%	32.8%	34.4%	
Payout ratio (adjusted) ^{3), 4), 5)}	42.8%	-	36.6%	34.9%	-	
Average number of full-time employees	29,423	27,985	26,069	24,344	22,590	5%

¹⁾ Proposed dividend for the financial year 2010.
²⁾ Dividend for the year as a percentage of net profit.
³⁾ 2010: Adjusted for divestment of shares in ZymoGenetics.
⁴⁾ 2008: Adjusted for pulmonary diabetes projects discontinuation.
⁵⁾ 2007: Adjusted for divestment of shares in Dako and AERx® discontinuation.

The diabetes industry

From a societal perspective, far the largest part of the costs for treating diabetes and its co-morbidities are the costs for hospitalization and treatment in clinics and at private doctors (healthcare services, so to speak). Novo Nordisk actually owns a diabetes hospital, the Steno Diabetes Center in Copenhagen, which is driven as a public hospital. However, the operation of the hospital is not perceived as business – rather as means of building expertise in diabetes treatment and for building credibility within the community of diabetes experts. The same could be said about many other diabetes related activities, which Novo Nordisk is engaged in, such as the World Diabetes Foundation, the Oxford Health Alliance or various diabetes research initiatives. The only explicit

diabetes *business* of Novo Nordisk A/S is the pharmaceutical drug business, covering insulin, GLP-1 (another blood glucose regulating hormone) and tablet treatment.

Besides the institutional care at doctors, clinics and hospitals, the diabetes care industry consists of the following sub industries within pharmaceuticals and medical devices, with estimated turnovers from 2010⁸:

- Insulin: 90 BDKK
- Insulin pumps (devices and utensils, exclusive insulin): 10 BDKK
- GLP-1 (a new drug for Type 2 patients): 5-10 BDKK
- OAD tablets: 90 BDKK
- Blood glucose monitoring (BGM) devices and test strips: 50 BDKK.

At Novo Nordisk there have, as can be seen in the historical case description, been attempts to expand the business into the blood glucose monitoring (BGM) market. Traditionally, the BGM and the insulin market have represented two separated sub industries, because the value chains of the two businesses have little in common, apart from serving the same end users. Thus, no global industry players were persistently active on both the insulin side and the glucose monitoring side in the focal period of this longitudinal case study (1980-2008).

In general, the ***insulin industry*** is a relatively stable industry, dominated by a few of well established companies, displaying 'low velocity' (slow rate of change, long product lifecycles). As an example, the NovoLet® prefilled insulin system was launched in 1989 and had a product lifecycle of no less than 20 years (undergoing incremental improvements). The industry today is dominated by three global players: Novo Nordisk, Eli Lilly and Sanofi. Lilly and Sanofi both have a much broader pharmaceutical product portfolio – Novo Nordisk is the only of the players, which is focused on diabetes (app. 75% of the sales come from diabetes products).

The most substantial change in external market conditions within the studied period (1980-2008) was the enormous *growth* in the market due to the pandemic of Type 2 diabetes beginning in the later decades of 20th century. However, the Type 2 diabetes market is very different from the Type 1 market, in terms of patient population, prescribed treatment and partly also the profile of the healthcare professionals dealing with the patients. Therefore, it took many years for the industry players to re-orientate their businesses towards the Type 2 market.

From the discovery of insulin in 1921 and forward, the general development on the product side was a competition in purifying animal insulin. From 1982, manufacturing of human insulin was possible, by using gene modification technology on yeast cells. In the 1990's, insulin 'analogues' were

⁸ The turnover for 2010 has been estimated by a strategy manager of the NN device area

introduced. These are insulin molecules, which have been artificially modified to achieve certain characteristics, such as prolonged effect or very fast effect. Since 1985, where Novo introduced the NovoPen®, injection devices also have been a competitive factor. Thus, in 2004, only 44% of the insulin sold worldwide was sold in traditional vials – the rest being sold in cartridges for devices (durable insulin pens) or in pre-filled devices (prefilled insulin pens).

Like the rest of the pharmaceutical industry, the insulin business chases the 'block buster' business model; i.e. it's a game of massive investments in R&D as well as in clinical trials and manufacturing, which are paid back by large volume sales, creating a revenue stream of 1 billion USD per year from each drug as the minimum target.

Structure of the rest of the chapter

The chapter follows the structure of the 3 empirical studies:

1. First, the case study analyzes **the historical development of the strategy** for the medical device innovation activities at Novo Nordisk 1980-2008, beginning with a brief summary of the development of the entire period. Thereafter, the period has been divided in 6 phases, divided by major organizational changes. These phases are analyzed one by one, looking for drivers and processes of change in innovation strategy.
2. Following the historical case study, the development in the **innovation project portfolio** throughout the studied period is analyzed.
3. Thereafter, the **dominant management logic** within the medical device innovation area in 2007 is analyzed.

Part 1: The historical case study

Summary

The medical device activities began separately in the two companies Novo and Nordisk around 1980. Several factors paved the way: a) the prevailing management dogma of diversification, where devices fit well in as yet a business opportunity; b) developments in diabetes treatment made multiple daily insulin injections necessary for the patient, and continuous infusion from insulin pumps was discussed as the future; c) Eli Lilly developed and launched recombinant human insulin in 1982, and this disruptive technology threatened to make animal insulin obsolete – both Novo and Nordisk were years behind, and hence were looking for other parameters of competition. After some years of positive experiences with medical devices, the two companies merged in 1989 and organized the device activities in a separate division, in parallel to the drug divisions. The ‘honeymoon’ after the merger was a very optimistic and entrepreneurial period, and devices (especially disease monitoring devices) were envisioned to become a substantial business of its own. However, the corporate business portfolio after the merger was far too broad – a focusing process started, also inspired by the new management dogma of ‘core competencies’ (Prahalad & Hamel, 1990). In 1992, a crisis hit the company badly, and this amplified the ongoing process of divesting ‘non-core’ business areas. The device activities were confined to only comprising insulin pens – insulin pumps and monitoring devices were terminated. In 1995, the device area was moved to a Production subunit. Within the limited scope of insulin pens, there was here a blooming activity of incremental product innovation until the next strategy shift in 2001; now devices were again envisioned to create substantial new business, including glucose monitoring and *‘everything the patient needed to control his/her disease’*. As a new organizational frame, the device innovation activities were separated from device production and got status as an independent R&D unit within corporate R&D, having the same status as the drug R&D units. This new phase experienced a setback already in 2002, due to a new crisis which made the corporate top management team far more cautious and conservative. Thus, the glucose monitoring projects were closed down in 2004. The strategy, however, was not officially altered until 2005, where the device innovation activities were integrated into a drug research unit. The strategy now was ‘back to basics’, i.e. insulin pens. In this period, the device innovation was modest, both quantitatively and qualitatively. By yearend 2008, the device innovation activities were reorganized again.

All in all, there have been two waves of device-based innovation strategy, where devices were foreseen to create a business of its own – 1988-92 and 2001-05 – the rest of the period 1980-2008, devices have been perceived as complementary assets for innovation, which should sustain the drug-based business strategy. See an overview of the phases in table IV-1.

	Early attempts to device innovation (1980-1987)	The period around the merger (1988-1992)	The quality crisis (1992-1994)	Harvesting (1995-2001)	The vision of closed loop (2001-2005)	Integration into the drug research area (2005-2008)
General characteristics	<i>Exploration and learning:</i> Search and diversity; gradually organizing and institutionalizing.	<i>Entrepreneurialism;</i> organizing for innovation in a new division; strategy building. Extreme optimism.	<i>Shock;</i> focus on core competences. Turn-around of device innovation activities.	<i>Exploitation:</i> Consolidation, focus, alignment. Blooming product innovation, within a restricted area.	<i>Exploration</i> – emphasis on new business creation. Diffusion, diversity. Extreme optimism.	<i>Exploitation:</i> Consolidation, focus, integration. Back to basics.
Overall vision or purpose	Supporting new diabetes treatment forms (so-called basal-bolus treatment and pump therapy)	The vision of patient-centered <i>homecare</i> , supported by a <i>medical system</i>	Getting back on safe track	Device activities should <i>support the drug business</i> via market differentiation	The visions of <i>closed loop</i> and <i>system integration</i> ; 'one-stop-shop to diabetes'	The 'value added pharmaceutical product', to <i>secure NN leadership</i> via market differentiation
Autonomous / induced strategy	Mixed picture – mostly autonomous	Autonomous	Induced	Induced	Autonomous	Induced
Top driven change or bottom-up	Top driven	Top driven	Top driven	Top driven	Top driven	Top driven
Role of devices: Core / complementary	Novo: Complementary. Nordisk: Core.	Core	Complementary	Complementary	Core	Complementary
Corporate organizational structure	Multidivisional (M-form)	Multidivisional (M-form)	Multidivisional (M-form)	Functional (U-form)	Functional (U-form)	Functional (U-form)
Organizational setup of device activities	More or less hidden in small departments	Own division	Subunit under the Diabetes Care Division	Subunit under Production (in new corporate, functional organization)	Device R&D separated from device production, as one of 3 functional areas at corporate R&D	Device R&D integrated into the diabetes drug research unit as 3 VP areas
Value proposition for customers / users	Enabling more convenient treatment forms for patients (flexibility)	Enabling homecare of the patient	Convenient injection devices for the patient	Convenient devices for the patient, 'meeting individual needs and lifestyles' (via segmentation)	Better glucose control and convenience for the patient, via (intelligent) closed loop systems	Increased Quality of Life via convenient devices for the patient, combined with drug benefits
Glucose monitoring included in the development portfolio	Yes	Yes	No	No	Yes	No
Envisioned revenue from devices	Novo: No Nordisk Gentofte: Yes	Yes	No	No	Yes	No
Global industry players in order of relative market strength	Eli Lilly. Novo. Nordisk Gentofte. Hoechst.	Eli Lilly. Novo Nordisk (merged in 1989). Hoechst.	Eli Lilly. Novo Nordisk. Hoechst.	Eli Lilly. Novo Nordisk. Hoechst, which from 1999 became Aventis.	Novo Nordisk. Eli Lilly. Aventis, which from 2004 became Sanofi-Aventis.	Novo Nordisk. Eli Lilly. Sanofi-Aventis. Pfizer (inhaled insulin).

Table IV-1. Overview of the historical epochs of the device activities at Novo Nordisk. The following sections of Chapter 4 describe the phases in detail, one by one.

The phases are here defined by structural changes. If the structural change took place in the middle of a year, this year is attached to both periods – for example, DRU was established in the summer of 2005, hence the year 2005 is attached to both the PDS and the DRU period.

Phase 0: Maturing for medical devices (1923-1980)

The corporate DNA

Nordisk Gentofte⁹ was founded by the Nobel Prize winner in physiology, August Krogh. His wife, Marie Krogh, practiced as a doctor and researched in human metabolism. Furthermore, she had diabetes (Type 2) herself, and she consequently had a natural interest in diabetes. In 1922, August and Marie Krogh therefore went to Canada to visit the scientists, who had discovered insulin the year before. Being a Nobel Prize winner in physiology 1921, August Krogh easily persuaded the Canadian scientists to give him a license to manufacture insulin in Denmark. So, if we are looking for the roots of the internal corporate identity (Tripsas, 2009), I think it is fair to identify these as the combined scientific and medical standpoint of the founders (Novo being a break-out from Nordisk). This identity had impact of the framing of the business (Kaplan, 2008) and thus laid the ground for the learning cycles which established and reinforced the dominant logic (Prahalad & Bettis, 1986) of Nordisk as a science-based, pharmaceutical company. The impact of the founders' scientific and medical standpoint on Nordisk's identity can be recognized as late as the 1970's in this quotation from the official corporate history book: *"At the beginning of the 1970's, the situation at Nordisk was critical. The company had almost no exports. The reason for this was that the management, led by Hagedorn, did not want increased marketing of the company's products. What mattered most, the management felt, was research and the treatment of diabetes"*.

Novo had a more engineering oriented starting point: to build up the production, August Krogh had employed his manager from the mechanical workshop at his university laboratory, Harald Pedersen. Harald's brother, Thorvald Pedersen, who was a pharmacist, was also hired in. However, due to collaboration problems, the two brothers left Nordisk and founded Novo in 1925. Harald Pedersen was an engineer, and he designed a special metal syringe for injection of the insulin already in 1925. This Novo Syringe was the first customized insulin device and it was sold until World War 2, where supply problems stopped the production. Thus, if the 'founding fathers' of a company have impact on the internal identity of the company, then Novo from the outset would have a more production and engineering oriented approach to doing business, combined with higher emphasis on broad

⁹ Both Novo Industry and Nordisk Gentofte have changed names several times during their history. For the sake of readability, I discard this information and shall from here on refer to the two companies as respectively Novo and Nordisk.

commercialization: due to Nordisk's strong position in the home market, Novo was from the beginning forced to be more international.

Industry dynamics

Both Novo and Nordisk were active in improving the insulin products. The first problem to be solved was *"that the effect of the existing insulin products was too short – a serious disadvantage because patients had to inject themselves with insulin several times a day. Therefore, Nordisk and Novo turned their attention to developing a longer-acting type of insulin"* (quotation from "Novo Nordisk history"). Thus, Nordisk launched their long-acting insulin in 1936; Novo followed in 1938.

The next big problem was to get rid of the 'impurities' left from the basic animal material, since these substances made all patients form antibodies against insulin, and some patients even became allergic to insulin. After long research, Novo launched highly purified insulin in 1973; Nordisk followed in 1974.

According to an executive informant, the highly purified insulin meant great competitive advantage, which especially Novo used to capture market shares in Europe. The European insulin market had been very fragmented, with 21 European insulin manufacturers in 1972. These rather small companies could not make the technologically difficult leap to highly purified insulin, and hence competition got concentrated on fewer players, with Novo and Nordisk based in Denmark and Hoechst in Germany. Eli Lilly dominated the American markets.

Even though both Nordisk and Novo thus were successful in the competition within the core business, both companies diversified into many other business areas, in accordance with the management trends of their time (e.g. see Ansoff, 1965, on diversification). Nordisk for instance developed growth hormone for treatment of children with growth disturbances in the 1960's and blood plasma products for treatment of hemophilia in the 1970's. Novo, on their side, started up production of penicillin in 1947 and began producing industrial enzymes in the 1960's. The enzyme business grew rapidly and forced Novo to become even more international. In the late 1970's, the enzyme business had become bigger than the insulin business, and the enzyme managers at Novo joked about selling off the insulin business; it didn't grow so much, anyway.

Diagnostic systems

One more example of diversification from Novo deserves to be described, since it implied some learning for the top management team with relevance for device innovation. Around 1976-77 Novo acquired a small Danish company, which had developed a so-called Cerebrograph – an electronic equipment for measuring the blood circulation in the brain. Hereby Novo established 'Novo Diagnostic Systems' as a business area. However, sales never really took off. An executive informant explains: *"This taught me two things: first of all this was a highly specialized field. Secondly, this was an area, where you competed with Siemens, Japanese companies etc., and therefore it was no good that you came with just one product. The other companies competed on modularity: measuring equipment, which 'talked' with each other – so it was systemic solutions being sold...the possibility of getting a*

significant position in the market, as a one-product-company, was small. It was an area where we were not so sharp, and the competition was quite different from insulin: when you develop your diagnostic scanners, the competitors can just take a screwdriver and dismantle it and see how it is made. – [Why did you then acquire this company?] – That was also a wrong decision. But we were looking for opportunities for growth, you know. ...You can say that the reason why we jumped into it was the aspiration for new opportunities – and then an analysis, which was insufficient, due to lack of expertise”.

Concluding on the period 1923-1980

The early development shaped the corporate DNA in the form of internal identity (Tripsas, 2009). From the founders, Nordisk inherited an orientation towards science, pharmaceuticals (insulin) and medical (specialist) treatment of diabetes. Novo seems to have inherited a more pragmatic and commercial identity, compared to the extremely science and research grounded Nordisk. These initial identity traits of course affected the management cognition, when top management set direction for the business; the basic identity will always affect the worldview or core beliefs, on which strategic cognition is based.

Both companies were successful with their insulin business; still, they went through an era of diversification in search of growth opportunities, which led them into many other business areas. Only in one case, a new business area took over from the original insulin business: the enzyme business of Novo in the 1970's and 1980's became bigger than the insulin business and in fact drove the internationalization of the company further.

At Novo, the experiences from Novo Diagnostic Systems shaped the cognition at corporate management level about the importance of deepening the competencies within the selected business areas and about developing a full portfolio of complementary products within each area. This learning seems very important for the later entrance to medical devices as part of the product offering within diabetes, since it defined a rationale for complementing the basic insulin offering with medical device products.

Phase 1: Early attempts within device innovation (1980-1988)

Insulin industry

The introduction of highly purified insulin in the beginning of the 1970's meant a strong competitive advantage for the four companies, who mastered this complex process technology: Eli Lilly, Novo, Nordisk and Hoechst (mentioned in order of market size). However, the insulin molecules still were animal, derived from the pancreas of cows and pigs. Therefore, research was made in order to find methods to produce an insulin molecule identical to the human. The small biotech company Genentech Inc. was founded 1976 to explore and commercially exploit "*a new scientific field called recombinant DNA technology*¹⁰". The first application was human insulin, achieved via genetic engineering of yeast cells, which would then produce human insulin molecules as result of the fermentation process. They licensed out the technology to Eli Lilly, who thereby were able to market the first recombinant human insulin in 1982, setting back competitors. Hoechst was hit worst, because they were not even able to experiment with the new technology because of German legislation against gene manipulation techniques.

Novo had increased the company's global market shares since the introduction of highly purified animal insulin. However, the recombinant human insulin represented a truly disruptive technology, which could make highly purified animal insulin obsolete. As long as insulin was manufactured based on animal pancreases, the production volume would be limited by the supply of animal material. At the same time, there was increased awareness about Type 2 diabetes and the possibility of applying insulin treatment at earlier stages, in order to avoid late complications of the disease. In combination with the explosion of Type 2 diabetes, this intensified treatment led to an enormous growth in the global demand for insulin in the subsequent decades, with two-digit growth rates. Without the invention of the recombinant technologies, which made the manufacturing process independent of the supply of animal pancreases, it would simply have been impossible to meet this explosion in demand. In other words, both technologically and market wise, the invention of recombinant insulin had crucial impact.

Confronted with the threat from the recombinant technologies, which Novo must have known about at least from 1976 on, Novo made two moves:

¹⁰ <http://www.gene.com/gene/about/corporate/history/timeline.html> accessed 2011-06-05

- Novo developed a new technology, by which animal insulin molecules chemically were altered to become identical with the human insulin molecule; so-called semi synthetic or biosynthetic human insulin. This way, Novo was able to launch what they called 'human insulin' in 1982, the same year as Lilly; thus Novo could claim to be on par with Lilly (however, Novo's manufacturing process was still based on animal material).
- 1982, Novo bought shares in ZymoGenetics Inc. in the USA to get access to similar recombinant technologies as Genentech had provided to Lilly. This collaboration resulted in Novo being able to launch recombinant insulin in 1987 (five years after Lilly). – Novo took full ownership of ZymoGenetics in 1988.

Nordisk took a similar approach as Novo, and developed biosynthetic human insulin, which was introduced 1984, two years after Novo. Nordisk also started research on recombinant technologies but never managed to get recombinant insulin on the market before the merger with Novo in 1989. Hoechst, as already mentioned, was prevented from acting because of German legislation against gene modification technologies.

Novo's and Nordisk's move into medical devices, see below, partly can be explained in the perspective of the competition from Lilly's recombinant insulin.

Corporate management cognition

Back in the late 1970's, Novo was aware of the research in recombinant technology; but they did perhaps not perceive Eli Lilly as a technology leader. An executive informant explains: *"Lilly truly was first with the biogenetic human insulin. But that was the first invention they had made since they introduced insulin in 1921 or 1923. They had built their business on a license from Nordisk to manufacture NPH-insulin [long-acting insulin patented by Nordisk] and a license from Novo to manufacture Lente-insulin [long-acting insulin patented by Novo]. When I came to Novo [in 1972], the sales of Eli Lilly was split in one third in traditional, old fashioned insulin, one third NPH and one third Lente. In other words, two thirds of their sales were based on products licensed in from Danish companies. And in many cases insulin was sold over the counter in USA – I've stood in pharmacies and supermarkets and seen it myself – where Lilly sold it as 'pay for two, get three'. It was a totally different market."*

"Novo never really was under pressure commercially. Lilly of course had a marketing advantage or at least an image advantage by being first, but when you look at where they were present, then it was mainly in the U.S. They tried getting into our overseas markets, and they tried winning tenders in Latin America, but we slowly won market shares from them, also because our sales approach was different; our approach was still highly technical sale, meaning high science content, not trying to sell it cheaper and all that stuff..."

"When we compared Lilly and Novo, then there was a huge difference in financial muscles. So we didn't get anything easy. On the other side, we were sure that it would take Lilly long time to build up the same basic knowledge in diabetes. It's characteristic that when they speeded up in late 1970's and introduced recombinant insulin, it was again via licensing in. They go out and buy technology. They are good at

marketing. [And Novo's strength is research?] – It's two things: It's the research, and it's the close relation to the patients... I don't remember exactly when, but it's a very important side track; during the 70'es, our goal was to be the world's best insulin manufacturer. We changed this to being the world leader in diabetes care. And if your goal is to be the best insulin manufacturer, then it's important that the packaging is fine and the referral note is folded neatly and the product is as it should be. But if you start saying "I want to be the world's best in diabetes care", then suddenly you place yourself on the other side of the table and look at it with the view of the person with diabetes".

Besides the above illustrations of Novo's science-based and patient-oriented identity, one should not forget that the corporate management mindset in the 1980's still was oriented towards growth via diversification. As an example, Novo in 1984 was developing and/or marketing: *pharmaceutical products* for diabetes, infections (e.g. penicillin), cardiovascular diseases, menopause hormonal treatment, etc. – *veterinary products* for a range of infections, vaccines, drugs against worms, feed supplements, hormones etc. – *diagnostic systems* for brain scanning, bone minerals, heart frequency etc. – and *enzymes* for a range of industrial uses. The attitude of diversification is clearly illustrated with this quotation from Novo's annual report for 1986 (my translation and emphasis): "*We continue to invest in products, which improve the life for diabetics. We target enzymes and enzymatic processes for our industrial customers. However, we believe that we can develop products in other areas, which will make life better – every day – for patients, other users, their employees, our own employees and for our environment. With our tradition of research and our ability to product development we shall utilize our experience in production and marketing to further **create business opportunities** within areas such as: Pharmaceutical drugs, especially for treatment of blood diseases, female diseases and nervous diseases – Procedures and **devices for delivery of medicine** – Natural, functional food ingredients – Special food, e.g. for patients – Special chemicals – Environmentally friendly substances for agriculture – Analytical reagents, amongst others for clinical diagnostics and food control.*" As can be seen, medical devices were seen as one of many diversification opportunities.

Entering medical devices

In the 1970's, several inventions within diabetes care had been introduced, such as blood glucose meters (BGM) for home use, which enabled patients to measure their blood glucose much more reliable than by using urine tests. A new treatment regimen for Type 1 diabetes had been presented: the 'basal-bolus' regimen, in which the patients should inject a long-acting insulin once or twice daily to provide a basal insulin level in the body, on top of which so-called 'bolus' injections were added at each meal to adjust for the effect of the extra carbohydrate intake. This resulted in a more stable blood sugar level, but also meant that the patients would have to inject insulin 4-6 times throughout the day instead of once or twice. As an even more advanced and expensive option, insulin pumps had been introduced; these devices continuously infused a steady supply of insulin.

At both Novo and Nordisk, the initiation of the device activities was encouraged by external discussions on diabetes treatment within the community of diabetes experts.

At **Nordisk**, the inspiration came from the ongoing discussion on the possible development of an *artificial pancreas*. The CEO of Nordisk initiated R&D projects for two of the core elements of an artificial pancreas: an insulin pump for the infusion of insulin, plus devices for monitoring the blood glucose level. Nordisk launched its first insulin pump, Nordisk Infuser®, in 1983. It was developed and manufactured externally and was one of the first insulin pumps in the world. To maintain the insulin pump product and to start own development of follow-up products, Nordisk established a Medico-Technical Department in 1984. As result, Nordisk launched a second version of the pump, Nordisk Infuser® Mark II, in 1988, as an improved substitute of the first version. This second version was both developed and manufactured in-house at Nordisk. Nordisk was relatively successful with the insulin pumps, in the sense that market shares grew from zero to above 50% in Europe. The total market, however, remained small – the customer base only counted app. 5,000 users as late as 1992, where Novo Nordisk divested the pump business.

At **Novo**, the competitors' interest for insulin pumps was discussed. An executive informant says: *"We thought a LOT about entering the pump business or not. But Novo people evaluated that it was not something for us. The basic idea of wearing a device, which mimics pancreas, perhaps was good; but the disadvantages socially, personally, hygienic and so forth by wearing a pump weighted against the idea. Also, the first pumps were constructed so that you almost needed to be an engineer to set them; there was no user friendliness. But there was no doubt that the basic idea of delivering small injections of insulin, whenever your body needed it, was right. So we started playing with the idea of making a pen, which could be "the poor man's pump". Simply, let's make something much more accessible, which everybody can use".*

A case study from 1993 (Freeze, 1993) describes it this way:

"All Novo's major competitors, including Nordisk, were developing pumps. Novo's marketing director at the time, Sonnich Fryland, was given the task of deciding whether Novo should do the same. "We determined that our expertise was in insulin, not in electronics. We didn't have the vaguest idea about such devices." Fryland also believed intuitively that patients, when all was said and done, "would not want to wear something on their bodies." Fryland discussed his conclusions with Novo's research director and the director of Hvidøre Hospital [Novo's diabetes hospital at that time] and decided that Novo would not develop a pump. Instead, they would:

- a) continue to develop insulin;*
- b) collaborate with companies that made pumps so they would choose materials appropriate for Novo's insulin; and*
- c) develop other devices for multiple injections."*

The inspiration for the solution came straightforward. An article in the medical journal 'The Lancet' (Paton et al, 1981) described a fountain pen like device, based on a disposable syringe, which made it easier for a patient to inject everywhere. Novo's marketing director found this interesting and conceptualized the idea of an insulin pen with replaceable insulin cartridges. A development project was organized more or less as 'skunk work', hosted by the Packaging department. NovoPen® was then developed partly by external partners, but managed from Novo, and production took place in-

house of Novo. Even if the pen was not an electronic device like the pump, it was still challenging. “*Had we known how difficult it was, we would never have started the project*”, an executive informant says. Not only was the technology, also the market unknown. Another executive says: “*Novo didn’t know how big it was, what they started with the pens*”. Thus, parts of top management viewed the idea merely as a ‘marketing gimmick’, and based on this perception some crucial decisions were taken, some of them having long term impact on the subsequent development of the medical device industry. As examples: 1) no patents were applied for, leaving it open to competitors to copy the idea (being the first such product, the patent options would have been broad and effective) and 2) it was decided to give away most of the pens as free ‘samples’ instead of selling them. This made sense for a marketing gimmick: the pens were meant for creating customer loyalty, with the expectation that the patients hereafter would buy the Novo insulin – very much like the Gillette razor/blade business model (i.e. selling the razors at low prize in order to profit from the blades – here, the insulin would be the profit generator).

After the launch in 1985 it quickly became apparent that the NovoPen® had hit an unmet market need and the product became popular. But according to a production manager, NovoPen® was not technically robust and not suited for mass production (the size of the demand had not been foreseen). Therefore Novo looked for an alternative, which could fulfill the needs for a mass-produced insulin device. The solution was a *prefilled*, disposable insulin pen made of plastic – which meant that insulin and device was one integrated unit, to be disposed when empty. The resulting NovoLet® project belonged to a joint venture company, Diabetes Care Products, which Novo had established together with a Danish plastic manufacturer, Pharmaplast¹¹, in order to develop and manufacture this plastic device. The launch of NovoLet® happened in the next period (1989).

Concluding on the evolution of the early attempts 1980-1988

Nordisk:

At Nordisk, the insulin pumps were seen as a door opener to dialogue with the diabetes specialists, who were perceived as the key customers. Thus, the strategy making was a theory-driven process. From the outset, insulin pumps were seen as enhancers of the existing insulin business – as complementary assets, in other words. In this sense, insulin pumps expanded the *existing* insulin business and hence could be seen as an ‘induced’ strategy. (*See the definition of autonomous and induced strategy in the Definition section of the Introduction*). On the other hand, the insulin pumps opened a new business based on devices via creating a separate revenue stream by selling the

¹¹ Pharmaplast was owned by the huge Danish conglomerate, Maersk.

expensive insulin pumps and the utensils (infuser sets) for these. Therefore, since the insulin pumps created new business and opened new product-markets, the strategy per definition was 'autonomous'.

Novo:

Novo of course had witnessed the same external development, but chose to stay out of insulin pumps. According to their analysis, insulin pumps would never become a mass market, and this argument seems more important to Novo than the potential access to dialogue with the diabetes experts.

Perhaps we here see a footmark of the two companies' slightly different internal identity (Tripsas, 2009): Nordisk with a deeply scientific and treatment oriented identity, setting the diabetes experts as the key customers; Novo being more pragmatic and forced to broad commercialization, because Nordisk from the outset had a dominant position in the home market.

According to an executive informant, Novo's top management had reformulated the overall corporate goal from being world leader in insulin manufacturing to becoming world leader in *diabetes care*.

This shift in identity opened for vertical integration of other elements of the value chain of 'diabetes care' than the drug itself. The shift matured top management cognition for embracing medical devices as part of the *diabetes care* business.

Consequently, Novo's managers welcomed the idea of the 'insulin pen' from the article in The Lancet in 1981 (Paton et al, 1981). The way they established the project in the Packaging department, implying large degree of external development, could call for a characterization as 'skunk work' or an autonomous initiative. On the other hand, the insulin pens were only envisioned to enhance the sales of Novo's insulin – not to create a business of its own. The insulin pens were perceived as complementary assets for innovation, which should support marketing of the insulin. In this sense, Novo's launch of insulin pens could be seen as an induced initiative, which expanded the existing strategy. However, in Novo's annual report for 1984, there's a 2-page article on the coming launch of the NovoPen®, written by the representative from Marketing in the development team, and it concludes (my translation): "*After more than sixty years of treatment with insulin based on vials and syringes, the development of the NovoPen® system seems a breakthrough in the insulin injection technology*". Even though NovoPen® was not foreseen to create revenue streams, one could therefore also regard the insulin pens as the entrance to new product-markets, and hence this entrance could represent an autonomous strategy.

General:

If we focus on the *internal* drivers of change in innovation strategy, it is clear that in both companies, the initiation of medical device activities is theory-driven, inspired by the dialogue within the community of diabetes experts (including article journals). This corresponds to Burgelman's (1991, 2002) description of induced strategy processes, which formulate the vision 'ex-ante', before starting the practical activities. The initiation of the device activities was not based on internal entrepreneurial experiments (as normally for autonomous strategy), but on reasoning or 'theory'. However, if we base the classification on Burgelman's (2002) explicit criterion of either expanding *within* or exploring *outside* the current strategy and its product-market environments, we must

classify the strategic initiatives introducing medical devices as *autonomous* strategy. The classification is not clear, because the initiatives on the two other parameters (see 'Definitions' in the Introduction), being top management driven and based on 'ex-ante' vision, do not represent Burgelman's normal case of autonomous strategy (Burgelman, 1991). If we instead look at another part of Burgelman's theoretical framework, then these early device activities clearly lacked an institutionalized strategy and therefore represent the *emergent* state (Burgelman, 1988). In contrast to Burgelman (1991), the most important driver of change in strategy was probably *external*: The introduction in 1982 of recombinant human insulin, which had the potential to make traditional insulin obsolete (which it also did). It was a 'Strategic Inflection Point' (Burgelman & Grove, 1996) and called for action. Both Novo and Nordisk were several years behind Eli Lilly in this drug race and hence must have been looking for alternative parameters of competition; devices fit perfectly as such instrument of market differentiation. If we apply the model of strategic learning (figure I-1 in the Introduction), the learning cycle starts as theory-driven and, over successful experiments with insulin pumps and pens, leads to reinforced commitment to medical devices as part of the future strategy. See figure IV-4.

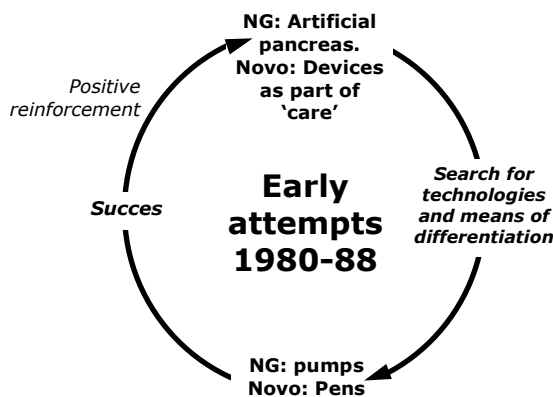


Figure IV-4. The strategic learning cycle of the early attempts (1980-88).

Phase 2: The period around the merger (1988-1992)

Insulin industry

Eli Lilly remained the biggest insulin manufacturer in the years to come, supported by the introduction of recombinant insulin. In the beginning of the 1990's, Lilly had at least 75% of the U.S. market¹² and therefore probably did not feel threatened by Novo's and Nordisk's launch of insulin pen systems. At least, Lilly did not respond to Novo's insulin pen; and in fact, insulin pens had a very slow adoption rate in the U.S. Perhaps Lilly had invested so much identity and pride in the invention of recombinant insulin that they insisted in seeing the drug as the market differentiator and therefore disregarded the new insulin pens. But I'm only guessing here. The fact is, however, that Lilly didn't enter the pen market until 1995. If we disregard Nordisk, who was less successful with their Insubject® pen, the first competitor product to NovoPen® was an insulin device introduced in 1990 by the U.S. company BD (Becton, Dickinson and Company), which was designed to fit the insulin cartridges from Novo. Being a pure device company, BD did not threaten Novo in the core insulin business. An executive informant from Novo said: *"What surprised me most, was how long time we were alone on the market. Throughout the 80s, the two market drivers are respectively the pen systems from Novo and the premixed insulin from Nordisk"*. Obviously, Eli Lilly must have perceived the market drivers differently.

Corporate management cognition

Novo's top management registered some trends within the pharmaceutical industry, as explained by an executive informant: *"There always have been waves, where the large pharma companies became interested in the diabetes market; now they wanted to enter. At this time also biotech firms emerged [like Genentech and Zymogenetics], so we had to calculate with biotechnical insulin manufacturers too. Or the scenario could have been that the two of us [Novo and Nordisk] competed in the European market until we both were completely tired out, and then one of the large companies would come and make a bet on one of us...There was no doubt that Novo had a very strong position with the pens and Nordisk with the premixed insulin – so you didn't need an Einstein to figure out that it would be a good idea to merge the two"*. The merger was announced January 1989. At that time, Novo was 4-6 times bigger than Nordisk, measured on all key parameters. Therefore, it became crucial for top

¹² Source: <http://www.fundinguniverse.com/company-histories/Eli-Lilly-and-Company-Company-History.html> accessed 2011-06-06

management to avoid the feeling of Novo taking over Nordisk. Consequently, each functional area was analyzed one by one and compared between the two, and the most competent unit would continue. This way, the reorganization after the merger was completed around September 1989 and resulted in appointment of more managers with a background from Nordisk compared to Novo. This signal was perceived as crucial for building a common corporate identity. Similarly, both companies' CEO's continued jointly – however, the CEO of Nordisk had cancer and died 1990.

The merger resulted in managerial optimism – as explained by an executive informant: *“By the merger, we suddenly get in new product areas, the palette is much larger, and everybody is excited – now we can join in with the large companies and so on...”*

Medical device level

In Nordisk, top management had followed a vision of making medical devices the *‘third business leg*, besides two existing pharmaceutical divisions, Diabetes and Biopharmaceuticals (the latter taking care of other diseases than diabetes). Consequently, Medical Systems Division (MSD) was established in 1988. The overall vision was patient-centered homecare, supported by a medical system, comprising the drug, the delivery system and the monitoring system. See figure IV-5.

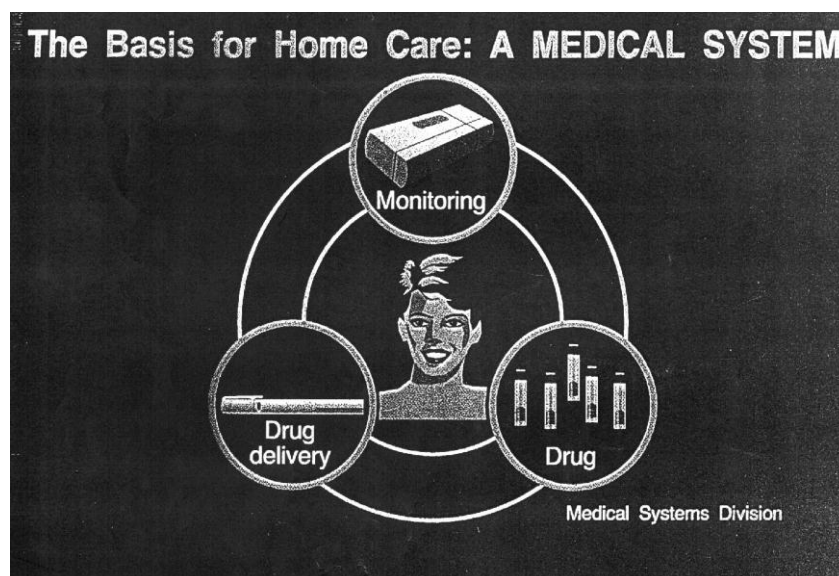


Figure IV-5. The Nordisk vision of a medical system, from around 1988. “Monitoring” in diabetes refers to glucose monitoring devices. “Drug delivery” refers to injection and infusion systems: insulin pens and pumps.

As a genuine division, MSD comprised the usual business functions: Marketing, R&D, Production, Quality, Regulatory, Logistics etc. The revenue stream for the business unit was envisioned to come from the sales of insulin pumps as well as utensils/accessories for the pumps (infuser sets etc.), to be supplemented later with revenue from selling monitoring devices and utensils for these. According to an informant, the monitoring devices were seen as *the* future revenue generator for MSD – injection devices were seen as less important (remember that the insulin pens were usually given away as free ‘samples’ and would therefore not create revenue by themselves).

The CEO of Nordisk, assisted by another member of the executive team, played a major role in the establishment of MSD. The activities grew rapidly, and by the merger in 1989, MSD employed 119 persons. *“It was a dynamic period, something happened all the time – it was full steam ahead all the way through”,* as one informant puts it.

At the merger, Nordisk was recognized by Novo as having the strongest organization for medical devices. Consequently, MSD was continued as the organizational frame of the joined device activities with the status as one of five divisions in the Health Care Group of the merged company (see organization charts from before and after the merger in respectively figure IV-6a and IV-6b). MSD continued to cover the usual business unit functions.

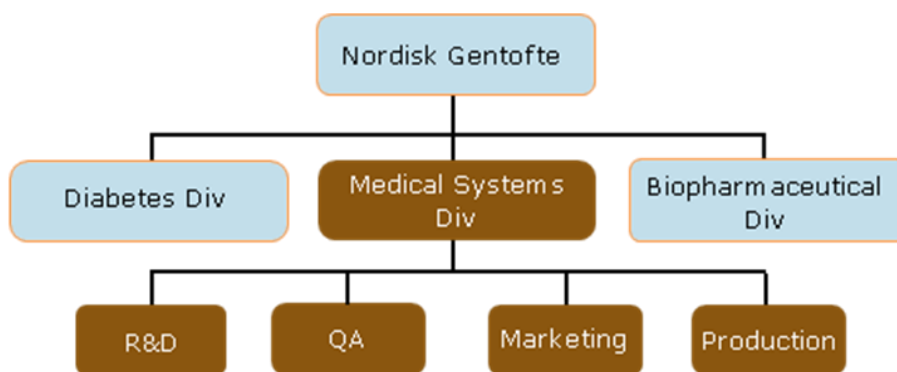


Figure IV-6a. The MSD organization before the merger in 1989. Biopharm = non-diabetes related.

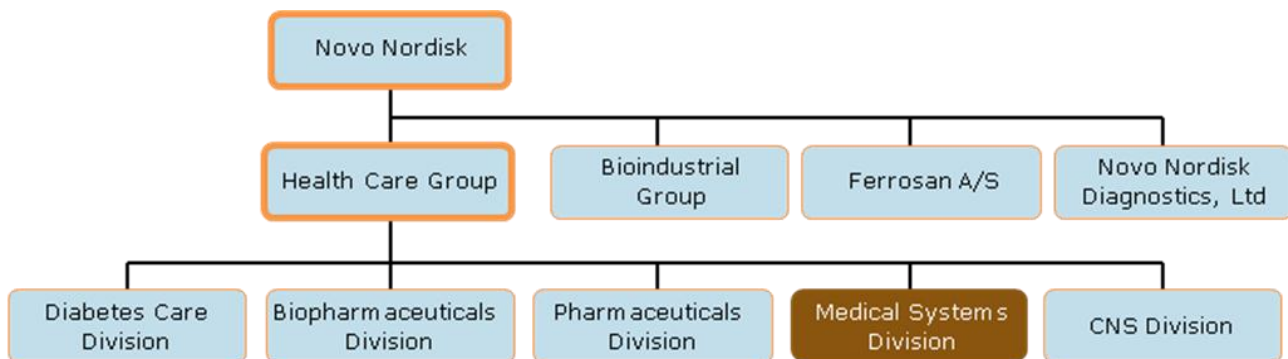


Figure IV-6b. The Novo Nordisk organization after the merger in 1989, with MSD as a division of Health Care Group.

The time after the merger has been described by informants in the device area as very optimistic and entrepreneurial, opening for a lot of innovation projects. Furthermore, the innovation projects established before the merger were continued. The most significant of these projects was Novo's development of the prefilled insulin pen, called NovoLet®, which was launched the same year as the merger (1989). NovoLet® changed the business model: the drug and the device until then had been separate parts, of which only the drug generated revenue for Novo Nordisk. With the new NovoLet®, the device could neither be sold nor sampled (given away for free) apart from the insulin – instead, the drug-device system was sold together at a higher price per insulin unit, compared to insulin sold

in traditional vials or in cartridges for durable pen systems. The NovoLet® system therefore introduced a third insulin business paradigm, besides insulin sold in traditional vials and insulin sold in cartridges for durable pen systems (or for pumps). Eli Lilly saw this; they followed with their similar prefilled pen system in 1995.

Because of its simplicity¹³ (no filling of insulin or shift of insulin cartridge was needed) the new product category was well suited for the broad segment of Type 2 diabetes patients. Hence, the integrated drug-device systems gained success. A 1997 Financial Times report states: *“Insulin was the largest single product category [in the total diabetes market in Europe], helped by the success of the more expensive disposable pens, prefilled with insulin, which are rapidly becoming the standard form of insulin therapy in most countries”* (Adamczak, 1997, p. 1).

NovoLet® was established as a joint venture between Novo and a Danish plastic manufacturer, Pharmaplast. The plastic components were produced by Pharmaplast, and the first part of the assembly process was carried out by the joint venture company, Diabetes Care Products, at Pharmaplast's site. Thereafter, the products were handed over to Novo, who took care of the final assembly of the drug container (the insulin cartridge).

Novo Nordisk then took the strategic move to acquire the joint venture company, Diabetes Care Products, from the partner Pharmaplast. The decision was driven by management recognition of the future importance of this integrated product. As a key informant states: *“Marketing saw it as pure packaging. But if you look at it, then we actually make more money on the plastic than on the insulin. Damn it, if we sold all our insulin in vials, we would have no business. What makes the difference? - That we fill it in cartridges and put them into devices. That's our business. That's why I've fought for making devices part of Novo Nordisk's core business; both in development and production wise”*. Following this logic, Diabetes Care Products was acquired in 1990 after initiative from the MSD top. The manufacturing of prefilled pen systems was integrated into MSD, in parallel to the existing manufacturing of durable pen systems.

Since both Novo and Nordisk had their durable insulin pen systems, it was natural to initiate a common development project for a Novo Nordisk insulin pen. The result was NovoPen® 3, launched in 1992. The brand name of NovoPen® was kept, because it had the widest market acceptance, almost as a generic name for the product category. Technically, NovoPen® 3 was a compromise between principles of the pen systems from both companies. After solving some initial technical problems, NovoPen® 3 became robust and gained market acceptance as the most sold durable

¹³ “NovoLet” is Danish for NovoEasy

insulin pen for more than 15 years. In 2010, it was still sold; but it was being phased out in favor of NovoPen® 4 country by country.

Concluding on the evolution of innovation strategy 1988-1992

Although driven by top management, the establishment of medical devices with Medicals Systems Division can be interpreted as an autonomous strategic initiative for two reasons:

1. The idea implied a complementary business model (revenue stream from devices instead as only from the two drug areas). Hence, devices were internally labeled '*the third business leg*'.
2. The vision of homecare opened for entering new product-markets, such as glucose monitoring products, which represented a distinct market served by a separate industry.

The aim of MSD was to make a revenue stream of its own based on medical devices, also by selling devices to other companies; devices were to become the *core asset* of this new business unit.

Thereby, the device innovation strategy differed from the established strategy. On the other hand, the medical device business was perceived *one* 'business leg' in a diversified corporation; medical devices were not envisioned to substitute the drug business. The device organization should continue also to *support* the two pharmaceutical drug divisions with insulin pens etc. for their drugs; so from the drug divisions' point of view, MSD was seen as a supplier of *complementary* assets for their drug business.

Consequently, the move into medical devices could be seen as an induced strategic initiative, extending the current drug strategy. However, following the explicit definition by Burgelman (2002), the MSD initiative explored *new* product-market environments, for example insulin pumps and glucose monitoring products, and in conclusion must be defined as an *autonomous* strategic initiative.

If we apply the model of strategic learning (figure I-1), then the entrepreneurial management approach within MSD surely led to trial-and-error learning. A typical example is the learning from the collaboration with Pharmaplast in the joint venture company Diabetes Care Products, which ended with Novo Nordisk taking over the joint venture. However, the entrepreneurial experiments did not *alter* the vision of patient-centered homecare; only substantiated it. The overall strategic direction was envisioned by Nordisk' top management team from the outset in 1988 (or probably already in 1987). Consequently, the innovation strategy must be characterized as *theory-driven* rather than experience-driven. The strategic learning cycle of MSD is modeled in figure IV-7. The vision of homecare led to the exploration of medical devices as a new business, with diverse product innovation experiments. The results were mixed: the pump business was successful, but the monitoring projects never succeeded (only one product was launched; and had to be recalled, due to malfunction). Only in one case, medical devices were sold to another company.

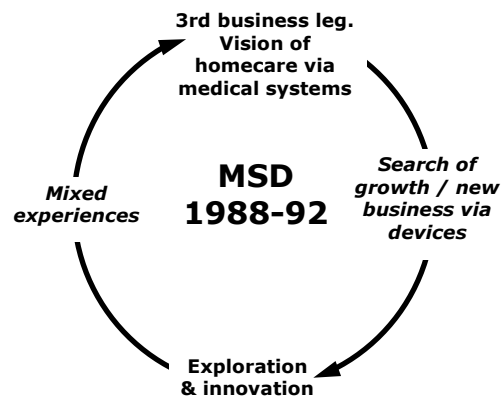


Figure IV-7. The strategic learning cycle of MSD, 1988-92.

Phase 3: The quality crisis (1992-1994)

Insulin industry

After the introduction of recombinant human insulin, the next step was the invention of so-called *insulin analogues*. These are insulin molecules, based on the human insulin molecule, but artificially modified for achieving special effects, such as very rapid metabolic effect or a very long lasting effect. Eli Lilly was engaged in research on insulin analogues, and also Novo Nordisk had done some research, but had given it up, due to potential cancer risks from these drugs.

The growing Type 2 diabetes market continuously attracted attention within the insulin industry, since it became more common to prescribe insulin to Type 2 patients. Novo Nordisk' response, amongst others, was to invest in and push the market towards insulin sold in cartridges for devices or in prefilled devices, and to position these product categories as more user friendly (compared to traditional vial and syringe) and therefore well suited for the broader segment of Type 2 patients. The use of insulin for treatment of Type 2 diabetes was enhanced by the publication of the first of the so-called *major outcome studies*, namely the public research program 'Diabetes Control and Complications Trial' (DCCT), which was a large study on treatment of diabetes patients in the U.S., which concluded that intensified treatment with insulin provided better treatment outcomes.

Corporate level – cognition and crisis

Top management seems to have been inspired by the new management dogma about focus on core competencies (Prahalad & Hamel, 1990), facilitated by dialogue with external consultants. An executive informant explains: *"After the merger, the company suddenly gets bigger, we get more competencies and business areas, and more resources – and the subsequent business strategy is very broad, also broader than the resources and competencies could cover. I guess that's why the progress was not as immediate as hoped for... a very broad portfolio, much bigger than our resources and management competencies could cope with"*.

The focusing of the business began already in 1991 when Novo Nordisk divested the veterinary business, and continued thereafter. Let me quote the annual report for 1991 (my emphasis): *"In accordance with our strategy of focusing our efforts on our main business areas, we divested Novo Nordisk Diagnostics Ltd, UK."* In the following years, numerous business areas were closed down or sold.

These focusing efforts were amplified by the fact that Novo Nordisk ran into problems at both internal and external frontiers. Internally, top management realized that the company was lagging behind the competitors on the drug side; the pipeline of new diabetes product was too weak. A newly appointed management team of the Diabetes Care Division therefore initiated two projects for developing insulin analogues – first a project for fast acting insulin, and later the same year (1993) also a project for long-acting insulin. *"Now we also had long-acting insulin on the way, and after many years it began to look a bit brighter. But we were behind – we had simply nothing [in the pipeline*

before]", as stated by an executive informant, who added: *"We were still frontrunners on insulin pens. We had the NovoLet®, which had full steam ahead, and we were surfing on the NovoPen® wave, and even though NovoPen® 2 never became a success, we still had total device leadership at that time"*. Externally, however, other problems occurred. In 1993, the U.S. Food and Drug Administration (FDA) criticized the insulin manufacturing at Novo Nordisk; according to FDA, the manufacturing did not live up to the U.S. standards of *Good Manufacturing Practice* (GMP) with regards to the sterilization process. The sterilization of the insulin, when filled into vials or cartridges, is one of the core steps in the manufacturing process of insulin. The critique from FDA were received with skepticism from many internal experts; they perceived Novo Nordisk as the world's leading insulin company, so of course they knew better than FDA how to manufacture insulin – as an executive informant described this skepticism. The perception of FDA's requirements as not being valid might have deepened the conflict or postponed a proper reaction. Therefore, the conflict with FDA escalated and resulted in Novo Nordisk losing a large part of its insulin sales in the USA throughout 1994, leaving the market open to Eli Lilly. As a culmination, the head of the Health Care Group at Novo Nordisk was forced to leave his position in 1994. In the end, Novo Nordisk had to comply with the requirements from FDA. The crisis meant an internal shock in the organization, since it hit the core of the core of Novo Nordisk's business and historical identity. As an executive informant says: *"It shook the very foundations of the company"*. The crisis is internally referred to as 'the GMP crisis' and is still a sensitive issue; even if it implied a steep learning curve for the organization by starting a long-lasting program for assuring quality throughout the manufacturing process. In the annual report for 1993, a new corporate vision is announced, listing 7 topics, one of them being Quality; *"The name Novo Nordisk must be synonymous with quality"*. The crisis is here touched upon indirectly: *"In the last few years the US authorities, in particular, have set far more stringent requirements concerning documentation of the many processes in the development and production of pharmaceuticals. As a result, we have greatly intensified our efforts in the quality assurance field. During the year the number of employees working on quality assurance tasks **more than doubled**"* (my emphasis). The annual report for 1994 is closer to admitting the severity of the crisis. The *Directors' report* begins with the words *"In many ways, 1994 was a difficult year for Novo Nordisk"* and few lines later goes on: *"a year when the company incurred substantial extra costs in connection with significantly increased quality assurance and documentation activities"* and *"...the delivery problems that arose mainly in the wake of the company's effort to fulfill the increasingly stringent quality and documentation requirements of the authorities. The net effect for Novo Nordisk of these delivery problems was a loss of global market share in 1994 of approximately 2 percentage points. While Novo Nordisk lost insulin market share in the US and Southern Europe, it consolidated its position in several other countries...By the end of the year, the [production] plants **had resumed normal business**"* (my emphasis).

The crisis amplified the movement for focusing the business on fewer areas. The official book of Novo Nordisk's history ("Novo Nordisk history", 2011) mentions a new business strategy: *"In 1994, Novo Nordisk implemented a new business strategy to ensure progress in a rapidly changing and ever more competitive world. Focus was on the two core business areas, Health Care and Enzyme Business, while*

other areas such as Ferrosan (dietary supplements and other over-the-counter products) and Plant Protection (biological plant protection) were divested.” In the annual report for 1994 is stated: “1994 was also the year when Novo Nordisk changed its business strategy. The sharpened business focus provides the basis for and belief in renewed profitable growth...The essence of the new strategy is increased focus on the company’s core businesses”. According to the annual report, the new strategy was launched “towards the end of 1994”. The new strategy also affected the corporate structure. The annual report for 1994 says: “Implementation of the new strategy required a substantial adaptation of the organisational structure. The former divisionalisation of business areas was replaced by a functionalized and process-oriented structure, and a number of staff functions were gathered at a corporate level.” According to my informants, this restructuring was implemented in 1995, implying a ‘reverse Chandlerian’ restructuring from a multidivisional to a functional organizational structure. Such U-form structure (Chandler, 1992) was a logical consequence of the corporate move from diversification towards focus on core business.

An executive informant, who was part of the creation of the new strategy in 1994, explains it this way: “The strategy process was amongst others a result of the quality crisis. Corporate management was not sure that we had the right strategic focus. I was asked, together with [name] and some consultants to analyze the long term pharmaceutical strategy...we should lay down the future track in order to become competitive. And today you can see how we since then [1994] have narrowed down and narrowed down, so that we are now [2011] a very diabetes focused company. We regard our core competencies as understanding proteins for treatment of chronic diseases, especially diabetes; the formulation and administration of these, the modification of these – and then to understand and relate to a group of people, who has a chronic disease, and the responsibility which follows...So it was just too broad [before 1994] – we didn’t have the structures and procedures and evaluation models and management competencies to secure the success of all this. Hence there has been a narrowing, a professionalization process, making it more effective... there has been a sharpening of the core competencies both at Novo Nordisk and Novozymes, as I see it – also due to changes in the environment. Other companies began being able to make similar products, which could compete with ours, and we lost market shares”. The same informant concludes on the learning from the quality crisis: “From the quality crisis we learned how important a well developed and robust quality system is, with training and documentation, - that might even become a competitive advantage, which I actually think it has become today”.

Medical device level

When the focusing process started in 1992, *medical devices* were disregarded as ‘core business’. It was suggested to give Medical Systems Division status as supplier in the form of an independent company, but this proposal met resistance by the MSD management: “We did not want to be treated like suppliers. At that time, insulin was a generic product. The whole value creation was in the innovation of the pen systems – so we said that we would rather give up our independence and become a part of the diabetes division and have influence there, than just being placed as a supplier”. The

company was (since the merger in 1989) organized in two main business units, Health Care Group (pharmaceuticals) and Bioindustrial Group (the enzyme business). Each of the business units was split into several divisions, as result of the fusion of multidivisional setups in both companies. Eventually, the device area became a subunit to the Diabetes Care Division in the reorganized Novo Nordisk in 1992 under the name Medical Systems. See figure IV-8 for an organizational chart.

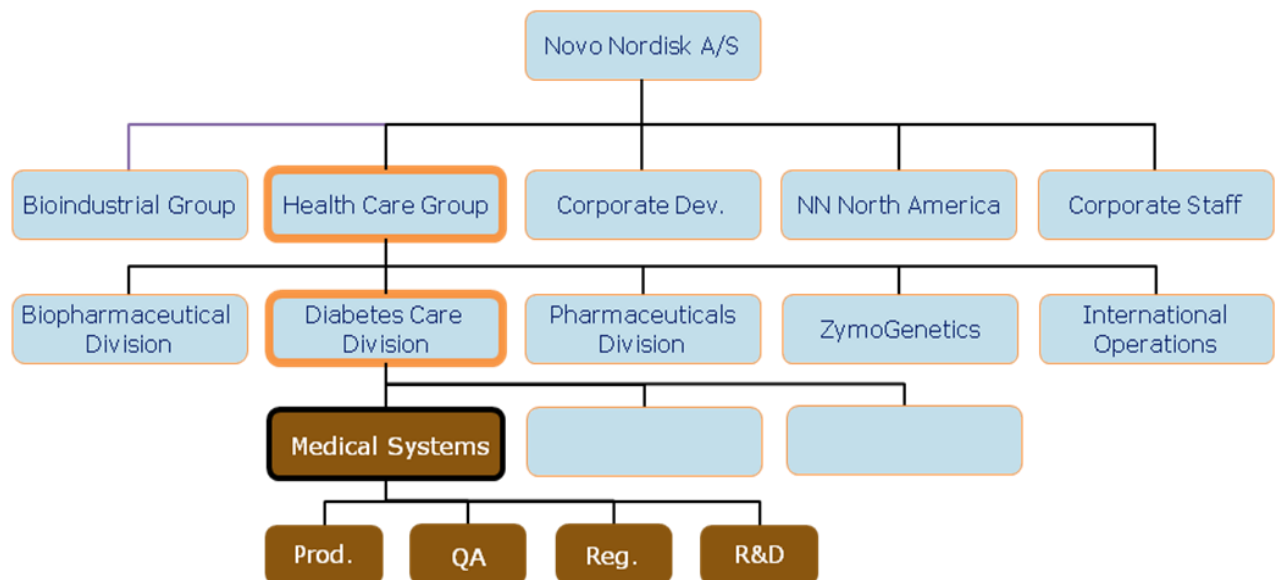


Figure IV-8. Medical Systems placed under the Diabetes Care Division in 1992. As can be seen, MS kept the usual functions of a division; except for a marketing function. The structure is 'M-form' = multidivisional (Chandler, 1992).

As response to the corporate quality crisis, MS was told from top management to discontinue both the insulin pumps and the monitoring projects; focus should be on insulin pens. An informant comments: *"The idea of being able to cover all aspects of treating diabetes was shot down. Medical Systems was only allowed to develop and produce pens. Hereby the strategy of Medical Systems Division was winged."* The informant here refers to the 'vision of homecare' as shown in figure IV-5. The pump projects were discontinued, and the existing customer base was handed over to a competitor. For several reasons: top management did not believe that insulin pumps would ever become a big market (at the end there were about 5,000 users of the Nordisk Infuser®), and at the same time these products required a costly service-oriented organizational set-up, including call centers to assist patients when using the complex insulin pumps. *"It's a different type of business than just pouring drugs out to the pharmacies"*, as stated by an informant. Furthermore, the customer complaint rates from the complex pumps were high compared to pharmaceutical drugs. Selling drugs via pharmacies only rarely results in customer complaints, so Novo Nordisk was not used to handling a relative high amount of direct complaints from the users. *"Novo Nordisk was not geared to this, it's was alien for the organization"*.

The development projects for disease monitoring devices were then stalled, partly due to technical problems, but also because of lack of business synergy, despite the obvious link in usage between

glucose monitoring and insulin injection. The pharmaceutical insulin business was primarily targeting the medical specialists, who prescribed the medicine to the users – it was a business-to-business market. Glucose meters were sold at pharmacies or even supermarkets; it was a consumer-driven business, which had no attention from the side of the specialists; they left it to the nurses to advise the patients. Therefore, the synergy with regards to customer base and distribution channels was absent. *“Strategically, it’s very difficult to make monitoring fit in; because it’s a totally different sales channel...so it’s because of lack of sales synergy that it doesn’t make sense”*, as an informant states. In other words: even though the device activities since 1992 were integrated in the Diabetes Care Division, the value chains (Porter, 1991) of the disease monitoring business and the drug business had little in common. As a consequence, the latitude of the medical device innovation was narrowed down when Medical Systems was restructured again during the corporate reorganization from divisions to a functional (U-form) structure, implemented in 1995. Still, even in these difficult years, there was room for radical innovation. March 1993, device managers created a vision about *“developing and marketing a third generation insulin device”* – the first two generations being the NovoPen® product line (including NovoPen 2 and 3) and the prefilled product line (NovoLet®). In October 1993, a new development project was formally established, which in 1999 resulted in the world’s first electronic insulin device (see the PDS epoch, 2001-2005). *“The project was started as a defensive move; we were behind the competitors in the drugs”*, an informant states, referring to the weak drug pipeline, see above.

Concluding on the evolution of innovation strategy during the crisis 1992-1994

Several factors led to the retreat from the autonomous MSD strategy. External events were important drivers, accompanied by top management interpretation:

- Apparently, top management realized that the business portfolio of the merged Novo Nordisk in 1989 was far too broad, held up against the management resources and organizational capabilities.
- Further, the shift in general management paradigm from ‘diversification’ (e.g. Ansoff, 1965) to focus on ‘core competencies’ (Prahalad & Hamel, 1990) probably has strengthened the wish to focus the business, brought to top management’s attention by external consultants.
- Top management also perceived the drug pipeline of Novo Nordisk as being behind competitors – especially with regards to insulin analogues.
- The GMP crisis amplified the corporate focusing process, and drove the change in device innovation strategy towards focusing only on insulin pens.

Thus, the focusing of the device innovation strategy was a *theory-driven* process, in which several external events were interpreted via top management cognition. The process aligned the corporation around the classic elements of the established business strategy – so it’s a clear example of an *induced* process. The most salient drivers were the above mentioned external events. Thus, the ‘internal ecology’ seems less relevant for explaining the strategic change than the ‘external ecology’.

Where the MSD period opened for seeing medical devices as a core asset for innovation, the withdrawal from the MSD strategy implied an explicit view of medical devices as complementary assets, which should merely support the drugs.

Interestingly, even within this period of crisis and conversion to the traditional dominant logic (Prahalad & Bettis, 1986), there is one clear example of an autonomous initiative in the ‘classic Burgelman’ (1991) understanding: In 1993, the local device management initiated the so-called ‘*third generation insulin device*’, which led to the world’s first electronic insulin device, Innovo®. The project aimed for an insulin injection device, and consequently was within the corporate induced strategy in that sense; but the mere perception of creating a ‘third generation’ product category is quite explorative in itself – and the integration of electronics in a medical device required a range of competencies, which did not exist in the company at the time. Furthermore, the project was initiated and hosted by the local device organization. Therefore, I regard this particular project as an autonomous initiative in the ‘classic Burgelman’ meaning.

However, when analyzing the *portfolio* of projects in this period, it is marked by the crisis, both in terms of few initiated projects and because most of the projects had a purely incremental nature (see the section in the present chapter analyzing the project portfolio).

The strategic learning cycle for this period is shown in figure IV-9. The main ‘theory’ was the concept of ‘core competencies’, in search of which the insulin pumps and disease monitoring projects were terminated, because they were seen as ‘non-core’. The successful definition of core competencies reinforced the strategy.

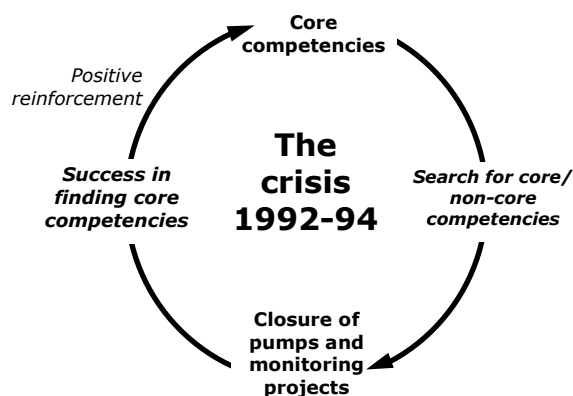


Figure IV-9. The strategic learning cycle of the crisis, 1992-94.

Phase 4: Harvesting (1995-2001)

Insulin industry

The pandemic of Type 2 diabetes became salient within this period, which amplified the gradual reorientation of the industry towards the Type 2 diabetes market segment. Type 2 patients are typically middle age to elderly and settled when diagnosed and often not motivated for radical changes of their lifestyle. Consequently, this market segment calls for simple and less intrusive solutions. In 1995, Metformin tablets were introduced by Bristol-Myers Squibb, which quickly became a de facto standard for treatment of Type 2 diabetes in early stages. Novo Nordisk developed a similar tablet, NovoNorm® (Prandin® in the U.S.), which was launched in 1998. Also, research on insulin for inhalation was started (amongst others by Nektar Therapeutics in California, who began testing this in 1999), based on a vision that treatment without injections would enhance the acceptance of insulin treatment for patients with Type 2 diabetes. This research made Novo Nordisk license in a development project for inhaled insulin in 1998 from the U.S. company Aerodigm Corporation.

In 1998, the main results of another public research program were published; showing clear evidence that intensified treatment of Type 2 diabetes resulted in better immediate glucose control and reduced late complications. It was the *United Kingdom Prospective Diabetes Study* (UKPDS); the largest clinical research study in diabetes ever conducted at the time. The study was carried out in the UK in 1977-1997. This study had substantial impact on the attitude of diabetes specialists, leading to more widespread use of insulin treatment for Type 2 diabetes.

Human insulin, introduced 1982 (see previous sections), now dominated the market. *“Use of human-type insulin has rapidly become the universal standard: animal insulin has virtually disappeared in several countries, and is little used in the rest.”* (Adamczak, 1997, p. 2, about the European market).

Also the user-friendly premixed human insulin (combining fast-acting and long-acting insulin in one), continued to grow, driven by the Type 2 pandemic. In 1996, premixed insulin accounted for 57% of the total insulin sales in Europe (Adamczak, 1997).

The research in the so-called insulin analogues was successful. However, Novo Nordisk was behind the competitors in the ‘drug race’, due to a weak drug pipeline in the beginning of the 90’s (see previous section). The first of the new drug products was a fast-acting insulin analogue, Humalog®, introduced by Eli Lilly in 1996 (Novo Nordisk launched a similar drug, NovoRapid®, in 1999), followed by the long-acting Lantus® introduced by French Aventis in 2000, who in 1999 had taken over the insulin activities from Hoechst (Novo Nordisk launched a similar drug, Levemir®, in 2004). Novo Nordisk invested in and pushed the market towards prefilled devices, also as a response to the Type 2 pandemic, since prefilled pen systems were perceived as the most simple to use. Eli Lilly entered the prefilled market with their Humalog® Pen in 1998. The pen had a dosing mechanism allowing a dose accuracy of 1 insulin unit – NovoLet® could only be set with increments of 2 insulin

units. Hence, Novo Nordisk started development of a new prefilled device, FlexPen®, launched in 2001, which again assured Novo Nordisk device leadership as perceived by the market.

Corporate management cognition

The crisis 1992-94 seems to have provided substantial learning for Novo Nordisk's corporate management team, but also other factors influenced the strategy towards focusing the business. An executive informant says: *"But in the 90'es we became aware of the mega-mergers within the pharma industry. For me and my colleagues it was important not to be taken over by somebody else; we wanted to continue as an independent company, and we had some discussions about how to stay as such. Our research colleague [name] expressed, what became our belief; namely that we should not end up as 'mini-big' pharma, trying to have a foot in all camps, being small everywhere... with our resources, we could perhaps put one horse in the race, but the big players would have 10 horses; and even quantity not always counts in research and development, then you still have higher chances with 10 horses than with one...so we decided that we wanted to compete with the big companies in areas, where they could not keep up with us. We were convinced that the knowledge we had within enzymes and insulin – on market and development, and the technologies, we possessed – even though others saw it as narrow, we perceived it as deep – lots of things could be harvested."* – Such was the reasoning behind the focusing of the business, which resulted in divestiture of units such as Ferrosan A/S, Plant Protein and Plasma Product Unit in 1995-96. Furthermore, it was decided in 1998 *"to work towards a separation of Health Care and Enzyme Business into separate legal entities"* (1998 annual report). This demerger was finalized in 2000 and marked the culmination of the efforts to focus the business. The Health Care business was continued as Novo Nordisk A/S; the enzyme business was established in a new company, Novozymes A/S.

This development deserves to be illustrated by the following long quotation from an executive informant – because he touches some fundamental aspects of complementarities and business synergy: *"There has been a fantastic synergy between the enzymes and the pharma part. When I worked in the enzyme business, it was bigger than the pharma part, and it was the enzyme business which first expanded globally. In the economic cycles, the need for technical enzymes, such as for food production, textiles and detergents, occurs before the ability to pay for healthcare. That's why it was the enzyme business, which was the first to establish own organization in the USA, in Brazil, in Japan, in China – and then, via institutionalized understanding of the foreign markets through the enzyme colleagues around the globe, you had a first mover advantage, when time was ripe for establishing pharma units. We already exported our pharmaceutical products to these markets, but we did not have our own organizations, and we did not have detailed political knowledge. When I worked in USA for the enzyme business, there were five pharma colleagues, or something like that – it was in the early 80'es – there were only 5 pharma colleagues in USA! – When I negotiated a license to manufacture enzymes in China, we got the license for pharma production as a spinoff – so when the company was split in two, we suddenly had an independent pharma company in China with independent business license to produce in China. But Novozymes had the biggest factory, likewise in Japan. It was also Novozymes, who took*

care of the fermentation process when producing insulin, because they had the fermentation knowledge. Then, because of Good Manufacturing Practices – the separation of food from pharmaceuticals and all this, combined with the completion of the globalization, then the synergies between the two businesses became less and less tangible. This, amplified by the rapid growth in the pharma part, led to the decision about splitting up the company. Indeed an exciting development”.

Besides the focusing of the business, another initiative from top management – also partly ignited by the GMP crisis – was to focus on **performance**, i.e. efficiency, profitability etc. Some of the background was rooted in the historical identity: Already in 1924, Nordisk was legally established as an independent institution, which had in its purpose statement that any profits should be used for scientific and humanitarian purposes. Also the merged Novo Nordisk was organized with a foundation as the owner of all A shares: *“the Novo Nordisk Foundation – an independent institution whose objectives were to create a solid basis for the operation of Novo Nordisk and to support scientific, humanitarian and social causes”*, as it is written in the official corporate history. The starting point in science, combined with such overall purposes, seem to have influenced the internal identity (Tripsas, 2009) towards altruistic values. According to one executive informant, the research environment at Novo Nordisk in the beginning of the 1990’s was university like, holding an academic arrogance towards the need of marketing new commercial products. Scientific research and medical treatment of diabetes was highly valued in this culture; ‘commercialization’, ‘sales’ and ‘profit’ were seen as less valuable (or even negative) concepts. Another executive informant says: *“We had some managerial challenges, because we said that we wanted to stay an independent company. There was an attitude, perhaps I exaggerate, that ‘here is peace and no danger, because we are owned by a foundation’. Where my attitude was: who wants to own a company which doesn’t perform? So if we run a company, we should be as profitable as anybody else...It was tough to get an organization, who perceived itself as the world champion within its area, to live up to what you actually could expect from a world champion, and this meant that we had to become much sharper in our objectives and much sharper in living up to our values, and we initiated a range of activities in order to secure our ability to survive [as independent company]”*. Quality management and lean management were parts of these activities, but also the creation of the so-called triple bottom line, which made the classical altruistic values measurable.

Looking towards the external environment, the diabetes experts these years preferred tablet treatment for Type 2 diabetes – and hoped for the development of inhaled insulin. An executive informant states: *“At this time, mid 90s, all prognoses said that Type 2 treatment would be tablet treatment...No doubt, we have a history of being a Type 1 company. Then, in the 90s, a huge market for Type 2 treatment emerges, and it is seen as primarily oral treatment [tablets] – even though some of our insulin is being used for Type 2 patients. That led us to enter the market for tablet treatment of Type 2”*. Hence, Novo Nordisk launched NovoNorm® in 1998. Furthermore, top management felt a pressure from competition to enter the development of inhaled insulin. As explained by an executive informant: *“I supported inhaled insulin, mostly for defensive reasons...when it showed that Pfizer*

followed the track and then also got it approved – we couldn't risk not to have inhaled insulin, if this suddenly would take over".

Medical device level

After the reorganization in 1995, Medical Systems, including both device R&D and device production, was placed as a subunit to corporate Production. See organizational chart in figure IV-10.

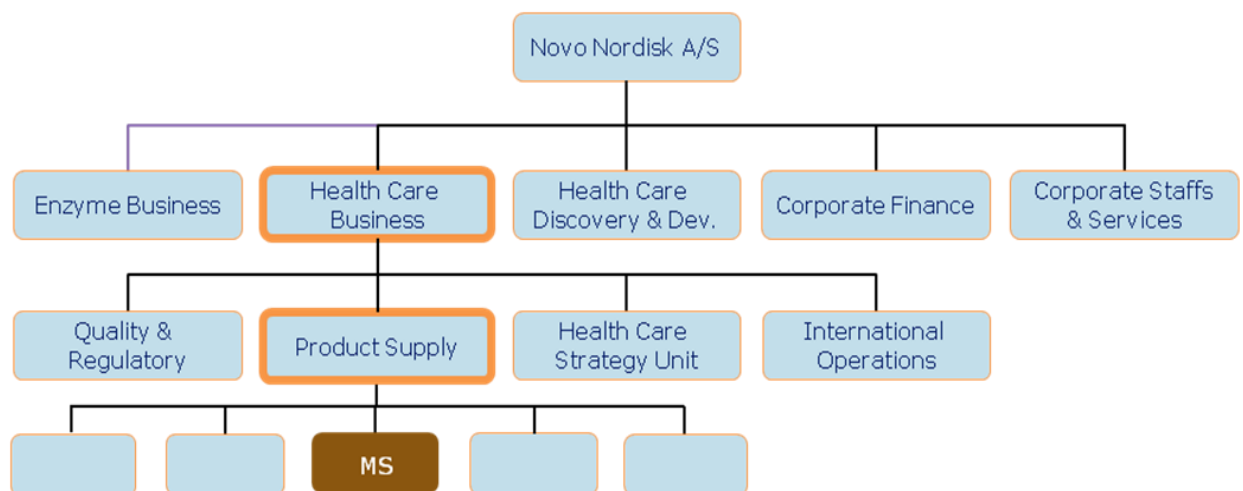


Figure IV-10. Medical Systems placed under Product Supply (i.e. Production) after the restructuring into a functional organizational structure, implemented in 1995.

The strategy for the device area was now to focus solely on *supporting* the pharmaceutical drugs with superior injection devices. In spite of this narrow scope, there is in fact an impressive list of new product launches (most of them representing incremental innovations) from the Medical Systems period, with a broad spectrum of insulin pens and accessories. On top of this, the world's first electronic insulin device with a memory function, Innovo®, was launched 1999. Innovo® had a display, which made it possible for the diabetes patient to see the time since the last insulin injection and how large a dose, which had been taken. This is a highly desired feature, since human memory sometimes plays games with us. Innovo® was a result of the “third generation insulin device” project initiated in 1993 (see previous section), and in the 1999 annual report it is also mentioned as a “*completely new insulin injection system*”.

According to an internal document, the device strategy aimed at fulfilling needs of various customer segments. Hence, the InnoLet® device was developed and launched 2001, targeting elderly people, where the electronic Innovo® was targeting a younger segment; and other devices were customized for children. A specific product launch deserves attention: Novo Nordisk made a partnership with the company LifeScan in U.S., owned by Johnson & Johnson. The partnership aimed at developing an integrated insulin device and glucose meter. The result was InDuo®, which had the Innovo® insulin device as the core, covered by a shell holding a glucose meter unit from LifeScan. Even both parts were electronic, there was no electronic connection between the two units. However, InDuo® was in fact the first product ever launched with physical integration of insulin delivery and glucose

monitoring. Such physical integration was often desired by patients in market research studies. InDuo® was launched in 2001, but flopped for several reasons, primarily marketing issues. A specific reason was the business model: reusable devices as Innovo® were usually 'sampled', i.e. given away for free to create customer loyalty. Innovo®, being an electronic device, was far more expensive than mechanical devices, and this extra cost would have to be held by the local subsidiaries, which would in the first place see this extra cost as a loss of profit.

Forced by competition, Novo Nordisk licensed in a development project from Aradigm Corporation in 1998 on inhaled insulin. This project required massive investments, also in the device system. The development was kept at Aradigm in California, and Medical Systems was not directly involved. According to an informant, Medical Systems was still run much like an independent business unit, despite its displacement under Production. Consequently, there was a pressure from the rest of the organization to force Medical Systems into the same (functional) logic as the rest of the firm; the autonomy of Medical Systems was seen as a problem. Thus, in 1996, the production of disposable pens was separated from Medical Systems. At the next restructuring in 2001, device R&D and device production were fully separated.

Concluding on the evolution of strategy in the harvesting period (1995-2001)

For corporate management it was vital to keep Novo Nordisk as an independent company. In order to secure independence it was perceived necessary to focus on selected areas and build deep competencies within these; *"we will compete with the big boys in areas where they cannot compete with us"* as expressed by an executive at that time. Michael Porter (1980) would have called this a 'focus strategy'.

The efforts to focus the business led to the corporate reorganization into a functional, U-form structure (Chandler, 1992) in 1995, which was better suited for deepening the competencies within a narrow area. When analyzing the internal drivers, the focusing process thus first and foremost is *theory-driven*, based on the reasoning just described; however, the external pressure of competition from large pharma companies drives the process as well; management reasoning interprets the external pressure from competition.

In the period after the corporate restructuring in 1995, the device area was placed as a functional area under Production. This implied relatively little attention from corporate management, and also relatively high degree of freedom, as long as the overall strategy was not challenged – i.e. focus should be on insulin pens. Some informants have mentioned this relative freedom as a positive side effect – and in fact, the product innovation seems to have bloomed, even though it was within a confined area, mostly unfolding incremental innovation projects (see the analysis of the project portfolio in a separate section of Chapter 4). Such an environment could be seen as ideal for autonomous initiatives in the classic Burgelman (1991) sense; but the actual innovation projects *extended* the established strategy – for example, supplementary products were developed such as needle inserters, and the devices were customized for different customer segments. There were no attempts to create new business or independent revenue streams based on devices, or to explore

new product-markets. In other words, with regards to device innovation strategy, the *induced* strategy was continued unchanged from the previous period, and the status of devices as complementary assets compared to the drug was never questioned.

The strategic learning cycle of the harvesting period (1995-2001) therefore displayed theory-driven search of market differentiation opportunities via product innovation, aimed at specific customer segments. The success with these activities reinforced the strategy of devices as means of market differentiation. See figure IV-11.

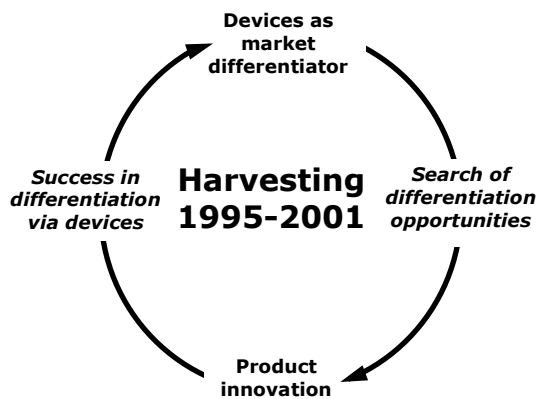


Figure IV-11. The strategic learning cycle of the harvesting period (1995-2001).

Phase 5: The vision of closed loop (2001-2005)

Insulin industry

The reorientation of the industry towards the diabetes Type 2 market continued. Hence, the long-acting insulin analogue Lantus®, launched 2000 by Aventis, gradually gained market share as typical insulin for treating Type 2 diabetes, since it was marketed as a 'once-daily' insulin, implying a simple and easy-to-understand treatment regime. In 2003, Lantus® had gained a 14.6% market share of the Western insulin market (USA-Europe), mostly based on sales in the U.S. This corresponds to sales revenues for Lantus in 2003 of 569.4 m\$ in Europe and U.S.A. (Hamilton, 2004). Also other insulin analogues gained increasing market acceptance. Thus, in 2002 Eli Lilly's fast-acting analogue, Humalog® (introduced 1996), passed the sales of the previously leading insulin product, the human insulin Humalin® in the U.S./E.U. market (Hamilton, 2004).

To address the exploding Type 2 market segment, the diabetes companies aimed for developing new drugs, first of all the hormone GLP-1 (glucagon-like peptide-1), which is well suited for treating early Type 2 diabetes, before the onset of insulin treatment. GLP-1 lowers the blood sugar level in a stable and slow-acting way, without the risk of hypoglycemia, which always is present when treating with insulin. A 2004 report states: "*Future growth drivers include the non-invasive insulins [e.g. inhaled insulin]...and the glucagon-like peptide-1 (GLP-1)*" (Hamilton, 2004, p. 13). In 2005, Eli Lilly introduced the first GLP-1 drug, Byetta®, licensed in from Amylin Pharmaceuticals. Novo Nordisk was several years behind in the development of their GLP-1.

However, Novo Nordisk was still successful in pushing the market towards devices. By 2002, insulin sold in cartridges for durable devices or in prefilled devices had overtaken insulin sold in traditional vials; 52% of the global volume of insulin was now sold in devices (according to internal statistics). Novo Nordisk especially pushed the prefilled insulin systems (NovoLet® and FlexPen®). During the 5-years period 2000-2004, the total market growth in volume of insulin sold was 0% annual growth for insulin in traditional vials, 7% for insulin in cartridges for durable pens systems and 16% for insulin in prefilled pen systems.

Novo Nordisk had also success in other ways. Besides the device-based strategy, an increased sales effort in the U.S. resulted in Novo Nordisk these years taking over the position as the world's largest insulin manufacturer, leaving Eli Lilly as number two.

In 2004, Aventis (including the insulin activities of the former Hoechst) was acquired by the French pharmaceutical company Sanofi-Synthélabo, forming Sanofi-Aventis. This merger gave financial power to the third largest insulin manufacturer. These three companies (Novo Nordisk; Eli Lilly; Sanofi-Aventis) now totally dominated the global insulin market. However, a new player had found an entrance: In 2004, the pharmaceutical giant Pfizer licensed in the development project for inhaled insulin from Nektar Therapeutics. Inhaled insulin was foreseen to have great advantages in the Type 2 diabetes market, because it made injections obsolete.

Corporate strategy

The change of strategy began at a special workshop in 2000 for the team of corporate managers from Operations (production, sales and marketing). The background was discussions in the pharmaceutical industry about diversifying from medical drugs into total healthcare solutions, as well as general attention to potential revolutions in diabetes treatment. The workshop was ignited by input from an external management professor on topics around possible future changes in diabetes treatment: What could change the whole business model? What were the unique strengths of Novo Nordisk? Why didn't Novo Nordisk set more outrageous ambitions for diabetes control and convenience for the patients? Why didn't Novo Nordisk play the role as system integrators and then deliver the most convenient products to the patient? – During the next half year, a taskforce driven by managers outside the device area made a detailed plan for a new device organization. After some consideration, the Executive Management Committee approved the plan and released the funding. The new device strategy was based on the so-called '*closed loop*' vision: A system mimicking the functions of the healthy body by combining an insulin delivery system with a blood glucose monitoring system. This meant that the monitoring of the blood glucose level and the infusion of the needed amounts of insulin could be maintained automatically in a '*closed loop*' of delivery and feedback. "*Closed loop was broadly discussed in the diabetes society – it was like the 'holy grail' of diabetes treatment*", as a key informant put it. The '*closed loop*' might resemble the 1988 vision of '*homecare*' (see figure IV-5). However, the big difference is the *continuous* monitoring of blood glucose and infusion of insulin, carried out by a more or less automatic system. Thus, to construct '*closed loop*', the devices had to move from mechanical products to '*intelligent products*', enabled by electronics and software solutions. Detailed business plans were created for the needed development projects, and the emphasis was on business creation, since the strategy again (like in the MSD phase) opened for entering the market for glucose monitoring. "*Yes, we wanted to develop total systems. Everything, the patient needed to control his/her blood glucose level. We wanted to be a 'one-stop-shop' to diabetes*".

A Financial Times report from 1997 might shed light on the background behind these visions (my emphasis): "*The trend has been towards **greater product sophistication**: urine testing has largely been superseded by blood monitoring, and insulin syringes are rapidly giving way to user-friendly injector pens. ... In the more distant future, hi-tech monitoring systems could transform implantable infusion pumps into a functioning artificial pancreas*". "*However, the main opportunities in the near future lie in the exploitation of new technologies, particularly for noninvasive glucose monitoring, especially **continuous monitoring**; and in more rapidly absorbed types of insulin, probably as inhaled insulin*." "*The market leaders of the future are likely to come from alliances already formed between the producers of insulin delivery products and the manufacturers of monitoring systems*." "*A number of alliances have recently been formed between manufacturers of insulin, insulin delivery systems, and monitoring systems... These strategic moves are expected to lead to **a new generation of diabetes***

products based on noninvasive monitoring technology and improved, probably in vivo, insulin delivery systems.” (Adamczak 1997, p. 3-4).

The systemic strategy, including glucose monitoring products, was envisioned to multiply the revenue from every diabetes patient, a so-called ‘value upgrade’, which in the strategy documents was related to the market evolution created by the introduction of insulin pens. One of the key persons involved comments: “*Novo Nordisk could get a bigger share of the pie via diversification into other parts of the diabetes market. And the executive committee saw that if anybody could do this, it was us. Also the board of directors approved that we should be more expansive*”. The needed competencies for developing new glucose monitoring devices and for the system integration were envisioned to be partly sourced in from external partners, partly built up via resource upgrades. Also acquisitions of specialized firms were considered – but in each case given up.

An informant, who assisted the creation of the new strategy, lists three main factors as driving the plans:

1. The vision of medical devices seen as ‘*the third business leg*’ (stemming all the way back from Nordisk in the 1980’s and the MSD period) had not been forgotten.
2. CGM: Continuous Glucose Monitoring, was introduced in 1999. Instead of single blood glucose measurements, a device could continuously measure the glucose level in the subcutaneous tissue, thereby enabling the patient to see the glucose level at any time, as easily as seeing the time at a watch (in principle).
3. The insulin pump market now grew rapidly (around 40% p.a.), driven by new types of pumps being introduced. The pumps represent the other side of the ‘closed loop’: the continuous insulin infusion.

The responsiveness from corporate top management to the new visions was influenced by optimism following the establishment of Novo Nordisk as an independent pharmaceutical company in 2000, where the enzyme business was demerged. Yet another factor was the fear of being left behind by competitors, in case they succeeded in exploiting the new technologies: “*If they succeeded, then we could risk getting reduced into suppliers of this muddy liquid, which was inside the pumps and devices, which were controlled by others*”.

The top management team, coming from the Health Care part of Novo Nordisk, was new in the role as a corporate management team. The new team saw the logic in the proposed strategy plans for lifting the device research and development activities out of Production; “*time was against having the R&D of Medical Systems placed in Production*”, as an informant says. Hence, device production and device R&D were separated, and the device R&D activities were moved from Production to the corporate R&D function. The two existing R&D units, the drug areas Discovery and Development, respectively responsible for early drug research and late drug formulation, were thereby supplemented with a new device unit, called *Protein Delivery Systems* (PDS). See organizational chart in figure IV-12.

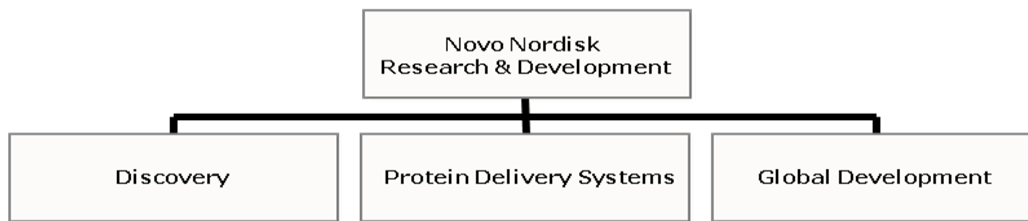


Figure IV-12. The device R&D unit, Protein Delivery Systems, placed in corporate Research & Development from 2001, in parallel to the two drug units, Discovery and Development.

A drug formulation department from the drug Development unit was transferred to PDS to ensure better system integration. PDS was publicly announced in August 2001, and the plan was to double up of the device related R&D activities. A part of the expansion was due to formal start up of a *technology research* unit for devices – such research previously had been embedded in the product development projects. Protein Delivery Systems was presented with these words in the annual report for 2001: “Novo Nordisk has committed itself to leadership in drug delivery. One primary research area is Protein Delivery Systems (PDS), and a new unit has been set up to develop innovative methods of administrating insulin and other therapeutic proteins. In practical terms, PDS combines Novo Nordisk’s expertise in diabetes protein formulation and insulin injection systems, for developing convenient and fully-integrated protein delivery systems for patients in several therapeutic areas. The unit focuses on injections devices, advanced continuous infusion systems and glucose monitoring systems.” In the same annual report, there’s a 3-page long article on “Leadership in insulin delivery devices”.

For the new corporate management team, the creation of PDS was also a way of opening a window for making medical devices a business of its own. I let an executive informant explain: “When we had carried out the split of the company in 2000, and we had experienced the boost in motivation it gave to make a sharper, better defined profile and strategy for the company...with some vision one could imagine the company from 2000 develop into a device company, a diabetes company and a biopharm company. It’s three different business areas, three different types of innovation and risk – therefore one could imagine that it would attract different types of investors...With PDS there was an ambition that we could sell our device knowledge and make it commercial to other companies. We believed that we were world champions within devices, so there ought to be somebody who could make use of this. One should also not exclude that we would actually learn something from working together with partners”. However, in 2002 the new corporate executive team was shaken by a crisis. The sales revenue for the first quarter of 2002 did not live up to the expectations – it even was necessary to announce a profit warning and adjust the budgets for the whole of 2002. An executive informant comments: “This implied a breach of confidence. The causes were partly internal – there were things, which we could do better, our internal control and forecasting systems probably were too poor – but it was also the global economy; it was just after 9-11 in 2001, which had provoked a sudden depression”. Furthermore, in the summer of 2002, a research project for tablet treatment had to be terminated, due to cancer risk. The annual report for 2002 begins with the words: “The year 2002 has been a very challenging time for

Novo Nordisk. On 10 April 2002 we announced that due to unexpected factors, full-year performance was not likely to meet our previous guidance”, and states on the same page “On 22 July 2002 we suspended the phase 3 trials of ragaglitazar (NN622), a promising dual-acting insulin sensitiser. This was done based on urine bladder tumour findings in one mouse and a number of rats.” The confrontation with these problems of course had implications for the new corporate management team. An executive informant comments: *“I think we got a rap on the knuckles as new management team in 2002. It made us swear that we should show them that we, damn it, could manage – so there was not much internal wrangling or fighting, we simply wanted to survive and show that we could do it. Therefore, we have had a high degree of continuity and internal trust within the team”*. One of the effects of the events in 2002 was the retreat from development of tablet treatment. An executive informant explains: *“We decided to concentrate on what we were good at, namely proteins. So no more synthetic chemistry and small molecules... It was partly a reaction to the NN622 project, which was stalled in 2002. We had a large portfolio of these projects; therefore it took some years to withdraw. But it showed that there was increasing distrust in this whole class of drugs, so we decided to stop”*. According to the same informant, the combination of financial problems and drug research problems in 2002 turned the corporate management team into a more conservative or internally oriented mode of management: *“In the following period, we strengthened our control and forecasting systems, and the whole management team focused on basic issues to ensure that we had a good understanding of our markets and where we were going. That was perhaps also a reason behind that it took so long time, before we took the strategic decision to terminate the research within small molecules. Remember, at the same time the dollar exchange rate decreased dramatically, so we needed to increase our productivity, because many of our expenses are paid in Danish currency. So this was principally a period with internal focus in order to become better at controlling the business and increase our productivity because of the weak US dollar...We overcame both the breach of confidence and the productivity crisis”*. In such management climate, risk willingness of course decreases, and this development hit back on the ambitious visions behind PDS, comprising complex ‘closed loop’ systems and business creation based on devices. I will let an executive informant explain the change in management view: *“We saw that there were problems within devices in getting new versions [of existing products] ready, and on top of that we were engaged in much more complicated devices, which we from desk analysis thought would be fantastic, including ideas of closed loop and all this. We made this integration of Innov[®]o and BGM, it was called InDuo[®], but we were not able to do it in a way, which was accepted by the market. The market turned towards more simple and convenient solutions – injections once daily, disposable devices etc. And in the end, we also moved in that direction, because we said ‘enough with all these complicated things’. We decided that we should not serve people outside our own business as long as we had problems with developing our own devices, which were one of the competitive advantages of Novo Nordisk. So as result, PDS was folded back again and we said ‘this is an internal part of Novo Nordisk and we don’t sell devices to others”*. This development in top management cognition implied a melt-down of PDS in the years 2004-2005.

Medical device level

With PDS, Novo Nordisk again aimed at entering the blood glucose monitoring market. This time the entry ticket was new continuous glucose monitoring technologies – that was, measuring the glucose level via a three-day sensor, which was inserted under the skin, instead of the single measurements via finger pricking. These technologies were premature, and the development had highly explorative character.

R&D for inhaled insulin was still carried out by the partner Aradigm Corporation in the U.S., but from 2004 Novo Nordisk took full ownership of the project by acquiring Aradigm Corporation. The project remained in the U.S., organizationally anchored in Novo Nordisk at Product Supply (i.e. Production), but PDS began to play a more active role in the development than the device area had previously done. This so-called AERx project continued to require massive investments.

According to some informants, the PDS strategy left little attention to the need for *lifecycle management* of existing products; that is maintaining the existing products with continuous improvements (often production-wise) or developing new versions with incremental improvements. One informant says *“There were skeptical people saying that we would risk losing our leading position in our core area. I guess this partly also happened. For a time we did not develop ‘engines’ for our injection pens. I guess it gave some sort of set-back. On the other hand, top management was not willing to increase the frequency of introducing new pen generations”*. An executive informant puts it: *“We kind of diluted the classical virtues – our resources within the classical disciplines – in such way that we lost momentum. And at the same time we placed our resources in high risk areas; it was too much ‘blue sky’ – we were too optimistic, we believed the solutions were just around the corner.”* A development engineer comments: *“We were happy to become a part of R&D; that’s where we belong. But the closed loop visions – well, it’s easy to write down such buzzwords...”*. The latter statement represents a critical attitude towards the new strategies, which was widespread in the device area; remember that the strategy plans for PDS were developed outside Medical Systems. A device manager expresses it: *“The establishment of PDS was not our choice [from Medical Systems]. It was driven from the top and by consultants with business plans for ambitious product areas – this was driving it, rather than knowledge on technologies. They were very little attentive to allocating resources for maintaining our injection systems. It was business plans all over”*.

Besides this internal skepticism, the ambitious strategies ran into some other challenges, namely the 2002 crisis (see above). One of my informants comments: *“It was an annus horribilis”*, and continues: *“Then we were in a chaotic situation with regards to financing our R&D activities – what did we really want? – which path should we follow? – with regards to drugs as well as devices. The whole trend was like: perhaps we should move back to basics, meaning only bet on insulin and GLP-1 on the drug side and injection devices on the device side...”*

This ‘annus horribilis’ had implications for the strategies of PDS. Initially, it was planned to acquire specialized companies within both continuous glucose monitoring and continuous insulin infusion in order to build on their competencies and technologies. The chaotic situation meant a setback in the

willingness to invest in such companies. Consequently, the only available way forward was in-house development. However, the complexity and risk of the projects had been underestimated, according to an informant; the technological challenges were much harder than envisioned. Hence, the continuous glucose monitoring project was given up in 2004, which was a de facto strategy change, as seen by a device manager. Furthermore, the drug formulation unit, which had been integrated into PDS, was transferred back to the drug development area to ensure the development of a GLP-1 drug, leaving PDS back with the device competencies solely. The skepticism towards the 'closed loop' vision increased and the visionary strategy behind PDS slowly was falling apart: "*the dream about the role as system integrator died*", as stated by an informant. "*The PDS visions were like romantic dreams*", as another informant stated it. This informant also points to the existence of different power bases behind respectively the initiation and the closure of PDS: The closed loop strategy behind PDS was driven by Operations (production, sales and marketing), who did not focus on the risk of such radical innovation projects – "*they did not assess the scientific reality*", as he puts it. According to this informant, the withdrawal from the closed loop strategy was driven by R&D. On top of these internal factors, which gradually made the PDS strategy fall apart, the competition in the traditional insulin device market began to threaten Novo Nordisk's leading position in devices. As result, reorganization was carried out in the summer of 2005.

Concluding on the evolution of the PDS strategy (2001-2005)

The second 'revolutionary' period (after the MSD period 1988-92) was initiated as result of a *reasoning process*, which can be traced back to a particular management seminar at an international business school in the summer of 2000. The strategy was then worked out via desk analysis during the next half year, driven by a management team outside the device area, supported by external consultants. The aim was to create advanced '*closed loop*' systems and to include more elements of the value chain of diabetes care into a '*one-stop-shop to diabetes*', just like in the MSD period. Hence, this top management driven, theory-based process *in content* was a truly *autonomous* strategic initiative; because it explored product-markets outside the existing strategy (cf. Definitions).

The vision was again to create a business of its own, based on the competencies within medical devices, which eventually could be demerged as a separate company. Thus, medical devices changed role from complementary to *core assets* for innovation.

Some inputs from the external environment played a role. Other pharmaceutical companies had tried integrating more elements of the value chain the years before (e.g. Lilly buying a distributor company), so vertical integration was seen as a potential trend, which might alter the market. Also the emergence of Continuous Glucose Monitoring in 1999 was seen as a potential threat, in case other companies would be able to develop integrated solutions, which would reduce Novo Nordisk' role in the value chain to supplier of '*muddy liquid*'. In conclusion, the transition into the PDS strategy was partly ignited by external factors, such as the potential future competitive landscape, in case the competitors succeeded with their initiatives. However, the external drivers were again mediated by management interpretation; top management reacted to the *perceived* potential risk.

The strategic learning cycle of PDS is a straight-forward theory-driven search for technologies, based on the visions of 'closed loop' and 'one-stop-shop to diabetes', resulting in explorative innovation activities, which never succeeded; hence the reinforcement from the experiences was negative. See figure IV-13.

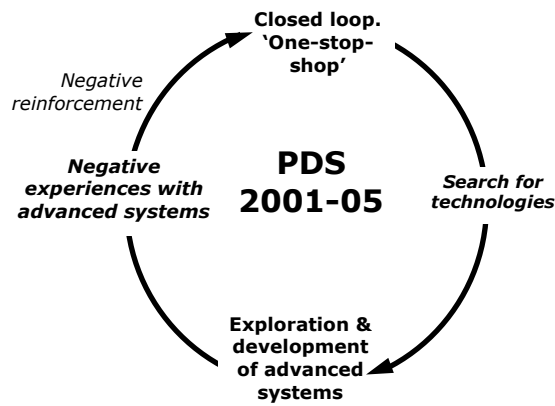


Figure IV-13. The strategic learning cycle of PDS.

Phase 6: Integration into the drug research area (2005-2008)

Insulin industry

Eli Lilly introduced the first GLP-1 drug, Byetta®, in 2005, and this totally new drug category grew in popularity driven by the increased Type 2 diabetes prevalence: September 2008, more than 6.6 million prescriptions had been dispensed¹⁴ and the sales had reached 0.59 billion USD¹⁵.

In 2006, Pfizer introduced the world's first inhaled insulin, Exhubera®. This product was, however, withdrawn again from the market by yearend 2007 due to slow market acceptance and concerns about increased risks of lung cancer. As a consequence, Novo Nordisk stopped its development project for inhaled insulin (AERx) from January 2008.

Sanofi-Aventis, who already had massive success with their Type 2 targeted insulin Lantus®, in 2007 launched this drug in a new prefilled device, called Solostar®, which was perceived as being on par with the FlexPen® from Novo Nordisk. For the first time, Novo Nordisk did not have absolute device leadership.

Tablet treatment for Type 2 diabetes ran into problems. Several new products showed to have side effects of increased cancer risk. These problems resulted in growing interest for insulin and GLP-1 treatment in the fight against the explosion of Type 2 diabetes.

Corporate management cognition

When asked if he regretted the PDS period, an executive informant replied: *"Yes and no. I of course could regret that the PDS period implied that we got a bit behind within the classical disciplines, because we had a different focus. The reason why I don't regret it is that it meant renewed focus on the drug delivery part, which we lacked; it gave the device area a feeling like 'we are somebody – they count on us, we are important, we are an organization with independent responsibility' and so on. And I think it also created some thoughts at corporate management that this [device] innovation needs attention. It should not just be an appendix to the drug; it is in itself a differentiating factor. So I don't think PDS lived in vain"*.

¹⁴ Source: FDA (2010-06-26 at)

<http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm113705.htm>

¹⁵ Source: <http://www.faqs.org/periodicals/201001/2019750421.html>, accessed 2011-06-25

The organizational response to the failure of the PDS strategy was to integrate devices within the drug research, which until then had been organized in the Discovery unit. Drug research was now split in two functional areas: Diabetes Research Unit (DRU) and Biopharmaceuticals Research Unit (BRU) – the latter taking care of research within other diseases than diabetes. According to an informant, the reason for this split was to create transparency regarding input and output within each research area. The device innovation was transferred to DRU, since most of the devices were targeted for diabetes. An executive informant explained: *“The logic behind was to gather responsibility for all diabetes innovation in one place with the formation of the DRU unit”*.

The problems with side effects from new tablet treatments for Type 2 diabetes opened for an expansion of the insulin market. *“The insulins got a renaissance”* as an executive informant puts it. He continues: *“Today you can say that the proteins have moved forward from being the severe final treatment to something you can apply much earlier in the treatment. Also now with GLP-1, which is another protein, you can perhaps even start before the onset of diabetes, to prevent the disease. **This means that our core competence area, where we are world champions, suddenly gets a much broader application to many more patients** – even before diabetes and perhaps for prevention, in future. This understanding has emerged over time”* (my emphasis). The executive here explains the gradual growth in application of treatment of diabetes with protein-based drugs: First, insulin was used only for the relatively small market of Type 1 diabetes. Then, insulin got accepted for treatment of the much larger Type 2 diabetes market. And finally, the other protein, GLP-1, potentially opens the market for *prevention* of Type 2 diabetes.

Medical device level

When PDS was discontinued in August 2005, the device activities were divided into three functional areas, which were integrated into the new Diabetes Research Unit, DRU. Besides the device activities, DRU consisted of the drug research areas from the former Discovery unit. See organizational chart in figure IV-14.

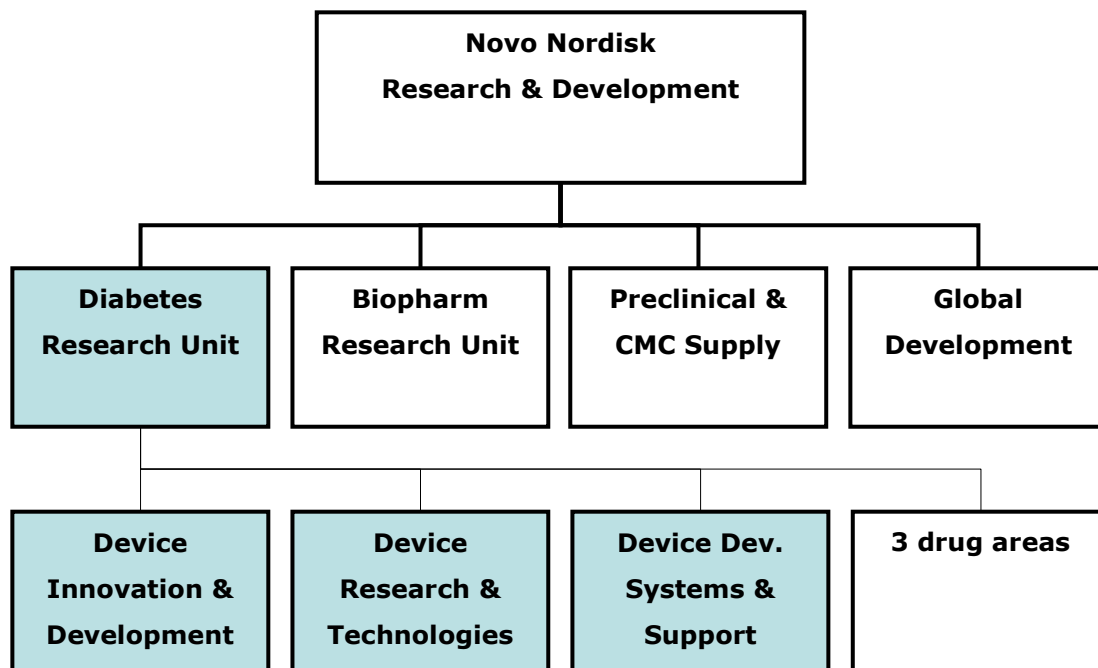


Figure IV-14. The device area placed as three VP areas within DRU, from August 2005.

The strategy for DRU was to *secure the leadership* of Novo Nordisk within the diabetes care market by building on the strength and synergy of integrated drug and device development within one organizational unit. The core competence was termed the “*value added pharmaceutical product*” as a description of the integrated drug-device system. The activities were focused, and the most radical innovation projects from the PDS phase were stalled. “*It was back to basics: let’s do what we are good at and know we can do*”, as one informant commented. Another informant calls it a return to the logic of the period of Medical Systems (1992-2001). One can say that the new strategy was still based on system integration, but now only integration of drug and device using the existing product systems, which Novo Nordisk had introduced two decades ago in terms of the durable and prefilled insulin pens. The system integration towards glucose monitoring as a parallel business to insulin delivery was given up.

A statement from an informant may illustrate the integrative view: “*That is our strength: we are the only [pharmaceutical] company, where device development is integrated; because it’s two different worlds [drugs and devices], and when it comes to quality and production, you can learn from devices. That’s the innovative and smart about it. The competitors cannot make the same quality, and it’s not integrated in their setup. So they’ll stay behind – at least, that’s my philosophy.*”

At project level, new drug candidates required new device innovation projects, GLP-1 being the most significant. To support the new drugs, a range of new device projects were started up – most were incremental, but also radical and explorative projects were initiated. However, within the relative short lifetime of the DRU phase, only few new products were launched. The only major product launch was NovoPen® 4 in 2006, and this rather incremental innovation project was actually started up years before the DRU period. The DRU phase was discontinued by yearend 2008 – for reasons, I cannot disclose, since these point into the next phase.

Concluding on the formation of the DRU strategy (2005-2008)

The background for establishing DRU should be understood as a *strategic retreat* from the former PDS period. External events had large impact on the withdrawal from the PDS strategy: the financial shake in 2002 implied decreased risk willingness, amplified by the failure of the tablet treatment project NN622 (see the description of the PDS period). These events moved top management to focus inwards, on control systems, profitability etc. This was clearly a mode of exploitation (March, 1991) at corporate level, which of course undermined the explorative strategy behind PDS. Furthermore, the fierce competition within the classic insulin pens threatened Novo Nordisk's historical device leadership, and also this external factor drove management towards a retreat from the explorative 'closed loop' strategy.

Another external event was the failure of certain competitors' tablet products in the market, displaying cancer risk, which increased the request for insulin and GLP-1 for treatment of Type 2 diabetes. This growth opportunity might have reinforced the investment in the 'closed loop' strategy, but instead led to a return to a purely drug-based strategy. The technical problems with the advanced device solutions, combined with the fear of getting behind within the classic insulin pens, pushed management in the direction of retreat rather than investment in the PDS strategy.

Thus, the DRU strategy was a return to a drug-based innovation strategy. Top management perceived the market changes as a '*renaissance*' for the *classic core competencies* – therefore, the strategy of DRU was *induced* – it was 'back to basics', staying within the well-known territories. Similarly, medical devices changed role from being core assets for innovation in the PDS strategy to being *complementary assets* in the DRU strategy – seen as *value-adding*.

Conclusively, the strategic learning cycle of the DRU period was anchored in a theory of 'back to basics', which again was a result of negative reinforcement of the PDS strategy. Since the process held an element of learning from the mistakes of the previous period, one can see the evolution as experience-based, learning from trial-and-error. The strategic search of DRU aimed at exploitation of the classic skills. See figure IV-15.

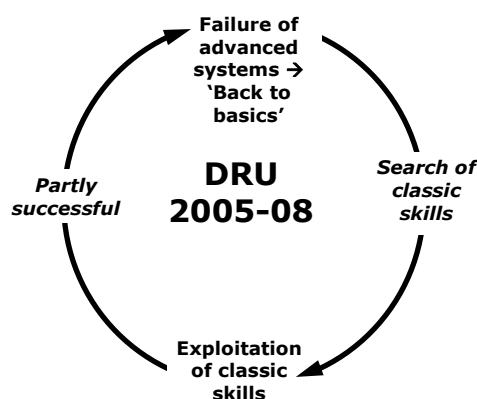


Figure IV-15. The strategic learning cycle of DRU; based on the negative experiences from the PDS period.

Part 2: The product innovation portfolio

A basic trait of corporate strategy is the existence at two levels, or in two realms: in the mental realm of reasoning, or 'theory,' and in the physical realm of action, or 'practice'. The current research project builds on the understanding that strategy making evolves in learning cycles between these two realms. Consequently, it is highly relevant to check the empirical validity of this presupposed connection: are changes in innovation strategy and changes in the actual innovation activities linked? Or do these realms exist independently of each other?

To conduct such empirical study, we need indicators of changes in strategic vision, or 'theory', on the one side; and the actual activities on the other side.

Changes in the 'theory' of strategy can be traced via changes in the formulated innovation strategy, as identified via the interviews. A more objective indicator is changes in the organizational structure, since these often reflect changes in strategy (cf. Chandler, 1992). An interesting question here could be to examine, which of these indicators (changes in the content of the formulated strategy; or changes in the organizational structure) that shows the highest interrelatedness with changes in the actual activities.

The composition of the device innovation *project portfolio* serves as indicator of the actual innovation activities. The portfolio of device innovation projects is analyzed throughout the studied period (1980-2008). By the collection of historical data, 102 device development projects were identified. Sufficient information for data analysis could be gathered for 95 of these (such as the nature of the project, year of start-up and year of project termination / product launch). 37 of these 95 projects led to new product launches within the studied period (39%). 43 of the 95 projects were terminated (45%). 15 projects were still ongoing by yearend 2008 (16%). When analyzing the nature of the project portfolio, two indicators seem especially relevant: a) the portfolio of *ongoing* projects (= the number of projects in operation per year); b) the portfolio of projects *initiated* in a given year. Also here, it is interesting to see, which of these indicators that shows the strongest relationship to the envisioned strategy.

For classification of the projects throughout the historical evolution, the concepts of autonomous and induced initiatives (Burgelman 1991, 2002) are applied. Burgelman & Grove (2007) make a similar attempt to classify the historical innovation activities at Intel as respectively induced or autonomous, measured by the relative deployment of development resources at critical times in Intel's evolution (Burgelman & Grove 2007, table 2), estimated by Andy Grove based on personal experience and company documents. The relative deployment of resources for autonomous initiatives in their assessment varies from 13 to 50% at different times in Intel's history. Unfortunately, I did not have access to data about the resource deployment at the different epochs of Novo Nordisk's device innovation activities, so I could not make a comparable assessment. However, it is interesting in itself

to see if a similar assessment of the balance between autonomous and induced activities can be established using the project portfolio as indicator.

Definitions

For practical categorization of development projects, the definitions in Burgelman (2002) are applied: “**Induced strategy** exploits initiatives that are within the scope of a company’s current strategy and that extend it further **in its current product-market environment**. **Autonomous strategy** exploits initiatives that emerge through exploration outside of the scope of the **current strategy** and that provide the basis for entering **into new product-market environments**” (p. 327; my emphasis). Based on the emphasized parts, the device development projects are classified as ‘induced projects’, if they aim for developing products within the product-market categories currently established by Novo Nordisk at the given time in history; and as ‘autonomous projects’, if they aim for developing products outside the product-market categories currently established by Novo Nordisk at the given time in history.

For the empirical classification, the intended aim of the development project is related to the product-market categories currently established by Novo Nordisk *by the year of start-up* of the project. This method results in relative high percentages of autonomous initiatives, compared to Burgelman & Grove (2007), because of the long development cycles in the pharmaceutical industry. If we for example take the new drug type GLP-1, Novo Nordisk launched its first product, Victoza®, in 2009, using the existing FlexPen® device. Taken by my empirical definition, all device innovation projects aiming for a device for GLP-1 that were started up *before* the launch of Victoza® in 2009 are therefore categorized as autonomous, since the product category was not yet established by Novo Nordisk. Hence, this empirical definition does not take into account at what time GLP-1 became a part of the *intended* corporate strategy (which would have been more correct for defining the degree of strategic alignment) – but such decisions can be almost impossible to track historically. By using the first product launch as the distinguishing year for the establishment of a new product-market, I get a pragmatic grip for the empirical classification.

The nature of the development projects is below related to both structural periods and strategic periods. *Structural changes* are defined as restructurings, in which the *entire* device innovation area at Novo Nordisk is moved around within the Novo Nordisk organization. Internal restructurings within the device area are disregarded. Structural changes are identified via the organizational charts. *Strategic changes* are defined as changes in: overall vision for or purpose of the device area; targeted customer segments and value proposition; field of activities; source of revenue. Changes are identified via statements in interviews and archival data.

Expectations

From my empirical definition of induced and autonomous, it is self-evident that the start-up period of the device activities would hold mostly autonomous projects, since the product categories first had to be established in the market and the strategy had to be institutionalized. For example, until the

launch of the first durable insulin pen (NovoPen®) in 1985 and the first prefilled insulin pen (NovoLet®) in 1989 all projects within these two categories were autonomous. Once these product categories were established, one could expect the relative number of autonomous projects to gradually decline; until the strategy was altered next time, most activities would aim for developing improved versions of the already established product categories (staying *within* the strategic frame). If – and only if – the strategy for the device innovation was changed and opened for exploration of new product-markets, one could expect to see changes in the *nature* of the development portfolio in the form of increased autonomous activity. As known from the historical case study in the previous sections, there was only one such strategic change after the initial institutionalization of the device strategy in 1988, which opened for entering new product-markets: namely the PDS strategy, formulated in 2000, implemented in 2001. The other strategic changes turned the strategy back to already established positions and capabilities within durable and disposable insulin pens. Hence, one could expect two peaks in autonomous activity: the early phase, up to the institutionalization in 1988, eventually including the MSD phase, and then again in connection with the establishment of PDS. The rest of the periods would be expected to be colored mostly by induced activities.

Basic measurements

The structural changes were set as follows:

1. 1988: Establishment of the Medical Systems Division.
2. 1992: Moving the device area to the Diabetes Care Division, as Medial Systems.
3. 1995: Moving Medical Systems to Production.
4. 2001: Establishing Protein Delivery Systems (PDS), thereby transferring the entire Medical Systems R&D to corporate R&D.
5. 2005: Moving the device R&D activities to Diabetes Research Unit.

The strategic changes were set as follows:

1. 1987: The strategy for making devices a separate business area, building on the vision of homecare centered on the patient (since MSD was established in the beginning of 1988, the strategy must have been formed during 1987).
2. 1992: Termination of the homecare strategy, hereunder the disease monitoring projects and the insulin pumps – the new strategy only included insulin pens.
3. 2000: The formulation of the ‘closed loop’ strategy, leading to the establishment of PDS in 2001 (delayed only for financial reasons).
4. 2005: Official termination of the closed loop strategy. Focus now on the ‘value-added product’ as the integrated device-drug system.

The restructuring in 1995 is not included in the strategic changes, because the strategy *for devices* was not altered.

The total portfolio of device development projects (not differentiated in autonomous and induced) is shown as the number of ongoing development projects per year in figure IV-16. The number of ‘*ongoing projects*’ includes all projects in operation that year: some were launched as new products,

others were stalled during the year; and some were still ongoing at yearend. Overall, the number of ongoing projects increases throughout the studied period, which is partly to be explained with increased resource input.

Interestingly, the development displays recurrent waves, following the structural changes: the number of development projects increases after each restructuring to reach a peak 2 years after (for the MS period 1995-2001 also displaying a second peak 4 years after), and then declines. This pattern shows also in the case, where the restructuring is not accompanied with strategic changes (in 1995). I first interpreted this pattern as the effect of a motivational boost after each restructuring: each reframing ignites entrepreneurial activity; after some years, the 'frame' gets worn, and in order to release a new period of growth, a new reframing takes place. This way, the repetitive cycles of expansion and contraction (the 'pulse beat') form an overall growth in the project portfolio. Perhaps the metaphor of a hermit crab could be used: it finds a shell for protection and lives in it until the shell gets too constraining; then it seeks a bigger shell and drops the old. When presenting this interpretation of figure IV-16 to a device manager, he replied: *'this gives a wrong picture of what happens; it is like as if the activity level decreases in the second part of each period. Rather, we focus the activities on a fewer number of projects'*. His statement clearly points to the weakness of using the number of projects as a measure: the resource input is not visible. His explanation implies that each restructuring opens a 'divergent' period, meaning that the latitude of the activities expand and the possibilities of the new organizational frame are explored – then a 'convergent' phase begins, where the portfolio of projects is narrowed down in order to exploit the most viable projects. If this explanation is valid, we should be able to track a pattern of two peaks within each period: the project initiation curve should peak in the beginning of each period, and the project termination curve should peak in the middle or end of each period. I have analyzed the data and indeed, this interpretation was supported: the number of project initiations peaked either by the year of reorganization or the year after. The number of project terminations peaked either in the middle or the end of each period. It therefore seems as if organizational restructurings have an impact on the activities, displayed as lifecycles of exploration and exploitation, reflected in the total number of innovation projects – regardless of whether or not the strategy is changed.

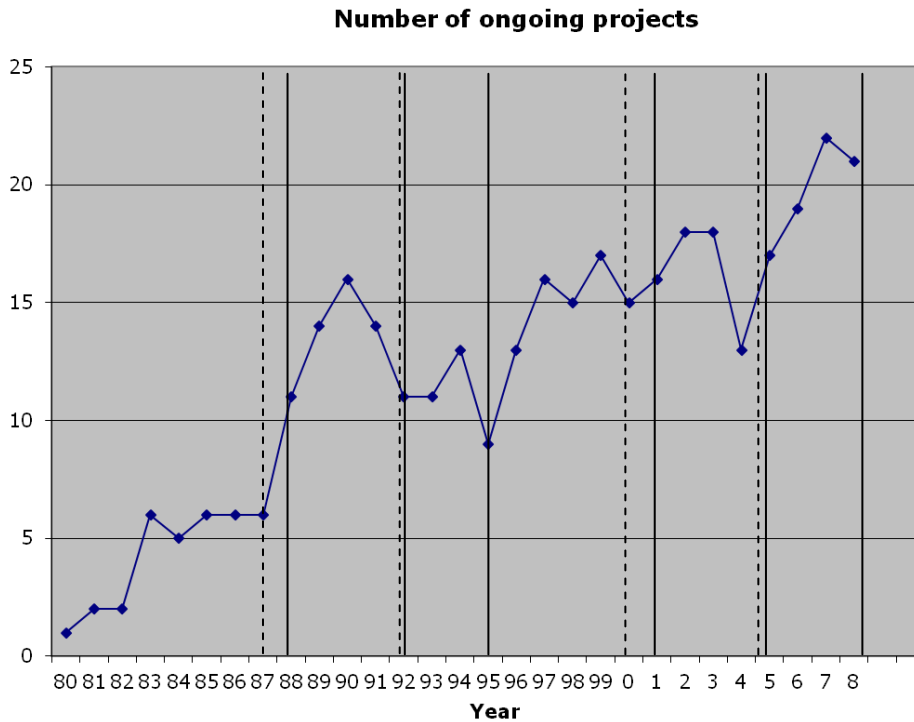


Figure IV-16. The total number of ongoing device development projects, year by year. Dotted vertical lines: Strategy changes. Full vertical lines: Structural changes. ‘Ongoing projects’ include all projects in operation that year – some were launched as new products, others were terminated during the year; and some were still ongoing at yearend.

The development of the nature of the innovation project portfolio

The nature of the project portfolio can be analyzed by using different sets of metrics. One way is to count how many ongoing projects that are in operation simultaneously, year by year, split in the two categories induced and autonomous. This is shown in figure IV-17.

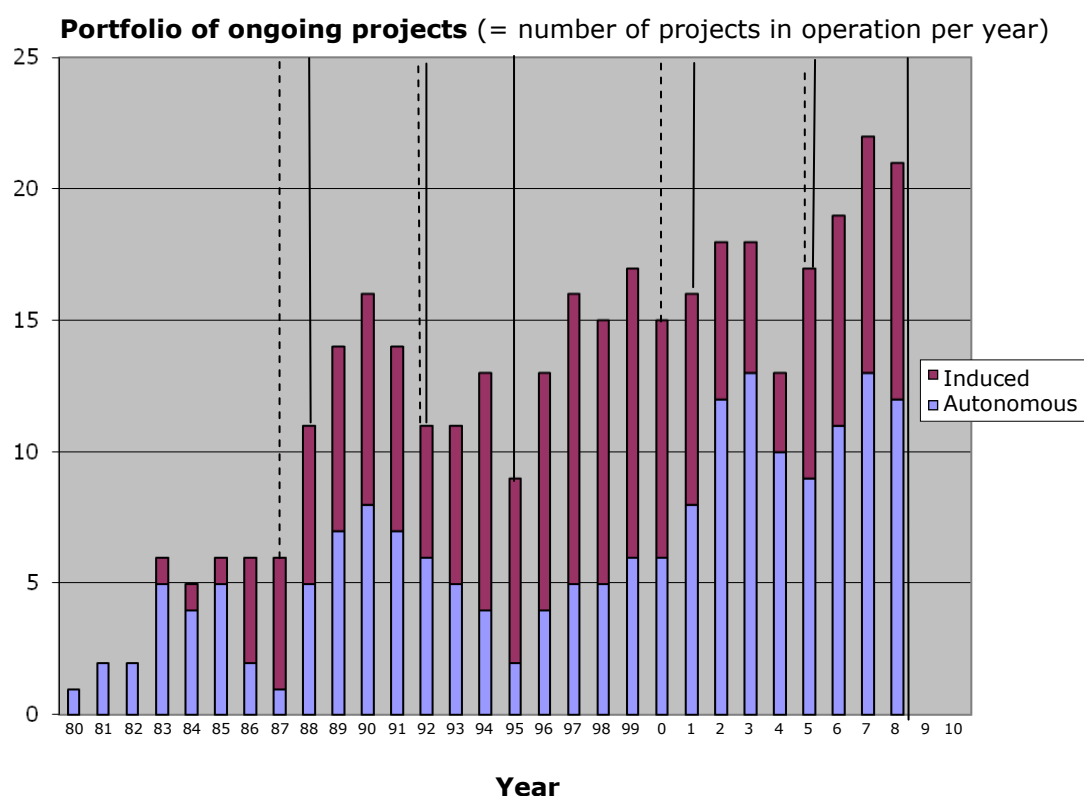


Figure IV-17. The portfolio of ongoing projects, split between autonomous and induced. Dotted vertical lines: Strategy changes. Full vertical lines: Structural changes. The graph indicates a cyclic pattern, which is analyzed in the subsequent text.

To see the link between strategy/structure and the project portfolio more clearly, each structural/strategic phase can be characterized by the relative distribution of projects in respectively induced and autonomous initiatives. Table IV-2 and IV-3 show this distribution for respectively the structural and the strategic periods.

Structural epoch	Early 1980-87	MSD 1988-91	Crisis 1992-94	MS 1995-00	PDS 2001-04	DRU 2005-08
Autonomous projects in average, per year	2.7	6.7	5.0	4.7	10.7	11.2
Induced projects in average, per year	1.5	7.0	6.7	9.5	5.5	8.5
Total average, per year	4.2	13.7	11.7	14.2	16.2	19.7
% autonomous per period	65	49	43	33	66	57
% induced per period	35	51	57	67	34	43

Table IV-2. Relative distribution of *ongoing projects* for each *structural epoch*.

<i>Strategy epoch</i>	Early 1980-86	Homecare 1987-91	Basics 1992-99	Closed loop 2000-04	Value add 2005-08
Autonomous projects in average, per year	3.0	5.6	4.6	9.8	11.2
Induced projects in average, per year	1.0	6.6	8.5	6.2	8.5
Total average, per year	4.0	12.2	13.1	16.0	19.7
% autonomous per period	75	46	35	61	57
% induced per period	25	54	65	39	43

Table IV-3. Relative distribution of **ongoing projects** for each strategic epoch.

These figures demonstrate that structural and/or strategic changes are in fact correlated with the distribution of development projects between autonomous and induced activities. In both tables, the percentage of autonomous projects starts at a high level (65% for structure and 75% for strategy), where after it decreases as expected until the ‘closed loop’ strategy results in establishment of PDS, where it jumps to a new height (66% for structure and 61% for strategy), to decrease after the termination of PDS. The distance between the lowest and highest percentage of autonomous projects is respectively a factor 2.0 for structural evolution (from 33 to 66%) and 2.1 for strategic evolution (from 35 to 75%). This evolution of the portfolio is graphically shown in figures IV-18 and IV-19.

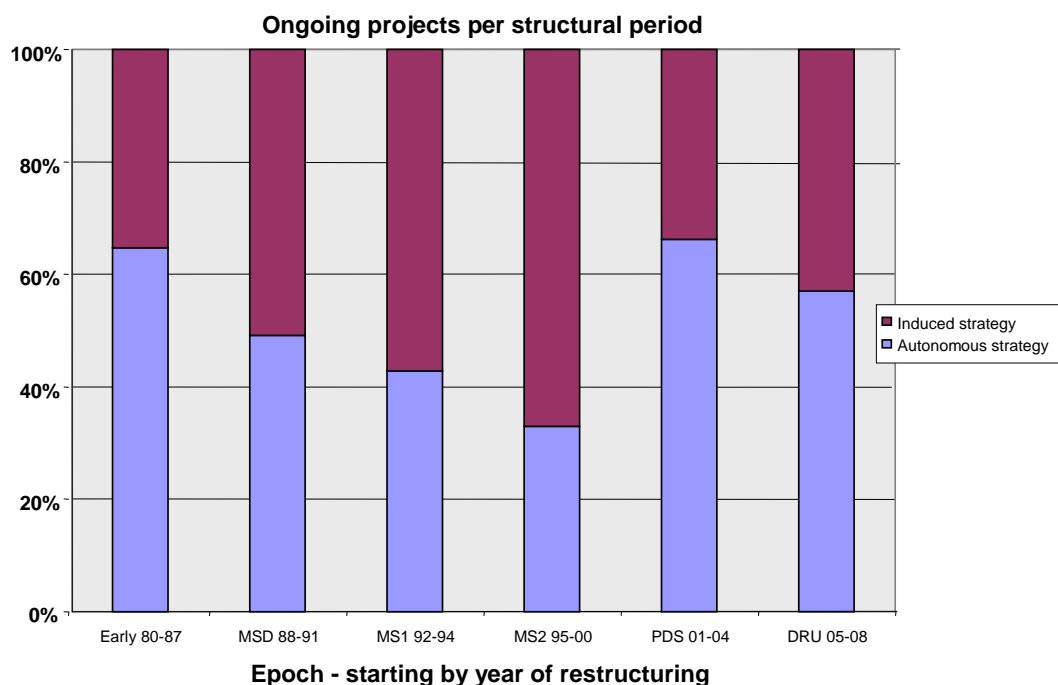


Figure IV-18. The relative distribution between **ongoing** autonomous and induced projects during the shifting structural epochs.

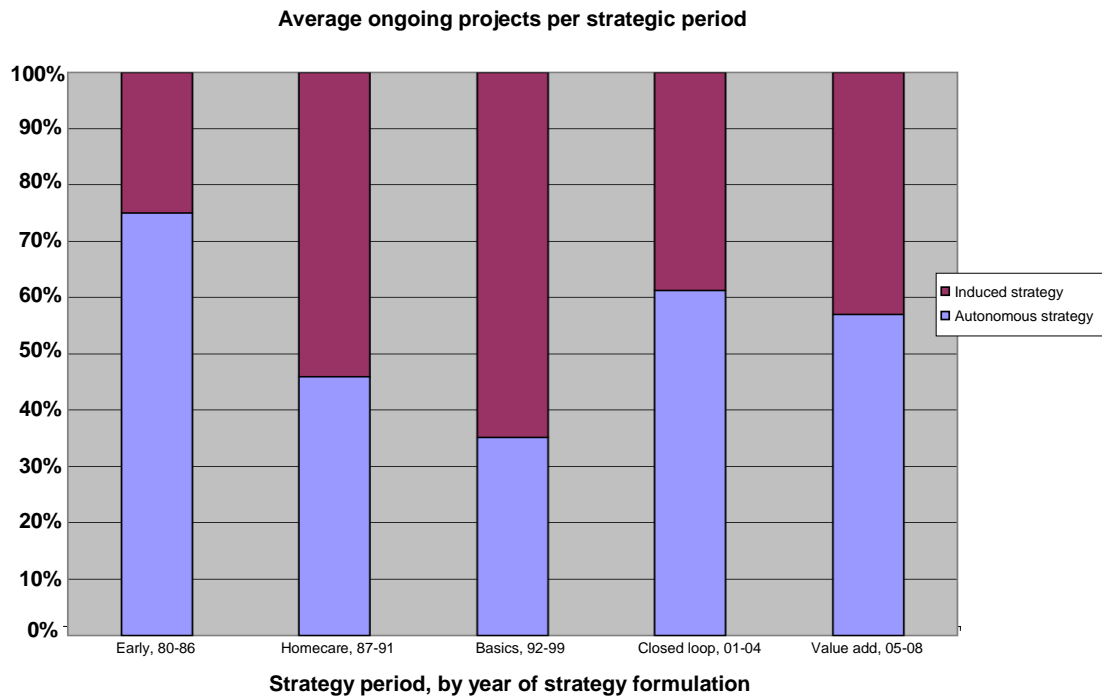


Figure IV-19. The relative distribution between **ongoing** autonomous and induced projects during the shifting strategic epochs.

The above statistics were based on the average number of ongoing projects per year. However, one could argue that ongoing projects not necessarily reflect the current strategy; projects are not so easy to kill, when they first have a business case, technological feasibility and a handful of missionaries to fight for their ‘child’ – thus, a project might often survive *in spite* of a changed strategy. Therefore, you only see a *gradual* decrease in autonomous activity over several phases, after each peak created respectively by the early attempts and by the PDS strategy. Some of the autonomous projects ‘hang out’ after the bar had closed, so to speak.

Following this logic, the impact of strategy on the product innovation portfolio is best obtained by the number and nature of the projects *initiated*, year by year. This is shown below in figure IV-20.

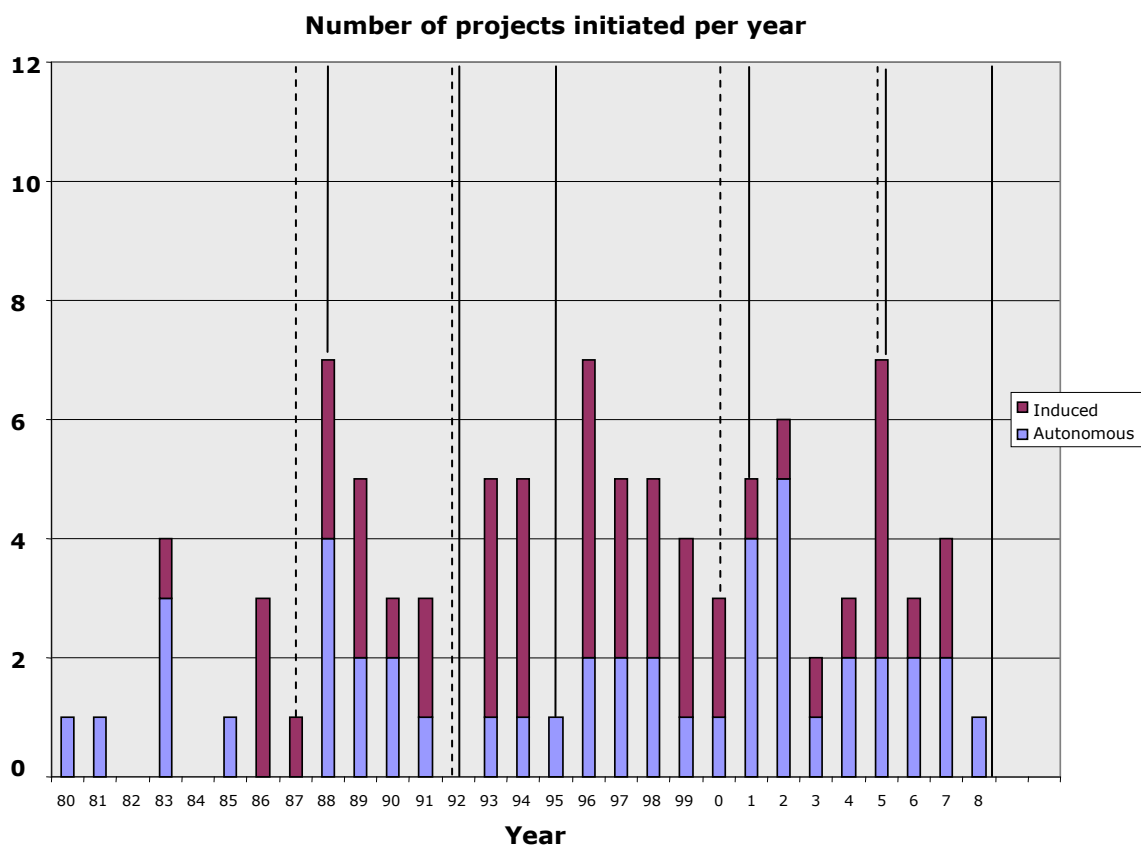


Figure IV-20 The number of initiated projects per year, split between autonomous and induced. Dotted vertical lines: Strategy changes. Full vertical lines: Structural changes. The evolution is analyzed in the following.

Furthermore, similar calculations as above have been made concerning the relative percentage of autonomous projects among the population of projects initiated year by year. Table IV-4 and IV-5 below display the results.

<i>Structural epoch</i>	Early 1980-87	MSD 1988-91	Crisis 1992-94	MS 1995-00	PDS 2001-04	DRU 2005-08
Autonomous projects initiated in total	6	9	2	9	12	7
Induced projects initiated in total	5	9	8	16	4	8
Total initiated projects per period	11	18	10	25	16	15
% autonomous projects initiated per period	55	50	20	36	75	47
% induced projects initiated per period	45	50	80	64	25	53

Table IV-4. Relative distribution of projects **initiated** for each structural epoch.

<i>Strategic epoch</i>	Early 1980-86	Homecare 1987-91	Basics 1992-99	Closed loop 2000-04	Value add 2005-08
Autonomous projects initiated in total	6	9	10	13	7
Induced projects initiated in total	4	10	22	6	8
Total initiated projects per period	10	19	32	19	15
% autonomous projects initiated per period	60	47	31	68	47
% induced projects initiated per period	40	53	69	32	53

Table IV-5. Relative distribution of projects *initiated* for each *strategic epoch*.

The observation that the *initiated projects* might provide a clearer ‘portrait’ of a strategic/structural period than the portfolio of *ongoing projects* is confirmed in the sense that the variance between the values is higher for the initiated projects. The pattern is the same: Starting with a high degree of autonomous activity, then decreasing until a jump in connection with the formation of PDS, thereafter decreasing again. The structural periods display the period of crisis in 1992-94 as a significant low of only 20% autonomous activity, whereas PDS jumps to an all-time high of 75% (a variance of a factor 3.75). The strategic periods have same pattern, but vary less; from 31 to 68% (factor 2.2). This difference in variance can be explained: the structure was changed in 1995 (to a new functional corporate structure) after having overcome the quality crisis, whereas the strategy for devices was kept focused on basic insulin devices all the way from 1992 to 2001. Since the strategy period thus covers a longer time span, the variance in portfolio gets leveled. The patterns are visually depicted in figures IV-21 and IV-22.

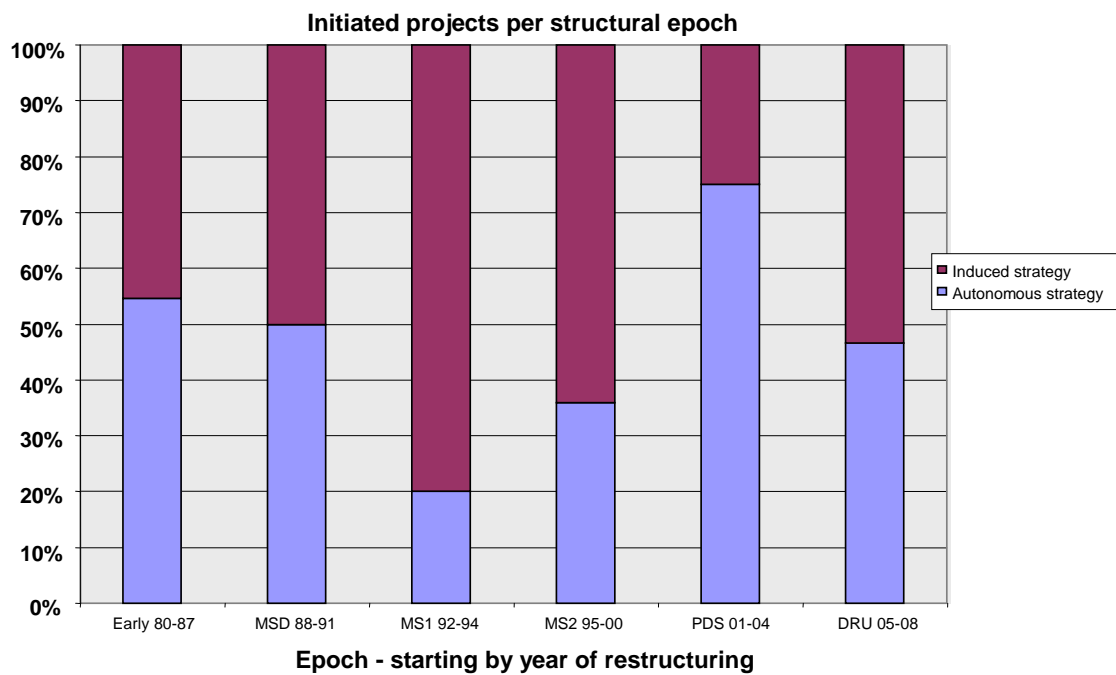


Figure IV-21. The relative distribution between *initiated* projects in autonomous and induced during the shifting structural epochs.

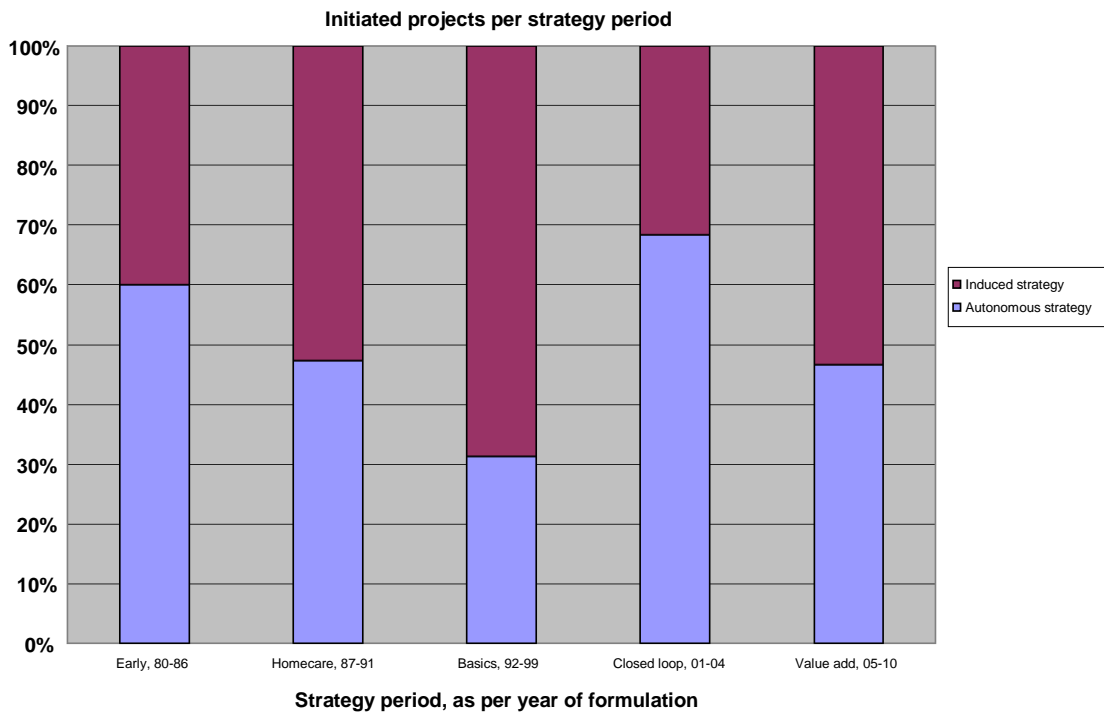


Figure IV-22. The relative distribution between *initiated* projects in autonomous and induced during the shifting strategic epochs.

Conclusion on the development of the project portfolio

The composition of the project portfolio developed as expected: The ratio of autonomous projects was high at the entrance to the medical device activities, and then decreased until a peak in connection with the launch of the new autonomous PDS strategy in 2001. After termination of the PDS strategy, the ratio of autonomous projects decreased again. So, the product innovation activities (strategy in 'practice') and the formulated strategic intent (strategy in 'theory') were actually linked. When analyzing the interrelatedness between strategy in 'theory' and strategy in 'practice', we can do it both ways:

- Going out from practice (i.e. project portfolio): For the total portfolio of *ongoing projects* (i.e. the total number of projects in operation in a given year), the *strategic* epochs provide higher variance in the balance between autonomous and induced projects than the *structural* epochs. For *initiated projects*, the *structural* epochs show higher variance than the *strategic* epochs; this can partly be explained by shorter lifecycles of organizational structures compared to the strategy lifecycles.
- Going out from 'theory', as expressed either in *strategic or structural epochs*: The *initiated projects* provide higher variance in the balance between autonomous and induced projects than the total number of *ongoing projects*, for both strategic and structural epochs. This stronger link between strategic intent and project *initiation* (compared to the total 'stock' of projects) confirms the basic idea that new strategic visions imply new activities.

We can also conclude that it is in fact possible to establish an assessment of the balance between autonomous and induced activities using the composition of the project portfolio as indicator: the *nature* of the project portfolio, classified in autonomous and induced projects, depends on the *nature* of the innovation strategy. Autonomous strategies indeed cause a significant higher ratio of autonomous innovation projects.

An interesting observation is the cyclic development: that each organizational restructuring implies a period of exploration, where many new projects are started up, until a peak in project closures marks a period of exploitation, in which the number of project initiations decreases (because the portfolio is focused), until the next restructuring starts a new cycle. These cycles in the *number* of initiated projects seem independent of whether or not the strategy is changed.

Part 3: Close-up analysis of device level dominant logic 2007

Since strategy framing is heavily influenced by the dominant general management logic of a company (Prahalad & Bettis, 1986), the case study includes a real-time study of the management cognition on innovation at the device area of Novo Nordisk, in order to determine the local 'dominant innovation logic'. The data capturing was done via in-depth interviews of a representative sample of 10 device level managers in 2007. Thereby, a 'snapshot' of the management mindset could be established. The method used is described in Chapter 3 and Appendix A.

At the time of the interviews, the device innovation activities were organized as three functional areas within the drug research unit, Diabetes Research Unit, DRU (see previous sections), which was characterized by an induced strategy.

Findings

The findings are presented in table IV-6 below in the form of synthesized statements from the interviews. Only statements, which were supported by at least 5 of 10 managers, have been included, since the aim was to capture the 'dominant logic' (Prahalad & Bettis, 1986); statements with at less than 5 of 10 supporters are below 'dominant'.

The synthesized statements from table IV-6 were condensed further into the following portrait of the *dominant innovation logic* at device R&D management level at Novo Nordisk in 2007:

The general management logic at Device R&D

- The business driver is the pharmaceutical drug; and we are as a company driven forwards by competition from pharmaceutical rivals
- Our core capabilities comprise user and market understanding; development of high quality products; and linkages to the Novo Nordisk organization
- Our primary customer is the end user, to whom we offer increased quality of life.

The innovation management logic at Device R&D

- The primary innovation enhancer is competition within the industry
- The primary innovation barriers comprise low risk willingness due to the 'success trap' (i.e. because of the vast success of the company, it is too risky to change anything – "don't rock the boat"); and a culture and processes geared to 'mainstream' business
- Consequently, our development portfolio is 'mainstream' = incremental innovation
 - And real breakthrough innovation would require alternative organizational setups and more early technology research.

<p>THE FOUNDATION OF OUR BUSINESS</p> <p>Our value offering Our primary customer is the end user, i.e. the patient, to whom we offer the following value propositions:</p> <ul style="list-style-type: none"> • Quality of life / lessen burden of living with diabetes • Convenient treatment systems • Easy and simple drug administration • Trust in quality and safety of our products <p>Our business The business model is based on profit from the pharmaceutical drug and the drug is the business driver. As a company, we are driven forwards by our competitors, again based on the drug as the primary market driver. Our main competitors correspondingly are pharmaceutical companies, first and foremost Sanofi-Aventis and Eli Lilly, secondary Pfizer [inhaled insulin].</p> <p>Our capabilities The core capabilities within the device area are, in order of importance:</p> <ul style="list-style-type: none"> • User and market understanding • Ability to produce high quality products • The link to the pharmaceutical side of the business • Our integration into the Novo Nordisk organization • Our long experience within the field of medical devices, which has led to a specific culture around devices • Our technical product knowledge <p>Our organization When considering if the device area could benefit from being an independent company, the answer is no; we need the integration with the rest of the Novo Nordisk organization. Our organizational identity is associated with a high quality image and solidity.</p>
<p>OUR INNOVATION ACTIVITIES</p> <p>We see the following enhancers and barriers with regards to device innovation:</p> <p>Innovation enhancers primarily consist of the pressure from competition within our industry. Innovation barriers are several:</p> <ul style="list-style-type: none"> • Our own organizational set-up and management systems often block new ideas • Our position as market leader; i.e. we are caught in the 'success trap': it's too risky to change anything • Limited resources and lack of prioritization • Our culture and processes are geared to being 'mainstream' and therefore may hinder innovation • We are as an organization not willing to take risks <p>Concerning management of our portfolio of development projects, we seem to have too little early discovery activities.</p>
<p>OUR INNOVATION IN THE FUTURE</p> <p>As we see it, we could benefit from experimenting with our organizational set-up, e.g.:</p> <ul style="list-style-type: none"> • 'Sandbox approach', setting up a creative sub-unit for early innovation • Independent units like R&D satellites or incubator units, for the more radical innovations <p>Further, we think we should strengthen the project portfolio in terms of more early options, researching technologies.</p>

Table IV-6. The synthesized statements from the 10 interviews at the device management team in 2007.

Concluding on the 'dominant innovation logic' 2007

The 'dominant innovation logic' extracted here is a manifestation of the formal strategy formulation about the "*value-added pharmaceutical product*", which again summarizes the perceived business synergy between the core pharmaceutical drug and the complementary medical devices. This integrative view on the value offering could be seen as synthesis of decades of learning from swinging the pendulum back and forth between drug-based and device-based innovation strategy. Another observation concerns the longitudinal perspective. Where the innovation *strategy* for medical devices at Novo Nordisk has shifted between emphasis on either support to the pharmaceutical drug or creation of a business on its own, the 'dominant logic' of the pharmaceutical company, rooted back in the initial identity of the organization, seems robust; it is still retained in the

interviews from 2007, in the sense that devices are perceived as supportive or complementary to the overall Novo Nordisk business – no visions of making devices a business of its own are expressed. However, all interviews were conducted within one specific strategic period (the DRU period, holding a ‘back-to-basics’ strategy); I have no systematically gathered interview data from the ‘revolutionary’ periods of PDS or MSD to compare with; theoretically, the dominant innovation logic of the device managers could have been different in these periods.

Chapter 5: The “whole story” – and theory building

Content

Introduction	139
Analysis across phases – the “whole story”	140
Trends in the underlying development	140
The overall pattern in the evolution of innovation strategy	142
The drivers of change	147
Discussing theory in the light of the case study	150
The role of management cognition	150
The role of autonomous and induced strategy	152
Building new theory – in the “middle ground”	159
Strategy as a mediator between internal and external ecologies	159
Revisiting the induced strategy process: induced strategic renewal	159

Introduction

This chapter analyses the case story as a whole, across the individual phases. It also discusses the theoretical framework in the light of the empirical evidence. Based on this discussion, some proposals for building new theory are made. As such, the chapter is the result of ‘stage 4’ in the case analysis procedure prescribed by Mintzberg (2007), called ‘Theory building’.

The chapter first outlines some overall *trends* in the development of the case organization and its context, across the entire period. Thereafter, it analyzes the overall *pattern* in the evolution of device innovation strategy, and the *drivers* behind. Subsequently, specific analyses are made of the roles of respectively top management cognition and of autonomous and induced strategy, in which the theoretical framework is discussed. Finally, the chapter integrates the analysis into a revised understanding of the induced strategy process.

Analysis across phases – the “whole story”

Trends in the underlying development

The changes in the insulin industry can be described both market-wise (the demand side) and product-wise (the technological progress):

- The development of the **insulin market** unfolds two fundamental trends. The first trend moves towards perfection of the diabetes treatment, driven by the diabetes specialists' desire for better glucose control of their Type 1 patients, who depend 100% on insulin injections for their survival. The second trend takes direction towards fulfillment of the exploding demand for treatment of Type 2 diabetes patients, driven by the pandemic of Type 2 diabetes. Where the first trend calls for sophistication of the treatment instruments in order to fine-tune the glucose control, the second trend calls for simple and convenient 'good-enough' solutions for the mass market of Type 2 diabetes patients.
- Concerning the **technological trends**, there are changes driven by drug inventions as well as by the introduction of insulin devices. On *the drug side*, the invention of recombinant human insulin in 1982 was a truly disruptive invention, which made animal insulin obsolete within two decades, and which was a precondition for the ability to treat the exploding Type 2 market with insulin. In the 1990's followed the first insulin analogues, and these 'designed drugs' enabled the modified insulin molecule to establish a more stable glucose level by itself, thereby simplifying the treatment for the patient. The introduction of *insulin devices*, especially insulin pens, also changed the treatment for the patient, enabling a more convenient and flexible insulin administration. Hence, from the introduction of NovoPen® in 1985, insulin sold in cartridges for pen systems gradually took over, and from around 2002 more insulin was sold in devices than in traditional vials, globally.

The trends within Novo Nordisk's overall corporate strategy within the period 1980-2008 fall in three: 1) the shift from diversification to “core business”; 2) the efforts for performance improvement; and 3) the reorientation towards the growing Type 2 market.

1. The shift from diversification to focus on core competencies and core business followed the shift in management dogmas, which was coincident with the merger of Novo and Nordisk, leaving the company with far too broad a business portfolio.
2. The two crises – the quality crisis in 1992-94 and the financial shake in 2002 – called attention to the need for improving business performance and control systems, and several programs were successfully conducted; e.g. lean management to increase productivity.
3. The reorientation towards the growing Type 2 market came gradually, enforced by the public research studies, such as the British UKPDS in 1998, and by the failure of certain tablet treatments in the first decade of the new millennium. In many ways, this reorientation is still taking place (2012).

The overall trends in the device innovation activities of Novo Nordisk reflect the overall trends in market development, displaying paths of sustaining as well as disruptive innovation. Christensen (1997) describes the introduction of NovoPen® as a case of disruptive innovation; this characterization is based on a concept of “disruptive technologies”, as in Christensen & Bower (1996). In later work, Christensen & Raynor (2003) define the concept from a more market-oriented perspective: “A **sustaining innovation** targets demanding, high-end customers with better performance than was previously available...**Disruptive innovations**, in contrast don’t attempt to bring better products to established customers in existing markets. Rather, they disrupt and redefine that trajectory by introducing products and services that are not as good as currently available products. But disruptive technologies offer other benefits – typically, they are simpler, more convenient and less expensive products that appeal to new or less-demanding customers” (p. 34). From this definition it is clear that the market trend requiring sophistication of the instruments for fine-tuned treatment of the Type 1 patients, satisfying the wishes of diabetes specialists, calls for sustaining innovation; whereas the emerging mass market for treatment of Type 2 patients with ‘good-enough’ solutions implies a track of disruptive innovation. It is also clear that the introduction of the first NovoPen®, meant as a tool for Type 1 patients to practice the new basal-bolus treatment regimen, from the Christensen & Raynor (2003) definition was a sustaining innovation, allowing finer glucose control with small doses of insulin. Also Nordisk’s insulin pump served the high-end customer segment with their advanced needs and was seen as the ultimate solution from a technical standpoint. This sustaining track, serving the Type 1 market and the diabetes specialists with yet more sophisticated products continued to be pursued through device innovations at Novo Nordisk, adding new features, intelligence (in the electronic Innovo® device), and integration with glucose monitoring devices (the InDuo® device). Even the PDS strategy, launched 2001, with its vision about advanced closed loop solutions, continued this trend for sophistication and complexity. Devices fit well to this *sustaining* innovation path, since it’s easier to add features and performance functionality to a physical device than to a drug molecule.

However, the devices also came to serve the *disruptive* path, pursuing simple solutions to the broad segment of Type 2 patients. The devices were able to fulfill this need, because prefilled insulin pens made the insulin administration procedure much simpler. Further, as commented by an executive, the invention of ‘intelligent’ insulin analogues allowed the device to be simple; the improved glucose control was instead achieved via performance characteristics of the modified insulin molecule.

In conclusion, the device innovation activities at Novo Nordisk were caught in a dilemma between the two overall trends in the insulin market – serving the advancement and sophistication of tools for glucose control, primarily addressing the Type 1 market – versus serving the broad mass market of Type 2 with simple solutions. The solution to this dilemma was not a result of decisions by local device managers, but came out of the external development, orchestrated by corporate management. The mass market of Type 2 diabetes won, armed with numbers and business cases – but it implied a clash with the initial identity of the company (stemming from the founders August and Marie Krogh) which was tied to science and expert treatment of diabetes.

The overall pattern in the evolution of innovation strategy

If we synthesize the phases of development of device innovation strategy as analyzed in the previous chapter, the development can be defined as five overall periods, divided by the transformations of device innovation *strategy* (see empirical definition in the methodology chapter), namely:

1. The **early attempts** with medical devices at the two companies, Nordisk and Novo (1980-88), where Nordisk started with insulin pumps and Novo with insulin pens. These were entrepreneurial activities, which still lacked a formal strategy. Thus, in Burgelman's (1988) terminology, the period represents the *emergent* state; before institutionalization of strategy.
2. The strategic vision of **patient-centered homecare**, based on a **medical system**, anchored in the new Medical Systems Division (MSD). MSD was established in 1988 as a business unit, which was envisioned to establish devices as '*the third business leg*'. Devices should create revenue streams of their own – partly by selling devices such as insulin pumps, partly by manufacturing devices for other pharmaceutical companies. The activities comprised drug delivery (pens and pumps) as well as disease monitoring devices (e.g. glucose monitoring). The MSD strategy was terminated in 1992.
3. The **focusing period**, in which insulin pumps were sold off and disease monitoring projects were stalled – focus was directed explicitly at insulin pens, and devices were to support the drug business. Devices were not envisioned to create revenue streams of their own. This phase was partly evoked by the quality crisis in 1992-94, and partly by Novo Nordisk being behind competitors with regards to the insulin pipeline. Thereafter, as result of the corporate restructuring into a functional organization, the device activities in 1995 were transferred to Production, keeping the name Medical Systems (MS), without changes in strategy – focus was still on insulin pens only. This organizational setup was kept until mid 2001.
4. In 2000, the new strategic vision for **closed loop** and '**one-stop-shop**' to diabetes was conceptualized. The implementation was postponed until 2001, where Protein Delivery Systems (PDS) was established as the organizational frame for the new holistic device innovation strategy. Thereby device R&D was separated from device production, which remained under the corporate Production unit. The strategy included both insulin delivery and continuous glucose monitoring and envisioned substantial revenue streams based on devices, including complex and expensive 'closed loop' systems.
5. A crisis already in 2002 undermined the risk willingness needed for the ambitious visions of PDS, and in 2004 the continuous glucose monitoring project was terminated; but the strategy was not officially changed until 2005, where the innovation strategy returned to a '**back to basics**' mode, i.e. focus should be on insulin pens, like in the MS period. The device innovation activities were integrated into a drug research area, Diabetes Research Unit (DRU). By year-end 2008, DRU was terminated.

The strategic learning cycle of each strategic period was analyzed in the previous chapter. These cycles are depicted in figure V-1 below (as in Chapter 4, the focusing period of MS has been split in two sub-phases: the crisis 1992-94 and the 'harvesting' period 1995-2001).

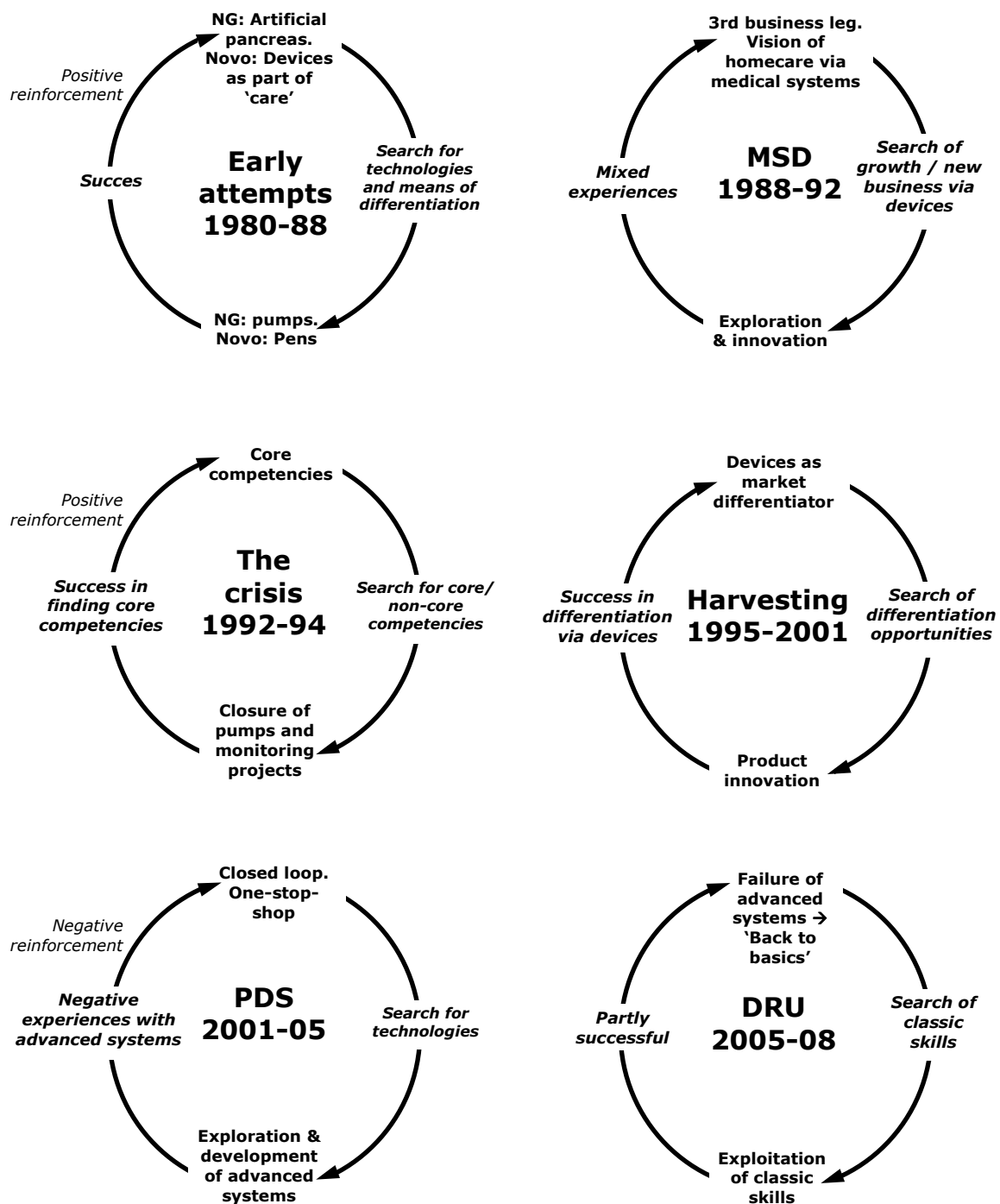


Figure V-1. The strategic learning cycles, phase by phase, as extracted in Chapter 4.

The strategic learning cycles in figure V-1 were useful in Chapter 4 for analyzing the strategy-making processes of each phase. They also provide evidence for the 'theory'-driven scenario of strategic reconfiguration, as shown in figure II-14. In the current case study, the strategic changes implied by respectively MSD and PDS did *not* begin with negative reinforcement of the existing strategy; rather,

these learning cycles were driven by forward-looking search for exploration. Such vision-driven strategic search does not resemble the normal behavioral understanding of strategy change as result of bottom-up processes.

However, these individual learning cycles are perhaps less useful for identifying patterns *across* the phases. To do so, the device innovation strategies can be classified as falling in two distinct modes:

- A. Autonomous, device-based strategy, including new business creation and a systemic or integrated approach to innovation. These strategies are ‘autonomous’, because they aim for creating new product-markets (see Definitions in Chapter 1).
- B. Induced, drug-based strategy, focused on devices as complementary to the drugs.

The result of this distinction can be seen in figure V-2.

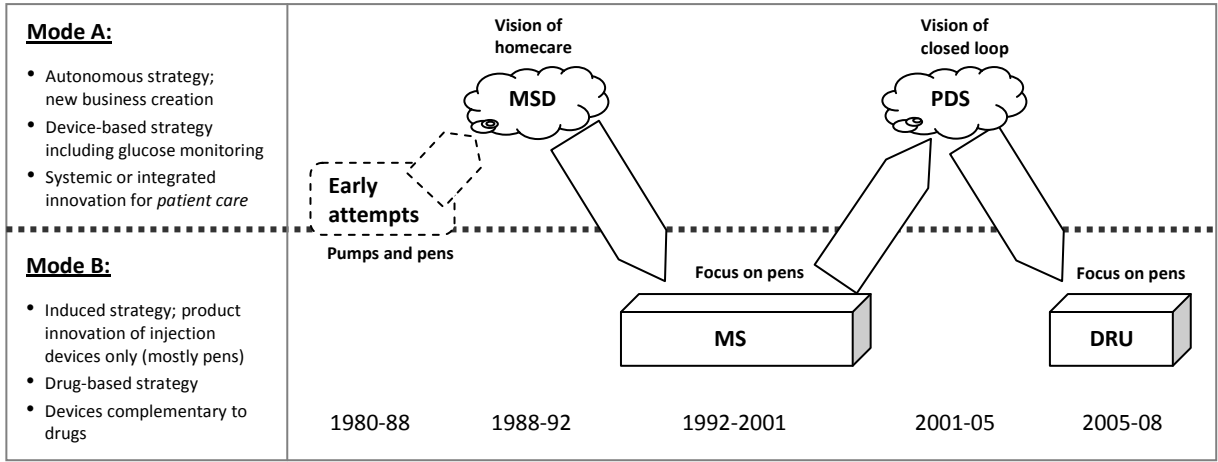


Figure V-2. A model of the development of device innovation strategy at Novo Nordisk. The ‘early attempts’ have a dotted outline, since these activities represent the ‘emergent state’ (Burgelman, 1988) – before institutionalization of strategy.

The model of the development, shown in figure V-2, of course leaves out many nuances of the strategic phases; that is the sacrifice you make in search of clarity from models. That being said, the *cyclic* nature of the development is striking. Generally spoken, one can identify the balance between autonomous and induced strategic activities in an a company at a given time – the analysis of the innovation project portfolio in Chapter 4 does so, and Burgelman & Grove (2007) do it for Intel Corporation at different moments of the company’s lifetime. Such analyses reflect a balance between autonomous and induced strategy ‘*in space*’ at a given moment. But only the longitudinal lens can provide the image of the balance between autonomous and induced strategy *over time*, as shown in figure V-2.

It is apparent that the two ‘revolutionary’ periods (MSD 1988-1992 and PDS 2001-05) aim for innovation at a more systemic level than the normal periods, which focus on the physical product itself. As put by a PDS manager: “Novo Nordisk could get a bigger share of the pie via diversification into other parts of the diabetes market. And the executive committee saw that if anybody could do this,

it was us”... “We wanted to be a ‘one-stop-shop’ to diabetes”. In such view, the physical product is one element in or component of the innovation.

The contrast between system and component has been expressed in theories on ‘architectural innovation’. This concept has been proposed at two levels of analysis. Abernathy & Clark (1985) describe ‘architectural innovation’ as follows: “*Innovation of this sort defines the basic configuration of product and process...it lays down the **architecture of the industry***” (p. 7, my emphasis). “*Using new concepts in technology to forge new **market linkages** is the essence of architectural innovation.*” (p. 10, my emphasis). In a later paper, Henderson & Clark (1990) describe architectural innovation differently: “*We define innovations that change the way in which the components **of a product** are linked together, while leaving the core concepts (and thus the basic knowledge underlying the components) untouched, as “architectural” innovation*” (p. 10, my emphasis). In Abernathy & Clark (1985) ‘the system’ includes market linkages, whereas ‘the system’ in Henderson & Clark (1990) is limited to the physical product itself. (For instance, they use an electric room air fan to illustrate ‘the system’). The two meanings of the concept are reflected in the case study at hand: the two ‘revolutionary’ periods (mode A in figure V-2) aimed for reconfiguration of market linkages, corresponding to the former definition of ‘architectural innovation’; the ‘normal’ periods (mode B in figure V-2) only aimed for reconfiguration of the product itself, referring to the latter definition. The challenges for corporate management seem to occur when the *architecture of the industry* is in play, i.e. when more elements of the value chain are included. In contrast, the architecture of the *product as a system* could be reconfigured throughout the entire period without disturbing the corporate strategy, so long as the product was defined as a system for drug injection.

The case of medical devices at Novo Nordisk to a large extent is a case of integration of a new set of complementary assets for innovation. Nordisk had a vision of making medical devices a ‘third business leg’ (beside the two drug businesses: diabetes and biopharm), so here the ambition was to make medical device competencies a core asset for innovation. Novo, in contrast, had no such visions, when they launched NovoPen®; the medical devices were seen as purely complementary assets. The start-up of the medical device activities, however, was like letting in a Trojan horse – soon, the medical device activities strived for independence and for becoming a business of its own. Both autonomous strategic waves, respectively MSD 1988-92 and PDS 2001-05, made the attempt to establish medical devices as the ‘third business leg’. These cycles of innovation strategy show that the distinction between core and complementary assets for innovation is dynamic and negotiable, not static.

The potential implications of the two ‘revolutionary’ strategies were profound, had they been realized; the consequences would have reached far beyond the device area alone. Why did corporate management at all let the medical device activities try to escape the role as complementary enhancers of the pharmaceutical drug? Well, perhaps it was exactly *because* the medical devices were seen as complementary assets that the corporate ‘immune system’ was not provoked – had medical devices from the outset been seen as a new business area, the corporate filtering mechanisms would perhaps have been more alert. The ‘camouflage’ as complementary assets made the experimental

strategies slip through the filter – since the strategic experiments were not perceived as a threat to ‘core business’. A veteran device manager said: “*“Why we succeeded with the only radical innovation ever in Novo Nordisk – the NovoPen® – ‘well, it sounds like a good idea, and it doesn’t really cost anything, and some 7,000 patients might benefit from it, why not try it’. So, in reality it was because we started in such small scale and with so small consequences for the firm that it didn’t really matter... it was so manageable and easy to oversee that it just slipped through. Management stalls if it something is so big that you risk the whole enterprise”.*

This context of integration of complementary assets differs from Burgelman’s research. Burgelman (1991) described the intra-organizational ecology of established and emerging *businesses*: in case, the established memory business and the emerging microprocessor business at Intel Corporation. The case of Novo Nordisk it not about two competing businesses, but about integration of some new complementary assets for innovation, which then repeatedly are utilized for visions about establishment of new business areas. Even though the two case contexts differ, the integration of new complementary assets for innovation at Novo Nordisk seems to generate managerial challenges just as serious as the integration and portfolio management of new business ventures, as demonstrated in the case of Intel. Still, the challenges are different. Where the management of alternative businesses requires portfolio management competencies, then the management of dynamics between core and complementary assets for innovation requires integrative competencies (Christensen, 2006).

It’s interesting here that throughout the entire period of the case study at hand, devices and especially utensils like injection needles have in fact have created revenue streams, which – seen in a Danish context – are substantial. However, within the normal (drug-centered) strategic periods, this income is not seen as *business* – it is not accounted for separately and there’s not made a profit and loss account for devices¹⁶. In other words, the actual value creation has existed ever since the introduction of insulin devices, understood as revenue streams; but these revenue streams only became explicit elements of the strategy within the autonomous periods, where the income from the medical devices and utensils for these was part of the *strategic framing*. This fact elucidates the role of cognitive frames in strategy.

The development of innovation strategy, as shown in the model of figure V-2, is the result of change processes, evoked by different drivers of change. We shall now turn towards these drivers; i.e. the events and processes of change behind the strategic transformations.

¹⁶ At least, if such accounts exist, they are not communicated in the organization.

The drivers of change

Based on the analysis in Chapter 4, table V-1 synthesizes the events and processes behind change in innovation strategy, transformation by transformation, divided into external and internal drivers ('drivers' understood here as events and processes).

External drivers are split in

- a) Industry or market trends
- b) Technological discontinuities
- c) Competition
- d) Externally evoked crises.

Internal drivers are divided into four dualities:

- e) The origin of the strategy: stemming from forward-looking cognition or back-ward looking experience.
- f) The 'gravity' towards the established strategy: does the strategic initiative stay *within* the established strategy = **induced** strategy, or does the strategic initiative explore new product-markets, *outside* the established strategy = **autonomous** strategy?
- g) The integration of devices: are medical devices seen as **core assets** for innovation, to create a business of its own – or as **complementary assets** for innovation, to support or enhance the sales of the pharmaceutical drug?
- h) The actor: is the change process driven by **top management** or **bottom-up**, i.e. organization-driven?

Like the model in figure V-2, the scheme in table V-1 does not capture all details, which were analyzed in the previous chapter, but provides an overview. For each strategic transformation, I have emphasized the most salient drivers of change.

Drivers of change of innovation strategy – transformation by transformation									
Strategic phase (year of start)			1) Early attempts with medical devices		2) MSD: vision of homecare (1987-88)	3) MS: focus on injection pens (1992)		4) PDS: vision of closed loop (2000-2001)	5) DRU: back to basics (2005)
			Nordisk (1980)	Novo (1981)		Crisis (1992)	Harvesting (1995)		
External drivers	Industry or market trends		Diabetes specialists discuss artificial pancreas and pumps					Vertical integration tried out (e.g. Lilly buys a distributor)	Cancer risk by tablet treatment → renewed focus on insulin
	Technological discontinuities		Recombinant insulin (1982)					Continuous Glucose Monitoring (1999)	
	Competition		Eli Lilly 1982: recombinant insulin (in development from 1976)			Competitors ahead in insulin pipeline	Pharma giants interested in diabetes		Fierce competition on insulin pens
	Externally evoked crises					FDA critique → GMP crisis			Financial shake 2002 + failure of tablet project
Internal drivers	Origin	Cognitive search (forward-looking)	Seeing pumps as opportunity	Broader goal of ‘care’ + analyzing pumps as opportunity	The vision of patient-centered homecare	Need to focus on ‘core competencies’	Wish for staying independent as company → corporate focus strategy	Desk analysis → vision of closed loop and ‘one-stop-shop’ to diabetes	
		Experience-based search (backward-looking)	(Learning from first pump – building up in-house competences)	Learning from Diagnostics + (Trying out pens – impact not foreseen)	Building on positive experiences with pens and pumps. Learning on the way.	Mixed results of MSD strategy	Success in finding core competencies		Learning from mistakes (problems with advanced devices + delay in classic insulin pens)
	Gravity towards established strategy	Autonomous (exploration outside)	Pumps as new business = revenue generator	Pens announced as a new paradigm	New business unit for devices as a ‘third business leg’			Creating new business – ‘value upgrade’ of market	
		Induced (expanding within)	(Pumps expand insulin business)	Pens as market differentiator		Focus on classic strategy – devices seen as market differentiator	Continued		Classic strategy: ‘back to basics’
	Integration of devices	Devices core assets	Pumps as new product		Devices core, as a ‘third business leg’			Devices core for new business / ‘value upgrade’	
		Devices complementary assets	Pumps expand and support insulin business	Pens as a marketing tool	Complementary assets, serving drug divisions with injection devices	Devices only seen as support to drugs	Continued		Devices seen as ‘value-adding’
	Actor	Top management	Top (CEO)	Top (marketing executive)	Top (NG CEO)	Top (executive committee)		Top (Operations)	Top (executive committee)
		Organization (bottom-up)			Local MSD management		Relative freedom (outside radar of top management)		

Table V-1. Synthesized overview of the drivers (i.e. events and processes) of change of device innovation strategy at Novo Nordisk, transformation by transformation. Based on the analysis in chapter 4, the key drivers are identified and marked here as emphasized and underlined.

The pattern which emerges is:

- The first entrepreneurial initiatives with medical devices (early attempts, 1980-88) were driven by *external events*: the discussion amongst diabetes experts on making an artificial pancreas, and the market introduction by Eli Lilly of recombinant insulin.
- The MSD strategy implemented 1988 was driven by *internal processes*: top management *cognition* (the vision of patient-centered homecare) and *autonomous* strategy.
- The retreat from the MSD strategy in 1992 was driven by *external events*: FDA's criticism leading to the quality crisis, and competitors being ahead of Novo Nordisk with regards to the insulin pipeline.
- The next transformation, implemented with PDS in 2001, was driven by *internal processes*: top management *cognition* (the vision of closed loop) and *autonomous* strategy.
- The gradual withdrawal from the PDS strategy, ending in 2005, was driven by *external* events: the financial shake in 2002 combined with increased competition on insulin pens.

Interestingly, the pattern in this case study clearly shows that strategic 'revolutions', which differ from the established strategy and from the underlying dominant logic (Prahalad & Bettis, 1986), are result of a process where *top management cognition* creates autonomous strategy. In contrast, the retreat from these 'mode A' periods (see figure V-2) is defensive; caused by externally evoked crises. In conclusion, the formula extracted from this case study goes: *Top management cognition drives the strategic renewal; external events drive the strategic retreats.*

I have modeled the overall evolution in figure V-3 below.

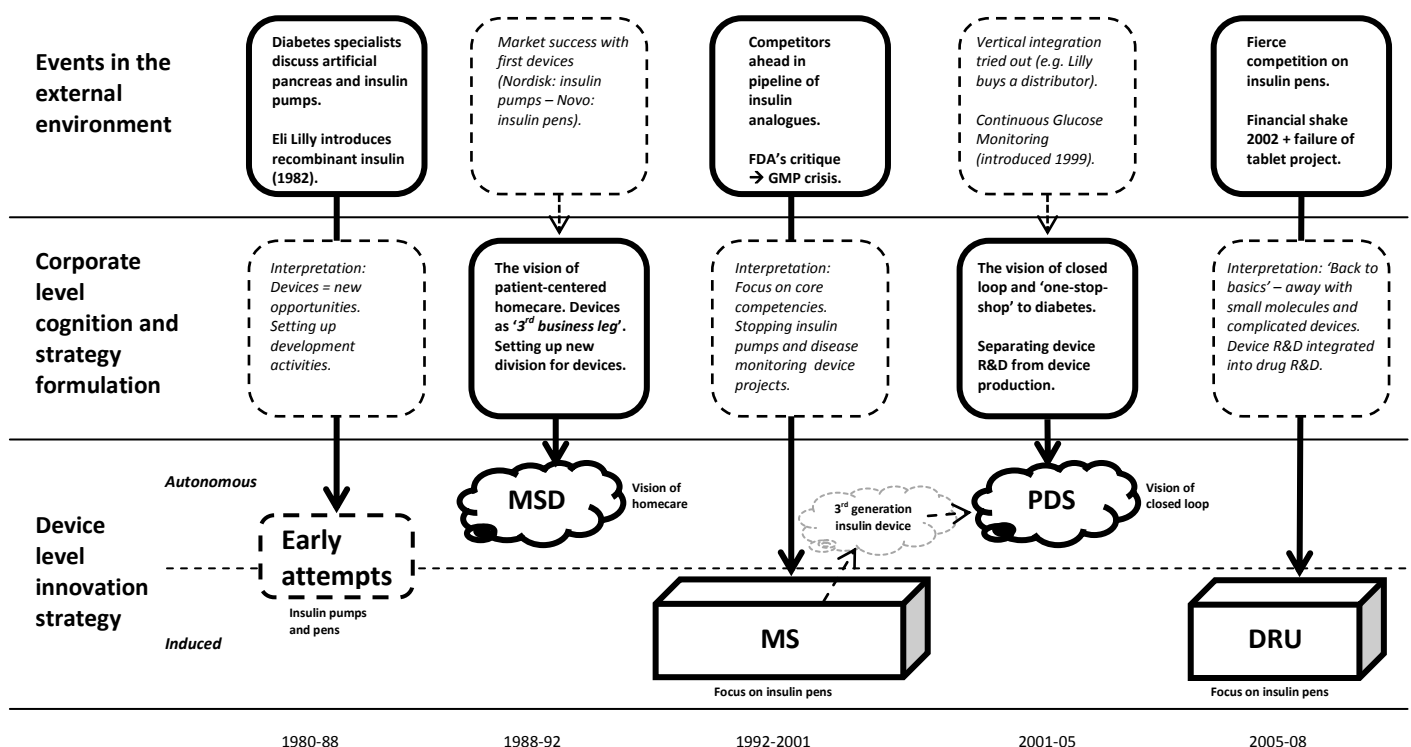


Figure V- 3. Model of the evolution of innovation strategy of medical devices at Novo Nordisk, displaying the most salient external and internal drivers of change and their resulting innovation strategies.

Discussing theory in the light of the case study

The role of management cognition

The development in the present case study displays a cyclic pattern, unfolding two waves of institutionalized, yet autonomous innovation strategy based on devices (the 'mode A' waves in figure V-2: MSD 1988-92 and PDS 2001-05). In both cases these autonomous waves lasted about 4 years, after which the innovation strategy was turned 'back to basics', i.e. the traditional drug-centered strategy. The two autonomous waves were first and foremost initiated as result of top management cognition and forward-looking search, and thereby the case differs from the widespread behavioral view on top management cognition seen as a filtering mechanism, which unfolds cognitive inertia and hinders strategic renewal. In the case of Novo Nordisk, top management driven cognitive search had a clearly *entrepreneurial* role by initiating the two autonomous waves – until the crises occurred, where the filtering mechanisms came into play. The autonomous strategy waves thereby counteracted the forces of 'co-evolutionary lock-in' (Burgelman, 2002).

In what sense did the autonomous strategies of MSD and PDS then differ from the established strategy? Here, we must look all the way back to the initial identity of the company in the 1920's, rooted in science and medical treatment of diabetes with the newly discovered insulin. In general, the *dominant management logic* (Prahalad & Bettis, 1986) of a company is built by positive reinforcement of successful activities. In the case of Novo Nordisk, this positive reinforcement led to the logic of a pharmaceutical company, based on manufacturing of pharmaceutical drugs, primarily insulin. In the 1970's, Novo changed the overall espoused goal from world leader in insulin manufacturing to world leader in diabetes care. The term "diabetes care" covers treatment services, disease monitoring and many other things beyond the pharmaceutical drug itself – the drug is just one component of the value chain of *care*. Hence, the goal of being a leader in "diabetes care" should in theory open the business for many more areas than insulin manufacturing. However, it does not seem as if the corporate dominant logic *ever* took the shift in system level from insulin manufacturing to diabetes care; at least, the only business attempts to realize the higher system level vision of 'diabetes care' were exactly the two device-based innovation strategies of MSD and PDS. These strategies contradicted the pharmaceutical dominant logic by not setting the drug in the center of the business. Consequently, these strategies were fragile – and at each externally evoked crisis, the corporate strategy bent back to the safe 'fetal position', focused on the pharmaceutical drug itself. The dominant logic thus seems deeply rooted in the internal identity (Tripsas, 2009) of the firm. Even in 2007, where I conducted the interviews at *device* management level, the extracted dominant logic was pharmaceutical; not device-based or 'diabetes care'-oriented. The pharmaceutical business logic and internal identity seem to form both the starting point and the 'safe harbor' of the company, in case strategic experiments fail. This observation reflects the equilibrium theory of the dominant logic, formulated in Bettis & Prahalad (1995). If we apply their analysis as shown in figure II-10, neither of the two autonomous strategic waves at Novo Nordisk (respectively the MSD and the PDS

strategy) achieved momentum enough to escape the gravity of the dominant logic before the two crises started the process of retreat. In both cases, the strategic visions were never fully implemented; partly because the needed product systems could not be developed within the available timeframe of four years. When external crises then reduced corporate risk willingness, the inherent uncertainties of these explorative ventures made corporate management withdraw from the autonomous, device-based strategies. One should also consider the observation from Prahalad & Bettis (1986) that the more successful a company has been, the more difficult it is to unlearn the dominant logic (p. 498). Novo Nordisk had indeed been very successful in the insulin industry, and consequently it was more difficult to change the prevailing paradigm of thinking. Imagine what it would have taken to make corporate management implement for instance the PDS strategy corporate-wide. Corporate management would have had to reformulate the strategy towards a device-based or systemic business strategy, based on complex treatment solutions, in which the drug was seen as one of many components in the total product offering. Such dramatic move would have required an immense success of the PDS strategy, implying revenue streams at least of the size of the revenue from the drugs. In other words, the envisioned 'value upgrade' of the market should first have proven to be viable. One can compare to Intel Corporation, where the official strategy was not changed from memory to microprocessor business until the microprocessor business had climbed to app. 75% of the corporate sales (Burgelman, 1991). This strategic inertia at Intel was partly a result of an internal identity, which was closely tied up with the memory business (Tripsas, 2009). If we return to Novo Nordisk, you should remember that an important element of the autonomous, device-based strategies of MSD and PDS was the inclusion of glucose monitoring products. Even though glucose monitoring devices are needed in diabetes care, these devices do not directly support the sales of insulin, and they were seen as alien to the corporate 'DNA'. For example, one veteran device manager told me that an executive manager had commented the inclusion of glucose monitoring devices back in the MSD period with the words: "*take that crab out of the portfolio!*". This resistance is caused by the history: glucose monitoring products were not a part of the original pharmaceutical identity and had not been part of the learning cycles, which created the corporate dominant logic. Hence, strategies building on inclusion of glucose monitoring products required a 'far move', as described by Bettis & Prahalad (1995), in order to succeed in escaping the established dominant logic (cf. figure II-10).

The reader might here make the objection to my analysis that the destiny of the two autonomous strategic periods (MSD and PDS) was instead result of lacking *organizational* plasticity, which characterizes mature companies, according to Gavetti & Rivkin (2007). However, the organization of Novo Nordisk *did* in fact adapt to the new strategies: new organizational structures were built, substantial new competencies were acquired and integrated, and new innovation projects were set up. So the 'structural context determination' (Burgelman, 1991) was in place; and still the new strategies failed, because the corporate dominant logic pulled the strategy back to the safe harbor, whenever external events threatened the 'core' business.

The role of autonomous and induced strategy

In 1980, both Novo and Nordisk were mature companies, which had dominant positions within the 59 years old insulin market. Thus, their management systems and business strategies were in place, and their industry was relatively stable. This starting point is very different compared to the organizations, which Burgelman (1988, 1991) builds his empirical research on: respectively internal corporate venture units in large firms (Burgelman, 1988) or Intel Corporation in the 1980's, which had been established in 1968 (Burgelman, 1991). Not only is there a difference between a 55 years old versus a 15 years old company, but also the two industries (the pharmaceutical industry versus the young IT industry) are very different. Consider Gavetti & Rivkin's (2007) analysis, which characterized young companies and especially young industries as typically dominated by action-based strategic search, whereas mature companies and mature industries were more likely to display cognition-based strategic search. For the 15 years old Intel in the young IT industry, it is therefore not surprising that the strategy making was marked by experimental initiatives growing from beneath in the organization – which is Burgelman's classic description of autonomous strategies. For the case of Novo and Nordisk in 1980, the institutionalization of corporate strategy took place long ago, and therefore the starting point was two companies with top management driven induced strategy processes. Following Burgelman's (1991) model of internal ecology of strategy making, new business ventures would in such case first be conceptualized locally, driven by middle managers. After series of successful experiments, the new ventures would be promoted for selection by top management, eventually to be integrated in the induced strategy – vision '*ex post*', top management cognition in retrospect, after local experiences. This was *not* what happened with the medical device activities at Novo Nordisk. In contrast, the new explorative initiatives were the result of top management cognition. Both the MSD (1988-92) and the PDS (2001-05) strategies were formulated with ambitious business creation visions '*ex ante*', before implementation of the strategies began. In the case of PDS, we are even able to track the birth of the strategy to a particular workshop for top managers within Operations in the summer of 2000, being worked out in detail over the subsequent half year; but the implementation was delayed for financial reasons until the summer of 2001. The strategy did not reflect 'retrospective rationalization' (Burgelman, 1988), but was rather proactive analysis and anticipation of novel opportunities. For both MSD and PDS, the retreat from the experimental strategy was also driven by top management, as reaction to external events. These retreats resemble what Burgelman (1991) labels 'reorientation'.

The MSD and PDS strategies were both *autonomous* in the sense that they explored new product-markets; however, they still were top management driven. The strategy-making process and the way to strategic change therefore seem very different to the processes modeled by Burgelman (1988, 1991). In the sense that the 'revolutionary' strategies at Novo Nordisk were *deliberate*, vision '*ex ante*', they resemble Burgelman's (1991) analysis of induced processes. Consequently, we could say that in the case of Novo Nordisk, the strategic experimentation was an integrated part of the induced strategy *process*. This analysis defines another role for induced strategy than modeled by Burgelman

(1991). Where the induced strategy process in Burgelman (1991, 2002) has the overall role of *selection and retention*, the induced strategy process in the case of Novo Nordisk also holds the role of *strategic variation*. Via top management cognition, the induced strategy process mediates between the external and the internal ecologies: when top management cognition anticipates novel opportunities inspired by events in the environment, corresponding new strategies for innovation are envisioned, the internal organization is set up, competencies are acquired and projects are initiated. When the projects fail, or when external events force top management to rethink the whole situation, then the strategic experiments are stopped, and the innovation strategy is turned back to 'normal mode'. In this sense, induced strategy is far less 'institutionalized' than in the analysis of Burgelman (1988, 1991). In fact, induced strategies with their vision 'ex ante' can be seen as *hypotheses*; thought experiments, which are tried out for real.

Burgelman (1991) recognizes the existence of *variation* created by induced processes, but this phenomenon is described as far more constrained than the creation of the strategies for MSD and PDS: "*Of course, this does not imply that there is no planned variation in the induced process. Clearly, there is room for core technology advances, new product development for **existing** product families, new approaches to marketing and manufacturing and so on*" (p. 246 – my emphasis). This characterization does not correspond with the revolutionary characteristics of the two strategic waves at Novo Nordisk.

Should we instead, in the terminology of Burgelman (1991), understand the two 'revolutionary' waves at Novo Nordisk as top management driven autonomous strategy? Burgelman (1991) mentions this possibility – however, the concept has no real role in his internal ecology model. In fact, Burgelman (1991) states: "***strategic renewal – major strategic change preceded by internal experimentation and selection – is the critical outcome of the autonomous process***" (p. 255 – my emphasis) and "*Autonomous initiatives can originate at all levels of management. But they are most likely to emerge at a level where managers are directly in contact with new technological developments and changes in market conditions, and have some budgetary discretion*" (ibid, p. 246). Also, Burgelman (1988) clearly describes the creation of new strategies in the emergent state as driven from beneath in the organization, step by step finding resonance at yet higher management levels, as the new ventures gradually succeed. Further, the *labels* used by Burgelman contradict the phenomenon of top-driven autonomous strategy: the semantics of the label "autonomous" indicate something which emerges independently or bottom-up. By contrast, only top management has the power to "induce" strategies into the organization. So semantics alone lead the use of the labels 'autonomous' and 'induced' strategy away from Burgelman's (1991, 2002) explicit definition, which is linked to the *content* of the strategy (respectively outside or within established product-markets). Instead, the semantics lead towards the more widespread use of these labels in literature (and even in Burgelman's own texts); namely linked to the origin of strategy as top-down versus bottom-up. Since this interpretation of the concepts is essential, I shall analyze the parameters for characterizing a specific strategic venture further.

As described in Definitions in Chapter 1, three parameters must be in play in order to characterize a strategic initiative as either induced or autonomous. The normal distribution of these parameters in Burgelman (1991, 2002) is such that *autonomous strategy* per definition explores initiatives outside the current strategy, is typically driven by local managers and follows a learning-from-experiments process (vision 'ex post'). In contrast, *induced strategy* per definition expands the current strategy, is driven by top management and follows a cognition-based process (vision 'ex ante').

Compared to Burgelman's normal characterization of autonomous and induced strategy, the 'revolutionary' strategies of MSD and PDS at Novo Nordisk explored business opportunities outside the current strategy, and hence *in content* (and per explicit definition) were autonomous strategies; however, at the two other parameters, they reflected the traits of induced strategy *processes*, being top- and theory-driven. Consequently, it is fair to identify these strategic initiatives, which originated within a mature corporation holding an institutionalized strategy, as part of the *induced strategy process*. Thus, I propose to label them *induced strategic experiments*. Such *induced strategy making process*, which aims for *strategic renewal*, is not present in Burgelman's model of internal ecology of strategy making (Burgelman 1991, 2002). The most radical of the induced modes of adaptation in Burgelman (1991) is 'reorientation', in which major changes in strategy follow as response to threats or crises – this phenomenon is seen in the present case study at the two strategic retreats in respectively 1992 and 2005. However, the proactive establishment of MSD and PDS does not resemble 'reorientation'. Compared to the evolutionary school of thought on strategy making, the case of innovation strategy for medical devices at Novo Nordisk represents an anomaly.

The difficulties of defining the strategic transformations at Novo Nordisk as either autonomous or induced may have to do with the very wide use of these concepts in Burgelman's framework. Sometimes the concepts 'autonomous' and 'induced' label concrete *initiatives* or projects (Burgelman & Grove, 2007), sometimes they label corporate *strategies* per content (Burgelman, 2002) and sometimes they label strategy making *processes* (Burgelman, 1991). This wide use may create confusion, since the induced *process* is characterized as vision-ex-ante, whereas the induced strategy *content* is defined as exploitation of established product-markets – this leaves no room for an explorative, yet vision-ex-ante strategy process.

Does this imply that we are back to understanding Novo Nordisk's strategy-making in a rational choice perspective such as in we find the positioning school? – I don't think so – for two reasons: First, there's the methodological reason. Rational choice theories are not concerned with the *process* of strategy formation – their focus is on variables and outcomes, in a *variance theory* tradition (Van de Ven, 2007). That makes the rational choice paradigm barren soil for cultivating a theory on the *evolution* of innovation strategy, which is the objective of the present research.

Second, the long-term storyline of the case study speaks against a pure rational-choice perspective. Each strategic transformation was surely driven by top management out of 'ex ante' vision; but if we take a longitudinal look at the evolution of the innovation strategy, then there certainly was no deliberate 'master plan' for this evolution. There was no 'vision ex ante' behind the evolution seen

over extended time. So, in a *longitudinal* perspective, the evolution represented trial-and-error. A rational-choice perspective does not necessarily exclude trial-and-error; for example, Lucas (1986) identifies a role for trial-and-error in the formation and change of the underlying rules and preferences, which guide the individual decisions. “Rational” is not opposite to “adaptive” in his view. Still, if we look for theories which analyze *how* the underlying rules and preferences (in case: the underlying strategic intent) change over time, then evolutionary theory on strategy making explains these *change processes* most directly.

Consequently, I have applied evolutionary models of strategy making in the current research project; but I need stronger emphasis on the *reasoning* aspect of strategic search, in order to understand the empirical evidence. In the case study of Novo Nordisk, the strategy making is theory-based, in the shorter time perspective – but still undergoing trial-and-error, in the longer time perspective. This duality comes into play, because the individual strategic visions are not written in stone, like the tablets of Moses; rather they are *hypotheses*, which are subject to learning from experiments over extended time. The case of Novo Nordisk displays several examples of top management reasoning, which illustrate this *hypothetic* nature of the theory-based strategic search:

- The executive informant openly talked about the strategic learning from the failed experiments with Novo Diagnostic Systems (my emphasis):
 - “This taught me two things: first of all ... – [Why did you then acquire this company?] – That was also a wrong decision. But we were looking for opportunities for growth, you know. ...You can say that the reason we jumped into it was the aspiration for new opportunities – and then an analysis, which was insufficient, due to lack of expertise”. (See full quotation in previous chapter).
 - This statement illustrates that even such a serious decision as the acquisition of another company and the following attempt to build up a new business can be interpreted as a thought experiment or hypothesis, which is subsequently tried out in reality.
- The entrance into inhaled insulin was explained by executives as a defensive move, because other pharmaceutical companies were pursuing this track – in other words, the initiative built on the hypothesis: ‘*In case competitors succeed, we had better be prepared...*’
- Similarly, one of the explanations for the establishment of PDS was to see PDS as a defensive move, *in case* other companies would succeed with continuous glucose monitoring and closed loop: “*If they succeeded, then we could risk getting reduced into suppliers of this muddy liquid, which was inside the pumps and devices, which were controlled by others*”.
- The above examples display cognitive visions, which were implemented for a period of time and then withdrawn. There is also an example of a vision, which remained a vision, because the 2002 crisis changed the whole view: “*...with some vision one could imagine the company from 2000 develop into a device company, a diabetes company and a biopharm company. ... one could imagine that it would attract different types of investors...With PDS there was an*

ambition that we could sell our device knowledge and make it commercial to other companies. We believed that we were world champions within devices, so there ought to be somebody who could make use of this. One should also not exclude that we would actually learn something from working together with partners". The hypothesis about establishing a separate company based on the medical device competencies was not realized; even though PDS was launched, representing the first step in the realization of the vision.

- The establishment and especially the later termination of PDS were also partly explained by the hypothetical nature of the strategy: "*we were engaged in much more complicated devices, which we from desk analysis thought would be fantastic*"... "*it was too much 'blue sky' – we were too optimistic, we believed the solutions were just around the corner*"... "*the dream about the role as system integrator died*"... "*The PDS visions were like romantic dreams*".
- When asked if he regretted PDS, an executive informant amongst others stated: "*I think it also created some thoughts at corporate management that this [device] innovation needs attention. It should not just be an appendix to the drug; it is in itself a differentiating factor. So I don't think PDS lived in vain*". The executive here explicitly mentions the strategic learning.
- Again, we should not forget that the visions and strategies behind the establishment of PDS were both initiated and endorsed by top management. It was not an autonomous initiative from beneath, which slipped through the 'filter'. On the contrary, it was a top-driven induced strategic process formulating the vision 'ex ante'.

The current case analysis suggests an *induced* strategy making process at incumbents, which *experiments* with alternating innovation strategies over extended time, unfolding several lifecycles of strategy, which are launched and implemented as *hypotheses*, to be subject to learning. This understanding identifies an underresearched, entrepreneurial role of the induced strategy making process, in which top management cognition leads to strategic renewal instead of strategic inertia. Seen in contrast to the 'internal ecology model' (Burgelman, 1991), the present case study provides evidence for an alternative way of creating strategic variation *over extended time* within the setting of the 'steady state' (Burgelman, 1988) – i.e. after institutionalization of strategy: namely via vision-driven, yet explorative experiments.

The difference in the strategy making processes at Novo Nordisk analyzed here related to Burgelman's analysis (1991, 2002) of Intel Corporation might have to do with different units of analysis: Burgelman deals with general business strategy, whereas the present study analyzes the development of *innovation strategy* for complementary products. Burgelman's corporate perspective partly overlaps with innovation strategy: the emergence of the microprocessor business at Intel was surely a result of innovative activities. However, Burgelman (1991) primarily analyses how the microprocessor business gradually takes over from the memory products as the main business. This is a case study of the competition between two **business areas** (which both are established with each their customers) about the role as 'core strategy'. If we define innovation strategy as '*the strategy for the individual innovation activities with the objective to **create** product or business innovations*', then

an analysis of the evolution of the **innovation strategy** would focus on the much earlier development, in which the vision of developing future microprocessor products competed with other visions for alternative innovation activities. If we relate to my case study: the visions about developing glucose monitoring products and create substantial business hereof never made to the launch of a product – no business was ever established. Still, alternative innovation strategies (respectively device-based and drug-based) competed for becoming the core innovation strategy, just like different business areas competed on becoming the core business in the Intel case. In general, business strategies aim for growth; innovation strategies aim for growth via creation of future innovations. Consequently, one can say that the innovation strategy of a corporation is per definition experimental, even in a mature company. Hence, the corporate induced strategy process can hold the innovation strategy as an explorative or variation creating branch; a kind of strategy laboratory. When the case then also concerns complementary products, as for example medical devices at a pharmaceutical company, then the innovation strategy becomes more loosely coupled to the core business; therefore such strategy is perhaps even more likely to be perceived as means for strategic experimentation, seen from a corporate management perspective.

To conclude, the induced strategy process under certain circumstances may unfold vision-driven explorative strategic experiments as part of the evolvement of innovation strategy, which do not resemble the modes of induced adaptation as described by Burgelman (1991). These boundary conditions could be: a mature organization with an institutionalized corporate strategy, which via the innovation strategy experiments with the integration of complementary assets for innovation. Was the choice of Burgelman's internal ecology model then at all appropriate for the present research project? – Yes, because Burgelman's theory provided the best match to the *empirical case study* as well as to the overall *research question*. For the empirical case study, the concepts of autonomous and induced strategies gave meaning to the narrative I was constructing about the two modes of innovation strategy (see Figure V-2). Furthermore, Burgelman's framework was the most direct and internally consistent theoretical reply to my research question "*How does innovation strategy evolve?*" – we just need to take away the word 'innovation'. In Chapter 2, I identified some gaps with regards to the present case study, namely:

1. It remains open, whether the theory can explain the evolution of **innovation** strategy
2. Burgelman (1991) deliberately chooses an intra-organizational perspective, which puts little emphasis on the influence of external dynamics
3. Strategic variation in the induced strategy process is limited to 'reorientation', which terms reactive responses to changes in the environment. Strategic *renewal* is only seen as coming from the autonomous process.
4. Managerial cognition is mentioned, but has no central role in the internal ecology model.

The present case study has sought to fill out some of these gaps:

- When studying innovation strategy of a mature, knowledge-intensive company in a relatively stable environment, induced (vision-ex-ante) strategic experiments seem to be more salient as drivers of strategic renewal than autonomous initiatives.
- The external environment has vast impact, especially on strategic retreats – which resembles what Burgelman (1991) terms ‘reorientation’ of strategy
- Top management cognition plays an important role for both proactive search (via formulation of strategic visions) and for the gravity of the induced strategy (via the settled dominant logic).

The internal ecology model therefore provides a solid theoretical foundation, which can be expanded in order to explain the evolution of *innovation strategy* in a context of a mature, knowledge-intensive company.

Building new theory – in the “middle ground”

Strategy as a mediator between internal and external ecologies

The positioning school in strategic management theory (e.g. Porter, 1980) obviously has a strong orientation towards the external environment; focus is on the position of the company compared to competitors, suppliers, customers and other stakeholders. In contrast, the evolutionary school of thought is more focused on the internal environment – Burgelman's theory of '*intra-organizational ecology of strategy making*' (1991) is the principal example. The present case study builds on Burgelman's theory; however, external drivers seem at least as powerful as the internal drivers for the evolution of innovation strategy at Novo Nordisk. The pattern of evolution, which was extracted in the previous sections of this chapter, was that internal processes (first and foremost top management cognition) drove strategic renewal; whereas external events (competition and crises) drove strategic retreat.

The case study at hand elicits the induced strategy process as a mediator between internal and external ecologies: Towards the internal ecology, induced strategy is a selection-retention mechanism, just as analyzed in Burgelman's internal ecology model (1991). Towards external ecology, induced strategy is a variation-creating mechanism: it experiments with alternating innovation strategies, shifting between modes of exploration and exploitation (March, 1991), over extended cycles of innovation strategy. Through such learning cycles, the induced strategy process demonstrates plasticity in two dimensions:

- Towards the internal ecology via 'strategic context determination' of autonomous initiatives (Burgelman, 1991)
- Towards the external ecology via cycles of interception of changes in the environment, interpretation and strategy formulation, enactment of new strategies, interception of the response in the market and so forth.

Revisiting the induced strategy process: induced strategic renewal

Gavetti & Levinthal (2004) propose a new paradigm of strategy research based on the evolutionary school of thought, to be developed in the direction of rational choice perspectives. This requires evolutionary theory to overcome its narrow focus on organizational routines as the "DNA" of the company, which to a large extent excludes deliberation and cognition. Furthermore, according to Gavetti & Levinthal (2004), the traditional evolutionary view also is biased towards seeing routines and capabilities as developing "from below" in the organization, and the authors therefore suggest to "*pay more attention to the linkages across actors within the organizational hierarchy*" (p. 1315). Burgelman's 1988 article on "*Strategy making as a social learning process*" is interesting here, seen as research in the 'middle ground', because it explicitly analyzes the strategy-making process as interplay between action and cognition, which unfolds throughout the hierarchical levels. However,

Burgelman (1988, 1991, 2002) still sees strategic renewal only as coming from beneath in the organization, based on local experiments.

Burgelman's bias towards the behavioral perspective on strategic renewal may stem from the analysis of limited rationality and biased cognitive representations, going back to Simon (1955). One could instead apply the understanding proposed by Nelson (2008): 'bounded rationality' is ability to *reasoning* (making a 'crude' theory) as well as to *learning from trial-and-error* (to adjust or renew the theory). In this understanding, deliberate strategy is not only about control, as phrased by Mintzberg: "*If deliberate strategy is about control, then emergent strategy is about learning*" – (Mintzberg, 2007, p. 5). To contrast Mintzberg's statement, one could quote Porter (1991): "*the task of strategy is to maintain a dynamic, not a static balance*" (p. 97). In other words, deliberate strategy is *also* about learning.

Burgelman (1991) actually describes induced strategic learning cycles: after launch of a new induced strategy, a learning cycle begins, which identifies the basis for success in the market and integrates this learning into the vision (table 1, p. 254). This learning has the purpose to substantiate and strengthen the strategy, and Burgelman (1991) consequently sees it as the *retention* part of the induced strategy. The strategic renewal (the basic *variation* process) took place *before* this retention oriented learning. In fact, Burgelman (1991) states "*Induced initiatives allow managers to propose projects that **take advantage of the available organizational learning***" (p. 250) and "*In this [induced strategic] process, intentional strategy may serve the organization **to leverage – do as much as possible with – its currently available learning***" (p. 249) (my emphasis). So the induced strategic learning in Burgelman's analysis is a mainly matter of exploitation; not exploration (March, 1991). The analysis in the present case study discloses a different kind of strategic learning. The yet hypothetical innovation strategies are enacted for learning in the market as *part* of the creation of strategic variation. The process is induced, driven from top management; but still displays trial-and-error learning in the external environment, as suggested by Nelson (2008).

Let's look at PDS (Protein Delivery Systems, 2001-2005) as an example. Corporate managers from Operations formulated the vision about 'closed loop' systems in the summer of 2000. Over the next half year, corporate managers worked out strategic plans for realizing the vision, supported by external consultants and later also by selected managers from the device area. In the summer of 2001, the funding was released and PDS was established by separation of device R&D from device Production. Substantial new resources were hired in (adding app. 50 employees to the existing app. 80 employees; plus the integration of a drug formulation area). Executive management saw great corporate perspectives for the new innovation strategy of PDS – it was envisioned to lead to a revenue stream potentially as large as the insulin business and eventually to the establishment of an independent device company. However, as noted by Gavetti & Levinthal (2000): "*the wholesale shift in behavior driven by a new cognitive representation may result in a tremendous loss of experiential wisdom*" (p. 134). Remember that the PDS strategy was formulated by corporate managers outside the device area and was partly met with skepticism from the device managers. The vision was not

rooted in experiential learning, but in cognitive analysis. This might have undermined the successful execution of the strategy. One might interpret the tension as a 'framing contest' between different parts of the organization (Kaplan, 2008).

2002, the financial shake weakened the risk willingness of the executive team, supported by negative market experiences from the first electronic device systems (Innovo® and InDuo®), which had been developed during the previous period. These events blocked the further investments in technology acquisition, for example with regards to continuous glucose monitoring. When the internal development project for continuous glucose monitoring then also was delayed and later stalled, the PDS strategy in reality fell apart in spring 2004. Still, no change in official strategy was announced until the summer of 2005. In this period, from spring 2004 to summer 2005, PDS represented an example of what Burgelman & Grove (1996) call *strategic dissonance* – meaning misalignment in between official strategic intent and strategic action. In their terminology, one could see the crisis in 2002 as a 'Strategic Inflection Point', which called for reformulation of the strategy.

The innovation strategy of PDS was withdrawn before PDS achieved to influence the *corporate* strategy. Consequently, PDS – from a corporate perspective – still represented strategy 'in the making', being part of the ecology of strategic variation. The implications of the strategy had not been fully understood before implementation; the theory was 'crude', as Nelson (2008) terms it. Also after the public launch of the strategy in 2001, the vision had the nature of a hypothesis, to be tested out in the external environment. Thus, the induced *device innovation strategy* underwent learning cycles *after* the implementation of the strategy, still being a part of the strategic experimentation at *corporate* level. The device innovation strategy served as a learning lab for corporate strategy, so to speak. Perhaps one can see this sort of strategic experiment as *deliberate creation of temporary strategic dissonance*; the vision of PDS was far ahead of the actual experiences and capabilities. Successful execution of the PDS strategy would have dissolved the strategic dissonance by bringing strategic action 'up to' the visionary level of the strategic intent. Oppositely, failure in the execution would require the strategy to be reformulated in order to bring the strategic intent 'down to' the actual level of action (which was what happened). In this understanding, '*deliberate strategic dissonance*' is a way of creating induced strategic learning.

The present case study is not about the *corporate* innovation strategy at Novo Nordisk, which is mainly centered on developing new pharmaceutical drugs. Even though the case study thus is about a local innovation strategy, it is clear from the analysis that this local strategy in general was not developed from beneath – the process did not resemble Burgelman's analysis of strategic initiatives, which gradually gained resonance at yet higher hierarchical levels. Instead, the strategies were formed as part of the corporate induced strategy making process, from the top. In this strategy making, corporate management formulated a strategy for a local area, which served as strategic variation at corporate level; had PDS been successful in building up new product-markets, corporate strategy would have been reconfigured.

From the current case study of the evolution of innovation strategy, one could therefore propose that the new 'middle ground' of strategic research (Gavetti & Levinthal, 2004) embraces a dynamic role of the corporate, induced strategy process. In some cases it might even be relevant to apply the concept of 'perpetual disequilibrium' as proposed by Meyer et al (2005): "*as a theory of organizational action, "adaptation" is an unproductive concept in **nonlinear settings**. When discontinuous changes are rippling through an organizational field, **there is no equilibrium to be sought**, and the idea of organizational adaptation loses meaning*" (p. 457 – my emphasis). However, in the context of the present research project, discontinuity seems less salient than continuity; industry-wise as well as at the case organization. Perhaps it is exactly in such condition of relatively stability that the induced strategy process takes over the entrepreneurial role, which else is often linked to the emergent or autonomous sphere. Compared to local experiments and bottom-up autonomous initiatives, the corporate induced strategy process logically always will be more deliberate, controlled and institutionalized. But if we include the 'external ecology' in the analysis, then the corporate induced strategy process is also *hypothetical* or experimental in its enactment of strategic renewal, and is subject to entrepreneurial learning, which might lead to a reformulated 'theory' (Nelson, 2008). Innovation strategies here can serve as tools for deliberate creation of *induced strategic renewal*; it just requires a longitudinal perspective at multiple levels of analysis to recognize this entrepreneurial and experimental role of induced strategy.

Chapter 6: Conclusion

Content

Introduction	163
Findings.....	164
Contribution.....	165
Implications for research.....	168
Implications for management practice.....	169

Introduction

The present research project aims for understanding the evolution of innovation strategy, studied in the context of the medical devices activities of Novo Nordisk A/S; an incumbent pharmaceutical firm operating in a well-established industry.

The overall research question is “*How does innovation strategy evolve?*” with special focus on the ‘internal ecology’ model, stated in the research question “*What is the role of induced and autonomous strategy processes for the evolution of innovation strategy?*”

As a basic theoretical frame, Burgelman’s evolutionary theory on strategy making has been applied (Burgelman 1991, 2002). Some expansions of this framework were needed. First, the present study puts greater emphasis on analyzing the *external environment* and its influence on the internal strategy processes. Second, it includes the role of management cognition in the analysis; hereunder the corporate *dominant logic* (Prahalad & Bettis, 1986; Bettis & Prahalad, 1995; Prahalad, 2004), understood as an enduring top management worldview or mindset, based on reinforcement of experiences from the past. Third, the present research project focuses on the evolution of *innovation strategy*, as opposed to the general business strategy, defined as such:

- ***Innovation strategy*** is the strategy for the individual innovation activities with the objective to create product or business innovations (strategy understood as a plan for the future or a storyline of the past).

The empirical case study has some specific traits:

- It includes *multiple levels of analysis*: external dynamics; corporate events, top management cognition and corporate strategy; local events at the device area (cognition, strategy and structure); and concrete innovation activities (portfolio of innovation projects and product launches).
- It maps *long term patterns* – across several lifecycles of strategy, covering the period 1980-2008.

- It analyzes the relationship between a classic *core* product of a firm (insulin) and *complementary* products (medical devices), which hold the potential to either enhance the value of the core product, or to become a distinct business of its own.

Findings

The pattern in the evolution of innovation strategy for medical devices at Novo Nordisk was:

- The first entrepreneurial initiatives with medical devices (before 1988) were inspired by external events (competitor moves on the drug side and dialogue among diabetes experts). These first activities were highly successful.
- The institutionalization of the innovation strategy in 1988 with the establishment of MSD was driven by top management cognition holding visions for an autonomous, device-based strategy, which led to an entrepreneurial period and profound investments in devices. However, the results were mixed.
- The retreat from the MSD strategy in 1992 was driven by external events (crises and competition) and resulted in a drug-based innovation strategy. Within a confined scope, the device innovation activities bloomed for many years, successfully serving as means of market differentiation.
- The next strategic transformation, implemented with PDS in 2001, was driven by top management cognition holding extremely ambitious visions for an autonomous, device-based strategy, which led to substantial investments in device innovation. The high ambitions were never fulfilled.
- The retreat from the PDS strategy, completed in 2005, was again driven by external events (crises and competition), and turned the strategy 'back to basics', i.e. drug-based.

Hence, this case study provides evidence for an evolution of innovation strategy where top management visions drove the strategic renewal, and external events drove the strategic retreats.

The evolution can be interpreted as strategic learning cycles, in which successful results substantiated the initiatives (positive reinforcement), whereas negative results undermined the initiatives (negative reinforcement). The reinforcement cycles compromised external market feedback as well as success or failure in the internal product development.

The cycles unfolded a pattern of alternating modes of strategy, which content-wise could be characterized as either autonomous (device-based) or induced (drug-based). The autonomous cycles of device-based innovation strategy had the challenge to escape the gravity of the internal identity and the corporate dominant logic (Bettis & Prahalad, 1995), which was pharmaceutical and drug-centered. Both autonomous waves of strategy represented alternative strategy frames, because medical devices were here seen as core assets for innovation in contrast to the 'normal' periods of induced strategy, where the devices were seen only as means of market differentiation, i.e. enhancement of the insulin sales. Neither of the two device-based strategic waves achieved

momentum enough to escape the gravity of dominant logic for real – in each case, competition and crises made the strategy bend back to the safe ‘fetal position’, centered on the drug. Hence, the dominant logic showed itself as a more *enduring* component of management cognition than the more instrumental strategy formulation – like a deep structure (Gersick, 1991) of strategy making. Even though the two device-based strategy waves were surely autonomous *in content*, they were created out of top management reasoning, vision ‘ex ante’. In this sense, the strategy making followed the *induced strategy process* as analyzed in Burgelman (1991). As such, the two device-based strategy cycles can be seen as *induced strategic experimentation*; new innovation strategies were formulated as hypotheses, which were tried out for real, but still subject for learning. These strategic experiments could be seen as deliberate creation of *strategic dissonance* (Burgelman & Grove, 1996) in the sense that the strategic hypotheses were far ahead of the experiences and capabilities. The intent was to move the organization to follow the vision, thereby dissolving the dissonance between vision and reality over time.

The above analysis suggests an induced strategy making process at incumbents, which experiments with alternating innovation strategies through several lifecycles of strategy, thereby creating *strategic variation* over extended time. This understanding identifies an underresearched, entrepreneurial role of the induced strategy making process and of top management cognition. In emergent views on strategy formation (e.g. Mintzberg, 1994, 2007; Burgelman, 1991, 2002) reasoning and strategy formulation marks *the end* of an explorative and action-driven learning process. In the case study at hand, strategy formulation also marks *the beginning* of a theory-driven, yet explorative learning process: from the external ecology, the induced strategy process intercepts novel opportunities or threats; integrates these in the strategy formulation as strategic *hypotheses* in the form of innovation strategy; initiates the structural context determination (Burgelman, 1991) for the new innovation strategy; and enacts the new strategic hypotheses into the external environment, for example in the form of new products. Based on the response in the market, the new strategic experiments are either reinforced or withdrawn. This theory-driven and entrepreneurial learning cycle takes place *within* the top management driven, induced strategy process. In the present case study, such learning cycles seem to have counteracted the forces of ‘co-evolutionary lock-in’ (Burgelman, 2002).

Contribution

The present research project analyzes an entrepreneurial aspect of the corporate, induced strategy process, in which strategic visions drive explorative learning via alternating innovation strategies, which serve as a ‘strategic laboratory’ at corporate level. Hence, for innovation strategy, strategic variation and trial-and-error learning is not restricted to the autonomous initiatives in the ‘internal ecology’.

The induced strategy process displays adaptation and explorative learning in two dimensions:

1. Towards the **internal ecology** via strategic context determination, which intercepts valuable autonomous initiatives (as analyzed by Burgelman 1991, 2002). This is primarily a process of experience-based, backward-looking strategic learning, which reformulates the strategic vision 'ex post'.
2. Towards the **external ecology** via cycles of interception of environmental change, reasoning (interpretation) and strategy formulation, structural context determination, enactment of new innovation strategies, interception of the response from the market and so forth. This strategic learning process is primarily forward-looking, vision 'ex ante'; but experience-based learning also occurs, via feedback loops from the market.

Therefore, the induced strategy process can be seen as a dynamic 'exchange market', which mediates between internal and external ecologies in an iterative strategy creation process, by means of *induced strategic experiments*, i.e. enactment of alternating innovation strategies over time. This conception of the induced strategy process does not eliminate the 'internal ecology' model described by Burgelman (1991, 2002). Rather, it adds another layer of strategic entrepreneurship to the internal ecology model. See a model of my analysis in figure VI-1.

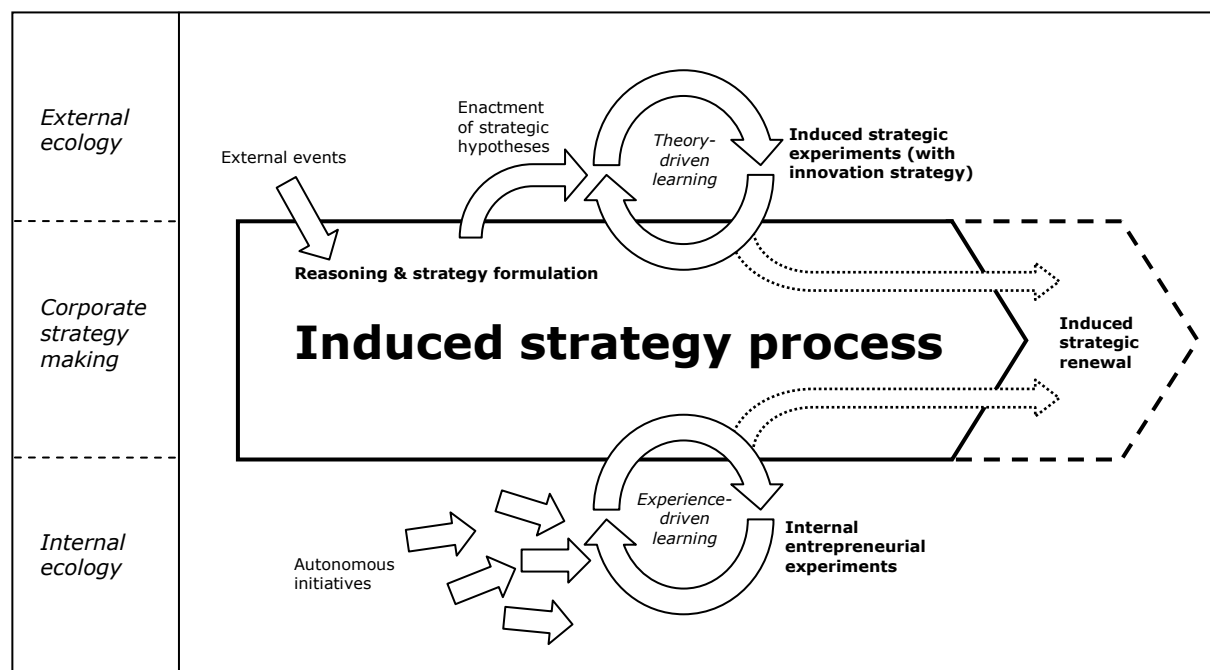


Figure VI-1. A model of the induced strategy process as an 'exchange market', mediating between internal and external 'ecologies'. The model shows an entrepreneurial role of the induced strategy process, displaying plasticity in two dimensions: Towards internal ecology by integrating successful autonomous initiatives, as described in Burgelman's 'internal ecology' model of strategy making (1991); and towards external ecology by enactment of induced experiments with innovation strategy. If these experiments are successful, the strategic hypotheses are reinforced, and this may lead to renewal of the corporate induced strategy. If the strategic experiments fail or meet significant resistance in the environment, the existing strategy and its dominant logic instead are reinforced.

This theoretical interpretation of the empirical case study leads exactly into the ‘middle ground’ between behavioral and rational-choice perspectives on strategy, which Gavetti & Levinthal (2004) propose as the future theoretical paradigm to be developed based on evolutionary theory: “*Strategic action clearly involves greater degrees of intentionality, so fuller representations of cognition would need to be incorporated into such theoretical efforts*” (p. 1310); and “*Work in this middle ground treats actors as boundedly rational—limited both spatially and temporally in their ability to evaluate the consequences of their choices. It also grapples with the challenge of adaptation in the presence of rival firms and shifting bases of competitive advantage*” (p. 1313).

In such ‘middle ground’, *deliberation* and reasoning should not be seen in contrast to *learning*. The use of conceptual dichotomies such as deliberate vs. emergent (Mintzberg, 2007, p. 4), cognition vs. action (Gavetti & Rivkin, 2007, title), control vs. learning (Mintzberg, 2007, p. 5), rational vs. behavioral (Gavetti & Levinthal, 2004, p. 1310) tend to trap our understanding – the conceptual relationships become either-or, not interactive interdependencies. Conversely, Nelson (2008) analyzes ‘bounded rationality’ as a dualistic ability to reasoning *and* learning from trial-and-error; this understanding dissolves the dichotomy. Such dualistic understanding seems required for decoding the dynamics of the multifaceted strategy making at mature companies. In the present case study, the duality is represented at different time perspectives: the strategic transformations were result of deliberate reasoning – that is the rational aspect – but the long-term evolution displayed trial-and-error – that is the ‘bounded’ aspect. We are here back to Lucas’ (1986) notion that the underlying decision rules continuously are subject to ‘adaptation’ via trial-and-error. The longitudinal lens enables us to discover the experimental or adaptive dimension of the seemingly ‘theory’-based strategy making.

In the same dualistic understanding, the induced strategy process can be seen as unfolding both modes of organizational learning described by March (1991), exploitation and exploration, practiced in two directions: towards the internal and the external environment. One could label these two directions of strategic learning respectively ‘inbound’ and ‘outbound’ (inspired by Porter’s labels ‘*inbound and outbound logistics*’ in the classic value chain analysis, e.g. Porter, 1991).

Inbound, strategy holds a function of alignment and control (cf. Porter, 1991). The whole purpose of strategy is to establish *enduring* elements of corporate behavior, thus selection and retention is needed within the ‘internal ecology’. Without this function of strategic selection and retention, the activities of a firm would pursue countless autonomous directions, in effect dissolving the strategy and the business itself. The dominant logic facilitates this function as an enduring element of management cognition: “*Interestingly, it provides a set of heuristics that simplify and speed decision making. This inherently results in ‘adaptive ability’, so long as changes in the underlying logic are not necessary*” (Bettis & Prahalad, 1995, p. 11). This function of alignment establishes the exploitation mode of inbound strategic learning. However, the induced strategy process also has a dimension of inbound exploration, by opening up for interception of autonomous initiatives: “*The capacity to activate and successfully complete such processes [autonomous initiatives and strategic context determination] can be viewed as a measure of the intelligence of the company’s internal selection*

environment and may be at the very heart of strategy making as an adaptive organizational capability” (Burgelman 2002, p. 355).

Outbound, strategy has a similar function of alignment of the activities and exploitation of established positions and capabilities. However, the induced strategy process also holds an explorative function via anticipation of change in the environment. This function is established through *experiments* with alternative strategies in order to sustain the adaptability and viability of the firm. Hence, strategic *variation* is sought by testing alternating innovation strategies as ‘strategic hypotheses’ via extended learning cycles in the market. For this purpose, innovation strategy serves as a ‘strategy lab’ for the corporate induced strategy process. Here, the gravity of the dominant logic poses a permanent challenge: it may momentarily loosen up for new innovation strategies, but it pulls back to safe territories whenever encountering crises.

	Inbound	Outbound
Exploitation	Expanding existing strategy and capabilities	Expanding existing strategy and established product-markets
Exploration	Strategic context determination of autonomous initiatives from the ‘internal ecology’ (Burgelman, 2002)	Experimenting with alternative innovation strategies in the market (potentially creating new product-markets)

Table VI-1. The strategic learning modes of the induced strategy process.

The above analysis (summarized in table VI-1) of the learning modes of the corporate induced strategy process builds on a longitudinal case study of the evolution of *innovation strategy* for a complementary product area within a mature company. More research is needed for generalization of such theory.

Implications for research

Burgelman (2002) sees an organization’s ability for strategic adaptation as depending on its ability to exploit the internal ecology of autonomous initiatives. This understanding builds on case studies of respectively internal corporate venturing units (Burgelman, 1988) and a young IT company in a young industry (Burgelman, 1991, 2002). The present research proposes that a firm’s ability for strategic adaptation might depend *both* on strategic context determination of autonomous initiatives (as in Burgelman, 2002) *and* on ability to exploit *induced strategic experiments* via enactment of alternating innovation strategies. However, this analysis of a more entrepreneurial role of the induced strategy process might be bound to the specific circumstances of the evolution of local *innovation strategy* or to the integration of *complementary assets* for innovation within the setting of a mature (incumbent) company in a stable industry. The big unanswered question remains: is the analysis of the present research project context specific, or does it have validity for other mature companies in stable industries? In any case, the existence of *induced strategic renewal* should be

examined further in research at the 'middle ground' of business strategy (Gavetti & Levinthal, 2004). The understanding of innovation strategies as *hypotheses* – serving as a laboratory for corporate strategic renewal – might here add to the theories on strategic search. Further, the idea of seeing induced strategic experiments as *deliberate strategic dissonance* might also be worth while exploring in theories about strategic entrepreneurship.

Implications for management practice

The first managerial learning from the case study could be respect to the positive power of internal identity and dominant logic. Surely, these forces may hinder strategic renewal, but they also ensure enduring qualities of the organizational behavior. In the case of Novo Nordisk, this conservatism has been fortunate. Imagine Novo having had an agile and entrepreneurial management style back in the 1970's, where the enzyme business had grown to become larger than the insulin business, and the enzyme managers even joked about selling off the insulin business, since it didn't grow anyway. By yearend 2011, the drug business held 32,000 employees and had a turnover of 66 billion DKK. To compare, the enzyme business (since 2000 divested in Novozymes A/S) had a turnover of 10.5 billion DKK and employed 5,800 people by yearend 2011. Top management of Novo in the 1970's probably did not foresee the explosion of the Type 2 diabetes market, which is the main cause of this difference; but a strong internal identity and dominant logic, originating all the way back to the founders, made it unthinkable to divest the insulin business – apart from the jokes at the management corridors. Strategic inertia can indeed be a sound force, when your core market holds immense growth potential, and your industry is relatively stable, compared to for instance the IT industry.

However, there is also reason to warn against 'co-evolutionary lock-in' (Burgelman 2002), implying that everything else than core business is seen as distraction. Strategic context determination of 'autonomous' strategies seems to be almost non-existent at Novo Nordisk – which according to Burgelman (2002) can threaten the long-term viability of the firm. One can discuss whether the fortunate and stable market conditions of Novo Nordisk make the 'internal ecology model' of autonomous initiatives obsolete. Does a company in an external environment, characterized by immense growth potential and relative stability, need anything more than the strategic learning from the top-driven 'induced' process? For Novo Nordisk, it takes a very long time horizon to get a glimpse of severe threats. Further, the company historically has proven ability to act when confronted with 'Strategic Inflection Points' (Burgelman & Grove, 1996) within the core industry. The introduction of NovoPen® partly as response to the threat of recombinant human insulin from Eli Lilly is one example. The establishment of the costly R&D project for inhalable insulin as response to the threat from Pfizer is another. In contrast, the very slow reorientation of the business towards serving the market of Type 2 diabetes is a negative example. Here, the internal identity and the dominant logic were barriers to the strategic reorientation, because of bonds to the diabetes experts and their

sophisticated treatment of Type 1 diabetes patients. Thus, one cannot exclude that Novo Nordisk's future strategic viability might depend on continuous experimentation with the innovation strategy. Currently, a so-called Innovation Culture project at Novo Nordisk comprises a handful of explorative projects. These activities, however, are financially prioritized very low. One could fear that more is needed for ensuring long-term strategic viability.

The medical devices have indeed been very successful market differentiators for Novo Nordisk, ever since the introduction of the first NovoPen® in 1985. According to several informants, the initial exploration of the device opportunities 'slipped through the filter' because devices were perceived as complementary assets, not core. This leads me to an important implication for management practice: *Explore and utilize the value of complementary assets!* These are perfect guinea-pigs for experimenting with innovation strategies without risking the core business, yet holding potentials far beyond what can be foreseen without real-life strategic experiments. No theory does it in itself – a combination of vision (theory) and trial-and-error *in the market* is needed. Perhaps you even find a gold vein from such experiments.

Another implication is that the successful integration of complementary assets is complex and dynamic – the balance between core and complementary will shift and be negotiated again and again. The integration of complementary assets for innovation in corporate strategy seems at least as challenging as the integration of different businesses. But the exploration of complementary assets for innovation offers a potential way to strategic renewal.

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Appendix A. Research method for the mindset analysis 2007-10 in detail

Content

Sample and data.....	176
The use of ‘cognitive maps’	178
One common ‘landscape’ model	179
The use of ‘creative questionnaires’ when interviewing	180
Identifying the dominant innovation logic.....	182
The weaknesses of the methodology.....	183

The purpose of this empirical investigation was to identify and analyze the ‘dominant logic’ (Prahalad & Bettis, 1986) of the device innovation area with regards to the management mindset on innovation – here termed ‘*dominant innovation logic*’.

The following detailed description of the research method has some overlap to the description in Chapter 3 of the research method for the 2007 analysis. Besides adding more details, the present description covers both analyses (2007 and 2010), even though the findings from the 2010 analysis could not be used, because of business confidentiality issues.

Sample and data

The unit of analysis was the device innovation area of Novo Nordisk A/S, in the period from June 2007 to September 2010. This unit existed within two different organizational structures at the time of the two investigations. A sample of 10 managers was selected as informants in 2007. These 10 were chosen in order to represent the organizational functions as broadly as possible. First of all, the VPs of the three functional areas were chosen, plus a VP from a governance unit, who was a former VP from the device area. The other 6 were department managers. In 2010, 6 of the informants from 2007 were still employed at the device area, including the VP from the governance unit, who now again had become a VP within the device area. These 6 informants were reused. 4 new informants were selected, again with emphasis on the broadest possible representation of the functions at the device area.

The interviews were conducted as qualitative, semi-structured in-depth interviews throughout the summer of 2007 and again in August-September 2010. See total list of interviews in Chapter 3. The 20 interviews lasted from 35 to 123 minutes each (mean 60 min.). All interviews were conducted in Danish. The 2007 interviews were broader in scope and therefore took longer time than the 2010 interviews, since the 2007 interviews included insights into the history of the device innovation at Novo Nordisk. – All interviews were recorded and transcribed.

The interviews were based on lists of questions, which included the themes a) industry identification; b) value proposition; c) core capabilities; d) product innovation portfolio; e) innovation barriers and enhancers.

The use of semi-structured in-depth interviews has the advantage of active influence by the informant on the direction of the conversation and thus can provide a genuine impression of his or her thinking. The other side of the coin, however, is that you do not walk away with 100% comparable data sets across the interviews, since the topics discussed not always are the ones foreseen by the researcher. Therefore, I regret today that I did not supplement the interviews with short questionnaires, to have two supplementary identical data sets for comparison.

Some disclaimers should be made concerning the effect of *self-ethnography* (M. Alvesson, 2003): The researcher was well known by the informants, including standpoints and attitudes. This might have influenced the way the informants expressed their opinions. However, this potential influence was constant over time and across the interviews. A perhaps worse problem was that the interviews were based on a mutual pre-understanding of the device area; many basic questions were not uttered, and many statements were uttered 'between the lines' via implicit connotations. There are two dimensions of this problem:

1. The cognitive; that I may have been blind to factors which would have fallen into the eyes of external observers
2. The communicative; throughout the data analysis I was able to use very condensed wordings, since I (being the only researcher) was familiar with all connotations and presumptions behind the wordings.

My way of working myself out of the second problem was to reformulate the aggregated condensed statements (called 'constructs') into full sentences, and to include explanations of the context when needed.

For the purpose of longitudinal studies, the method of in-depth interviews implies another problem. With a time interval of 3 years, the context of the interviews had changed and therefore different topics appeared relevant in the conversations. In 2010, I deliberately tried to stick to a basic skeleton of questions similar to the 2007 interviews, but differences in topics were inevitable. The differences increased the difficulties of direct comparison between the 2007 and 2010 data sets. My way to deal with this problem was to apply an identical thematic structure for the data analysis of both data sets. Furthermore, in 2010 I went back to the 2007 data (transcriptions as well as maps / summaries) in order to reexamine some of the topics, which had been emphasized more loudly in 2010. This way, a more symmetrical structure of themes could be applied for the data analysis. Again, the dilemma goes back to the desired data richness and uniqueness from using qualitative methods such as semi-structured in-depth interviews, weighted against the difficulties by cross-sample comparison and quantification of the results.

Summaries of the interviews were made in a format resembling ‘cognitive maps’ (see next part), and short follow-up interviews were conducted to get approval from the informants of the summary. The follow-up interviews were not recorded, but the corrections by the informants were noted and approved at the interview. These follow-up interviews typically lasted 15-30 minutes. Thereafter, the data analysis was based on the summaries as data input. See figure A-1 displaying the entire research methodology.

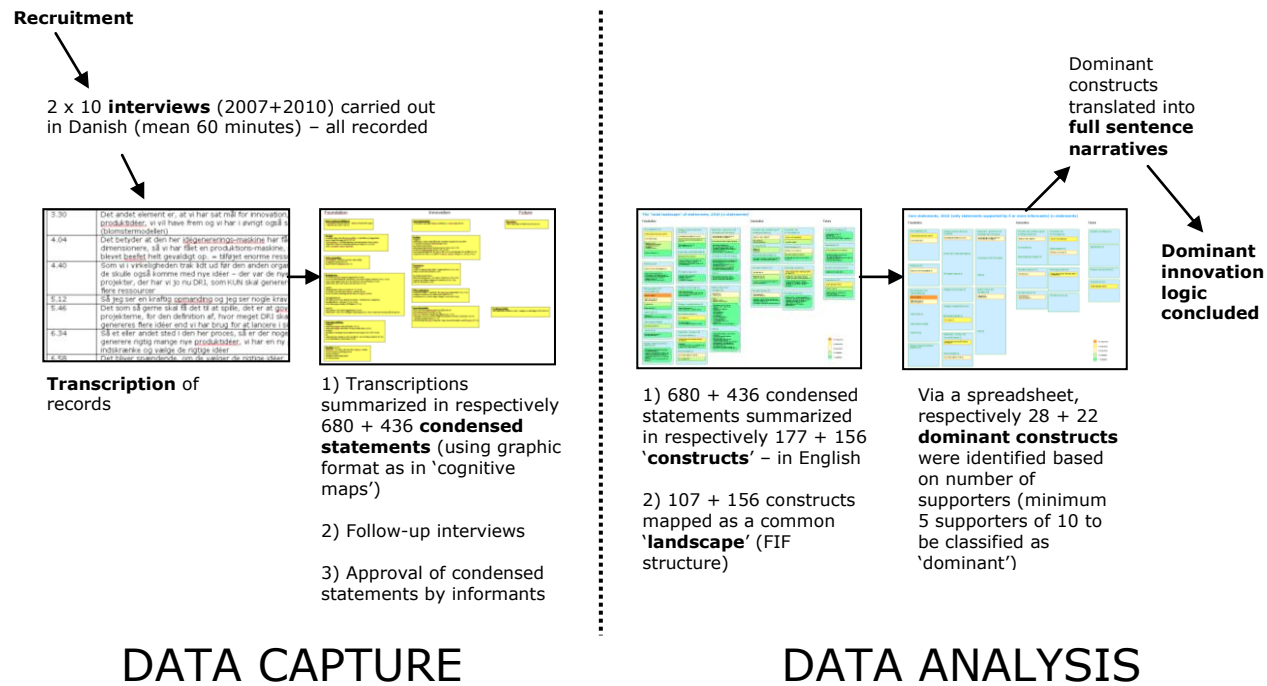


Figure A-1. A map of the research methodology, which is further explained in the following text. The numbers divided by plus (“680 + 436”) refer to the two years of investigation (2007 + 2010). (FIF structure: Foundation-Innovation-Future).

The use of ‘cognitive maps’

The concept of ‘cognitive maps’ is understood very differently in various contexts – sometimes referring to models or schemes in the minds of people – which rather should be termed ‘mental models’¹⁷ – at other occasions referring to artifacts such as graphic representations of the mental

¹⁷ For a discussion of the conceptual confusions in this area, see Swan (1997) and Eden (1992)

models. These graphic representations lay out a framework of constructs and relationships as a visual representation of how individuals perceive their environment (Fiol & Huff 1992). Many different techniques exist for making graphic cognitive maps, including software tools, and they can be made for many different purposes (Eden, 1988; Fiol & Huff, 1992; Barr, Stimpert & Huff, 1992; Bougon, 1992). The most prevailing form is *causal maps*, which outline the network of elements and cause-effect relationships found in individuals' view on a particular domain (Langfield-Smith, 1992). Since Prahalad & Bettis (1986) themselves mention cognitive maps, it was obvious to use this approach as one of the methods for eliciting the dominant innovation logic.

Based on the transcriptions of the interviews, the verbal statements were reformulated in slightly more general terms, so that each summarized or *condensed* statement could refer to more (typically 2-3) original verbal sentences. These condensed statements were then clustered in cognitive maps, using explicit themes from the transcriptions as well as themes implied by the interview questions (e.g. "core capabilities"). The 'cognitive maps' served first for intermediary presentation of the condensed statements at the follow-up interviews. After the informants' approval of the condensed statements, the maps served as data for the further analysis.

The 2 x 10 cognitive maps contained respectively 680 and 436 condensed statements in total in 2007 and 2010. This gives averages values of respectively 0.92 and 0.95 condensed statement per interview minute for 2007 and 2010.

One common 'landscape' model

The condensed statements were taken from the individual cognitive maps into a spreadsheet, reformulated in yet more generic terms, termed '*constructs*', so that each reformulated construct could cover several informants' condensed statements. At the same time, the language was changed from Danish to English. Exactly this part of the analysis is very sensitive to subjective bias from the researcher. You compare the condensed statements, two by two, and ask yourself the question: Do these two statements cover the same basic meaning, in spite of different wording? Or you compare a set of statements and ask: Could I extract a more generic meaning, i.e. could I reformulate these statements at a higher level of abstraction, so that the core of each statement is covered, even some details and nuances fall out? The answer to such questions can only be a matter of subjective interpretation – there is no right solution. This also implies that the number of constructs is not given from the data. If the statements are used directly as constructs, you have a 1:1 relation between the data and your constructs, but you also have not achieved the advantage of reducing complexity via models. If you are very rude in your interpretation, you achieve the advantage of a simple model, but you risk having damaged the validity towards the original statements. In my case, I think I had more respect for the data in 2010, implying a finer grid of constructs than in my first 2007 analysis. I managed this difference by going back to the data analysis for 2007 to loosen up the simplifications of the constructs and move closer to the data.

For the analysis, the constructs were clustered in three main spheres, Foundation-Innovation-Future (FIF), which basically formed a timeline of past, present and future. The FIF structure emerged out of

the data analysis in 2007 and was then reused in 2010. Within each sphere, the constructs were clustered in groups, resulting in a common structure of topics across the interviews for each sample. See table III-4 with the generic FIF structure.

The FIF structure was applied for the data analysis in the spreadsheet of the total constructs. The spreadsheet was used as an instrument for quantification; each construct was correlated with the data to determine exactly which of the informants who supported the construct in question in their individual statements. This way I could quantify how widespread each of the constructs was amongst the 10 informants. For traceability, the exact timestamps from the interview transcriptions of the statements in support of each construct were also noted.

The clusters of constructs from the spreadsheet were then transferred to a map, following the Foundation-Innovation-Future structure, comprising all constructs from the informants in respectively 2007 and 2010. In this total map, the constructs within each cluster were prioritized according to the number of managers behind each construct. In a traditional physical map of a landscape, the height compared to sea level is indicated with color codes from blue over green to yellow and more brownish nuances. This color-coding system was adopted for visualizing how widespread the constructs were amongst the sample of managers. The 'landscape' of management constructs formed three 'continents' (Foundation-Innovation-Future), and more clusters or 'countries' within each continent. The color-coding used the brownish nuances to indicate the constructs, which were most widespread within the management team, and so forth. This graphical representation of the management statements provided an immediate overview of the level of consensus. The total map can be seen in the right side of figure A-1.

The use of 'creative questionnaires' when interviewing

As suggested by Prahalad & Bettis (1986), "creative questionnaires" were applied in the data capture process. Three such methods were applied: 1) Project portfolio puzzle; 2) actant modeling; and 3) car metaphor. These are explained in the following.

In the *project portfolio puzzle*, the informants were asked to select a sample of development projects of their own choice and place them within a matrix, outlining four quadrants along two dimensions of innovativeness: Respectively as seen from a market perspective or from a technology perspective (see the generic matrix in figure A-2). Before the interview, the titles of all development projects were noted on small Post-It® notes, so that they could easily be placed manually on a print of the matrix. There was of course no 'right answer' to the task – the placement will always be a matter of assessment. This exercise was conducted to see if there was a common understanding of the distribution of the product innovation portfolio.

The project portfolio puzzle was quite time consuming and was therefore only applied in 2007, and only in 6 of the 10 interviews.

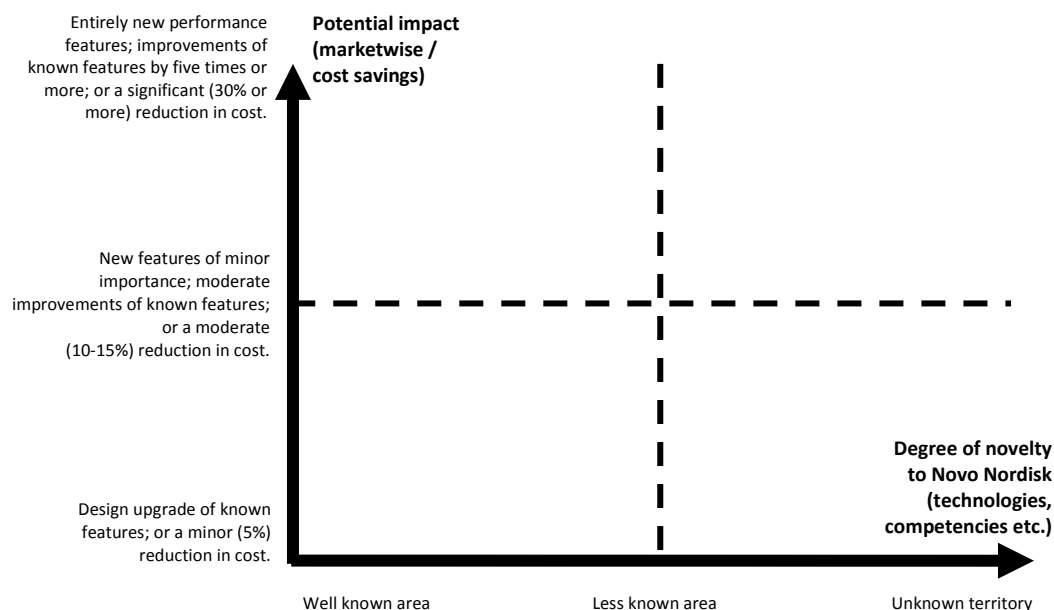


Figure A-2. The project portfolio matrix. The text describing the top score in the vertical axis is copied from the empirical definition of ‘radical innovation’ in Leifer et al (2000).

The **‘actant modeling’** exercise uses a model displaying the roles and structure of a common folklore story. This model has been a common part of the Danish high school curriculum since the 1970’s, where the author was taught to analyze literature using this model. It was originally developed by the French philosopher A. J. Greimas. For further information, please see Wikipedia under “actantial model”¹⁸. At several earlier occasions, I have experienced this model as a very fruitful dialogue enhancer for describing phenomena such as a company or a product. The exercise was used to get alternative insights into the informants’ view on their business, especially the value offering. The roles in the model are: The subject (“the knight”) striving for the object (“the princess”), enabled by a provider (“the king”) and a supporter (“the wizard”), fighting an opponent (“the dragon”), in the end giving the object to a receiver (often the subject himself). In all cases, I had set the subject as “Device R&D” and let it be open for the informants to identify the actors of the remaining roles. The generic model can be seen in figure A-3. The actant modeling exercise was carried out in 6 of the interviews

¹⁸ http://en.wikipedia.org/wiki/Actantial_model, accessed 2010-11-11, refers to the original source: Greimas, Algirdas Julien [1966] *Structural Semantics: An Attempt at a Method*

in 2007 and in all interviews in 2010. This tool was especially valuable for identifying the overall goal of the organization, the key stakeholders and the value proposition.

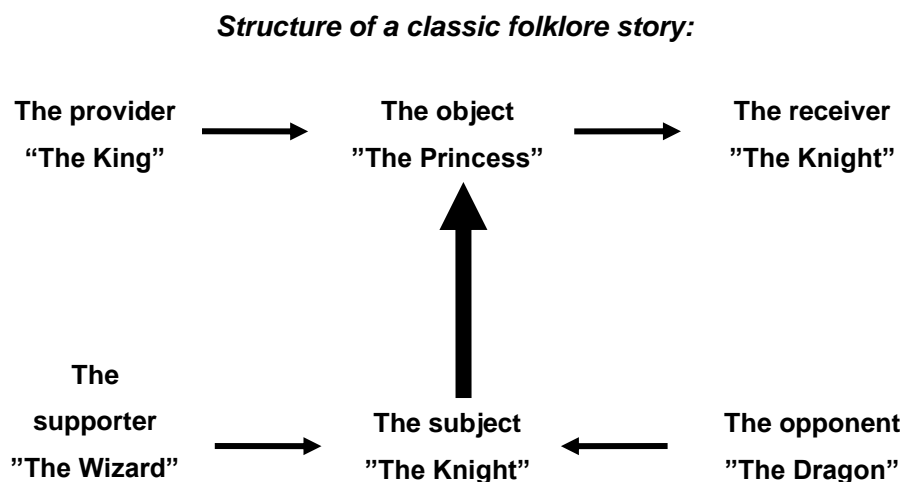


Figure A-3. The generic actant model as applied in the research¹⁹.

The **car metaphor**. A method often used in design is to encircle the identity of an organization, a product or a customer segment by using artifacts or images as metaphors for inner traits. It has shown to be easier for informants to express subtle, inner characteristics indirectly via such metaphors. The method of using metaphors is therefore often applied in product development activities, also at Novo Nordisk Device Research & Development. In my case study, I simply asked the informants: *"If Device R&D was a car – which car would it be?"* – And if the informants immediately named a car brand or car model, I asked *"Why?"* to get to the associations and characteristics, which led them to their choice. These considerations often gave very fine portraits of the culture or identity of the case organization.

Identifying the dominant innovation logic

The dominant logic is a worldview shared across the management team. Arguably, idiosyncratic individual viewpoints cannot belong to the 'dominant' logic. Therefore, to get a clearer picture of the management thinking, all constructs with less than 5 supporters (of 10 possible) were deleted from the total 'landscape' of constructs. As references for this criterion, Tyler & Gnyawali (2002) similarly

¹⁹ See for instance http://www.signosemio.com/greimas/a_actantiel.asp (accessed 2010-11-11)

assess the concept of 'shared cognition' in a management team such that 50% must agree in a small group; 40% in a large group (where 30 managers make a large group).

The relatively few constructs left (respectively 28 in 2007 and 22 in 2010) made a conclusive 'cognitive map' of the shared management perceptions. These dominant constructs were 'translated' into full sentence narratives, which outlined the dominant worldview of the management team. [Again, see figure III-2 describing the methodology].

The weaknesses of the methodology

There are several points in the data capturing and analysis, which are widely open for subjective influence by the researcher:

1. The researcher selects the questions raised during the interviews. Thus, the researcher, not the informant, defines the default elements of the worldview of the informant. However, the semi-structured interviews allow high influence from the informant on the course of the conversation.
2. After the informant has approved the summarized or condensed statements, the next level of abstraction is made solely by the researcher: namely the transformation from condensed statements to 'constructs'. This is a process of *interpretation* and reformulation for which there obviously is not a 1:1 solution, so the choices made are subjective.
3. The same disclaimers are valid for the last process step: the translation from dominant constructs into full sentence wording.

Some researchers use inter-subjectivity to reduce possible biases of the researcher, letting more researchers analyze the same data (e.g. Barr, Stimpert & Huff 1992). Still, also such inter-subjectivity might be biased by cultural backgrounds, values and other traits common across the team of researchers, and therefore may reduce but not *eliminate* the problem of researchers' subjectivity. In any case, being the sole researcher I did not have this possibility. On the other hand, there also is a strength in the sole researcher approach: all the way from conceptualization of the research questions, through data collection and data analysis there is only *one* subject to influence the results, so the researcher bias at least is consequent and coherent across the entire process.

Besides the 'sole researcher' problem, I also struggled with the subjectivity issues from "self-ethnography" (Alveson, 2003), see above. However, my belonging to the case organization had great advantages, such as unlimited access to data, easy access to informants and last, not least, the comprehensive background knowledge from which I could immediately understand the connotations of the statements, i.e. what was being said 'between the lines'. This pre-understanding enhanced the analysis from interviews into constructs; but in a way that is not easily traceable for outside researchers, who do not possess the same vast background knowledge and therefore might not see the link between a verbal statement and a construct. The part of the analysis using the constructs (e.g. the landscape model) is the least transparent; whereas the steps before consists of verbal statements or condensed statements, which are recognized and approved by the informants; and the

step after uses full sentence wording, which can be compared to the verbal statements in the transcribed interviews.

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