Innovations at the Boundaries of Sectoral Systems of Innovation and Production: A Study on the Pharmaceutical Industry

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Table of Contents

List of Figures and Tables

Tables

List of Abbreviations

AESGP	Association of the European Self-Medication Industry
AMG	Arzneimittelgesetz (Gesetz über den Verkehr mit Arzneimitteln)
ApBetrO	Apothekenbetriebsordnung
A&P	Advertising and Promotion
BfArM	Bundesinstitut für Arzneimittel und Medizinprodukte
CHC	Consumer Health Care
DiätV	Diätverordnung
FMCG	Fast Moving Consumer Goods
HR	Human Resources
HWG	Heilmittelwerbegesetz
LFGB	Lebensmittel-, Bedarfsgegenstände- und Futtermittelgesetzbuch
MPG	Medizinproduktegesetz
NemV	Nahrungsergänzungsmittelverordnung
OTCs	Over-the-Counter Pharmaceuticals
PTA	Pharmazeutisch-technische Assistenz
Rx	Prescription-only Pharmaceuticals
R&D	Research and Development
SBU	Strategic Business Unit
SGB	Sozialgesetzbuch

1. Introduction

1.1. Recent Development of the Healthcare Market

Over the last decades the healthcare market has changed drastically, responding to new demands for healthcare going beyond pharmaceuticals. The result of those developments is an extension of the healthcare market growing by the side of the traditional market for pharmaceuticals, comprising non-pharmaceuticals with health benefits. It is the *second healthcare market* (Henke 2009: 1; Krimmel 2005: 189; Roland Berger 2009:15) that absorbs the expansion of health to a wider range of products than pharmaceuticals only, closing a gap between the pharmaceuticals and the commodities market. With the advancements in technology of the last decades, more illnesses can be cured and often even be prevented. This has turned the attention to more (and often less 'serious') diseases than previously. – Health has become 'producible' and therefore almost 'consumable' (Sigrist 2006: 42); in any case it has become 'manageable'. This has turned the concept of health as being the opposite of sickness into a larger concept of an individually perceptive feeling; wellness, lifestyle and social trends now play a role (Roland Berger 2008: 15; Sigrist 2006: 224). While the treatment of acute illnesses remains the task of the physician, the management of health through the consumption of products that contribute to the individual well-being and prevention has become a new domain, lying in the hands of consumers;

> '[i]ndividuals today seek to take on the personal management of their own health. This force is compatible with the changing paradigm: the burden of health-maintenance is slowly shifting from the government and insurance companies to the specific consumer.' (Coletta 1999: 166)

The term *self care*, in the sense of personal health management, is often used to describe this broad approach of consumer-managed healthcare that spans over almost all aspects of life (Hasler 2002: 3779). The idea of health has been expanded to much more than its traditional meaning. A new demand for *health products* — food supplements, dietetic foods, medical devices, cosmeceuticals (cosmetics with health benefits) and (to some degree at least) Functional Foods - has emerged, going beyond classical pharmaceuticals, producing a new market that

1. addresses needs beyond the curing of illnesses, such as prevention and well-being/lifestyle,
2. includes no pharmaceuticals, yet health-enhancing products and
3. is highly consumer-oriented, quickly moving and brand-driven.

Within this larger idea of health, prevention of diseases plays a major role. The dramatic increase of diseases of civilization and of chronic diseases in Western societies, as well as the demographic changes they experience have moved the issue of prevention up the agenda (Sigrist 2006: 46). Many pharmaceuticals deal with preven-

tion, yet always with the 'medicinal' purpose of the prohibition of illnesses. Novel products and services tend to approach prevention from the angle of lifestyle and wellness, combined with health-related issues; the notion of wellness and of health as an element of the individual life-style play an increasingly important role. The range of healthcare products is no longer limited to pharmaceuticals consumed when ill. Instead, health products are consumed whenever possible: they are part of a lifestyle aiming at the prevention of illnesses through a holistic concept of healthiness, including the permanent consumption of foods, food supplements and other commodities with health benefits; the maintenance of individual fitness and well-being (and the preventative treatments its brings about) are central to the market.

This reflects what Sigrist (2006) describes as 'the new social element' (224) in the healthcare market, transforming lifestyle into *health-style.* His analysis concludes that four forces have traditionally impacted the market for pharmaceuticals: society, politics, technology and the economy. The emergence and growth of the expanded healthcare market stems mainly from social influences on health, such as health trends and the idea of lifestyle- and wellness-drugs. Medical aspects are only secondary. Of course, technological advancements and new scientific horizons have also contributed to this, as without them many new healthcare products could not be designed. Four major developments have set the change into motion:

1. Technological advances have made new forms of preventive therapies possible, which can go beyond the boundaries of classical pharmaceuticals (Sigrist 2006: 69).
2. Consumer empowerment and education with respect to health questions as well as the health-consciousness in general have increased (Santermans 2004: 42; Sigrist 2006: 104).
3. Demographic changes in the industrialized economies have lead to a greater importance and number of diseases of civilization as well as methods of preventive therapies (Hasler 2002: 3779; Santermans 2004: 42).
4. The costs of the traditional health system have exploded, stimulating firms to position health-related innovations outside the classical pharmaceuticals market (Sigrist 2006: 42).

Santermans (2004: 42) points out how those developments impact the healthcare market. Consumers are more educated, informed and mature than ever before when it comes to health questions. One consequence is a more equal and less hierarchical relation between the demander for health products and their supplier (physician, pharmacist, druggist). Hasler (2002) calls the result 'the self-care phenomenon' (3779): health is increasingly taken care of by the consumers themselves. This is possible, as the increased consumer-education allows people to make choices with regard to their health on their own. Of course, the independence of consumers is increased by the fact that they pay for the health products themselves. Products like dietary supplements or cosmetics with health claims are clearly beyond

the coverage of health insurance companies. This is in fact a key attribute of the new healthcare market differentiating it from the classical market of pharmaceuticals: it functions independently from governmental health plans and insurance companies, as health-related non-pharmaceuticals are never sold on prescription. Additionally, the expansion of healthcare to non-pharmaceuticals, up to ordinary commodities increases the availability and ease of access to health products, creating more room for self-care. Together with this comes a change and an extension of the user base, in the sense that demanders of health products are not only patients — acutely ill people — any more, but also average consumers. Healthcare products are a commodity that everybody can consume.

1.2. The Role of the Pharmaceutical Industry

By closing the gap between pharmaceuticals and commodities (foods mostly), the second healthcare market adjoins the traditional sphere of influence of the pharmaceutical industry. Ordinary commodities that were previously unrelated to healthcare have been 'charged' with health claims. This new product category is usually referred to as health products. The most prominent examples are probably food supplements (also called dietary supplements) and Functional Foods. Even though legally, food supplements are foods rather than pharmaceuticals, they carry clear health claims with respect to prevention and well-being. Suddenly, food is not just nutrition anymore, but becomes a special food that has a component incorporated into them 'to give a specific medical or physiological benefit, other than a purely nutritional effect' (Farr 1997: 59; see also Hasler 2002: 3772; Roberfroid 1999: 162). There is evidence that consumers choose to consume food supplements and Functional Foods to prevent illnesses from occurring or to alleviate symptoms of illnesses. Often, nutritional reasons are only secondary. Similar developments can be observed with respect to cosmetics that have been transformed into cosmeceuticals through the addition of active ingredients or the increase of the concentration of one product ingredient. They keep serving the initial purpose of cosmetics (skin care) but carry additional health benefits that have formerly been known in dermatology only (Zulauf 2002: 3). The administration form of health products is — with the exception of Functional Foods — similar to that of pharmaceuticals: food supplements and dietetic foods are administered as pills or powders, which positions them as *parapharmaceuticals*, just between pharmaceuticals and foods. Similarly, medical devices are physical devices or certain substances that are used for therapeutical or diagnostic purposes, while they are at the same time not functioning like pharmaceuticals.

In other words, the development of the consumer-oriented healthcare market has combined and amalgamated two worlds; it has bridged the previously existing gap between pharmaceuticals, as the exclusive products dealing with health, and ordinary commodities, such as food (figure 1). New product categories have emerged

that carry health to the borders of the classical first healthcare market; special foods and cosmetics are today often an alternative or at least the completion of health treatment.

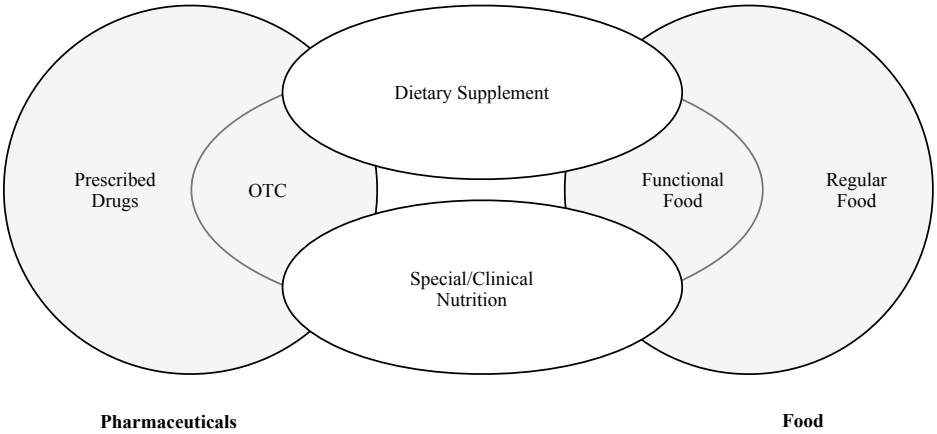

Figure 1: Consumer healthcare products as the bridge between foods and pharmaceuticals (adapted from Menrad 2001: 334)

This development shows that the demand for healthcare products has grown and diversified. Demand is no longer limited to physicians, hospitals and (indirectly) the patients only, but it has been extended to ordinary consumers. Also, the demand has grown in terms of the variety of products. The rise of Functional Foods, food supplements and cosmeceuticals shows that the issue of prevention and well-being is not bound to classical pharmaceutical products anymore. Health has become interwoven with the market of fast moving consumer goods, something that was unthinkable before. What one would expect therefore is an expansion of the innovation activities of pharmaceutical firms towards even more consumer-orientation and a concentration on lifestyle and wellness-issues, in order to exploit the new demand and opportunities.

Firstly, an expansion of the OTC (Over the counter, pharmaceuticals sold without prescription) segment in the direction of health products would be thinkable. Kartte (2008: 6) positions OTCs as the (potentially) most attractive segment of the new healthcare market in terms of revenue per capita and entrenchment in society and habits of consumption (figure 2). In this context, the new demand for self care products looks like an almost logical extension of the activities of the pharmaceutical industry. In other words, one may assume that in light of those changes, not only the foods and cosmetics industry, among others, should increase their innovation activities towards health products but that also the pharmaceutical industry should become more active in this field. After all, there is already the market for *self medication* in which the pharmaceutical industry sells non-prescription pharmaceuticals that are

consumer-oriented and partly directed towards prevention and well-being. Those *over-the-counter products* (*OTCs*) represent the *consumer healthcare market*, the 'conservative core' of the second healthcare market (Kartte 2008: 3). As Krimmel (2005: 189) underlines, OTCs represent the borderline to the new product groups in the second healthcare market (figure 3). OTCs are distributed more freely than prescription-only pharmaceuticals (Rx-pharmaceuticals), addressing the final consumer rather than the patient. In that sense OTCs represent the area of transition between the traditional market for pharmaceuticals and the second healthcare market (figure 3). In this context, the industry could exploit its strengths and partly adapt the OTC-business to the new demand. Positioning OTCs closer to the consumer by adapting their appearance to health products would be an option, as well as a focus on more wellness-related indications.

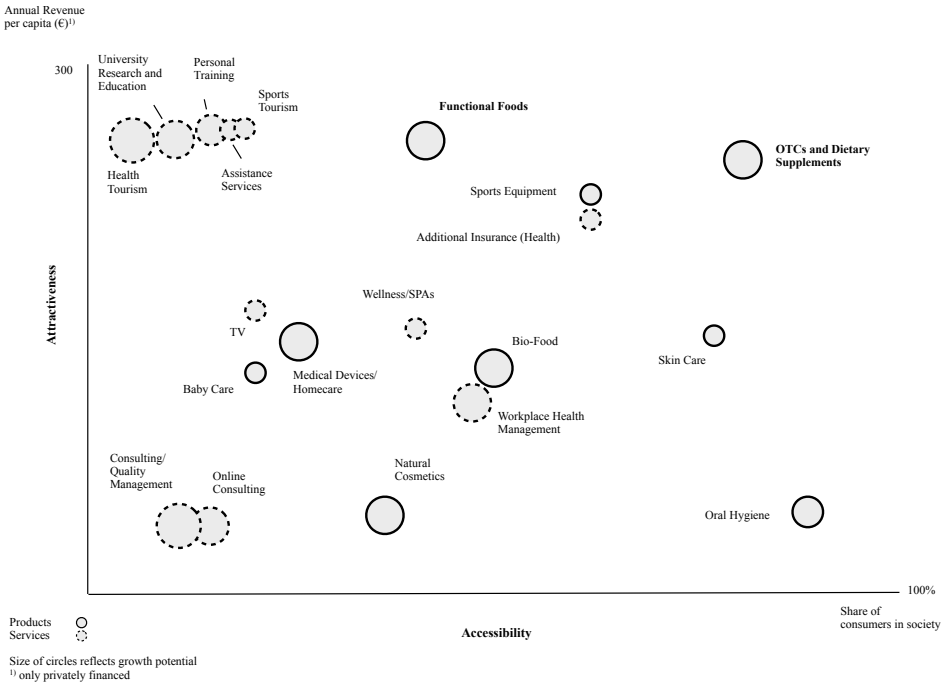

Figure 2: Sub-markets and products of the second healthcare market and their growth potential (adapted from Kartte 2008: 6)

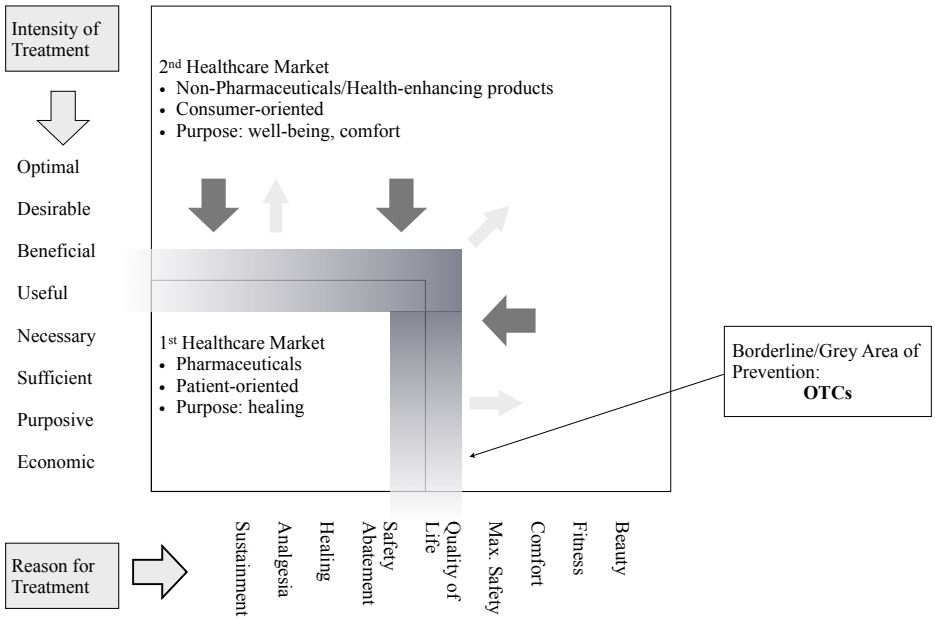

Figure 3: The grey area of prevention between the two health markets (own illustration, adapted from Krimmel 2005: 189)

A second scenario would be an increased focus on the already existing pharmacy-exclusive health products brands of the pharmaceutical industry. In addition to OTCs that are often seen as the ideal steppingstone into the new market segment, the health products market outside the pharmacy (mass market) would be another one. During the last 20 years, the pharmaceutical industry has built up a range of health product brands, whose size varies among firms (yet, they represent a fraction of the overall activities of the individual firms). Most of them are sold through pharmacies only (pharmacy-exclusive health products). Facing the growing demand for health products, one could expect the pharmaceutical industry to focus on the pharmacy-segment for health products and innovate in it.

Thirdly, an expansion of health products innovation activities beyond the pharmacy — to the mass market — would be thinkable. It would be the logical consequence of the market changes, as the market for health products has developed dynamics that seem to threaten the pharmaceutical industry, at least in the future. In the mass market, the foods and cosmetics industry has established itself as the superior player when it comes to health products. Big Functional Foods brands, such as Becel™, LC1™ or Actimel™ are present in the market, as well as food supplements and dietetic foods produced by the foods industry.

It can be argued that an expansion of innovation activities to the health products market is anything but difficult for the pharmaceutical industry. In the context of an emerging new market segment for health products, it would only fit if innovation activities in the pharmaceutical industry grew significantly with respect to the boundaries of its current field of activity. The pharmaceutical industry holds the monopoly on pharmaceuticals and with it comes an immense amount of knowledge and competences on health exclusive to this industry. Should it not be easy for the

industry to redirect resources and knowledge from the sophisticated Rx-innovation process to OTCs and/or health products, thereby expanding its innovation activities to the new and dynamic second healthcare market significantly? Does the industry not provide the perfect starting conditions for such a step?

From a regulatory perspective, health products are subject to much simpler standards and requirements, making their development considerably quicker and cheaper than for pharmaceuticals. Also, the regulatory frameworks of health products allow the innovating firm more freedom regarding health claims, marketing and the distribution structures. Pharmaceuticals are in deed designed for use in case of medical urgency only. Their consumption is supposed to last only as long as needed to cure an illness. Quite in contrast, the consumption of self care products is meant for a maximal duration; the consumption per se is partly the purpose (Sigrist 2006: 47). Yet, the pharmaceutical industry has available sophisticated knowledge and resources on the development of pharmaceuticals and is involved in the borderline market of OTCs and in the health products market already (to a mush lesser degree, however). As a response to the new demand at the boundaries of the traditional healthcare market, this knowledge should be transferred to the new market segments. The 'ease of innovation' of health products relative to pharmaceuticals even increases the incentives that the industry should feel.

Interestingly however, the pharmaceutical industry in Germany has remained rather passive with respect to the extension and growth of the innovation activities towards the second healthcare market. When looking at the part of the second healthcare market beyond pharmaceuticals that is controlled by the pharmaceutical industry (the pharmacy-segment), stagnation is to be observed (IMS).[1] The volume of the German pharmacy-market for health products has almost been constant over the last years, with a slight growth of 10% between 2010 and 2012.[2] In context of the entire pharmacy market however, pharmacy-exclusive health products ranged at a stable 3% between 2010 and 2012 (IMS).[3] In light of the increasing innovation activities of the foods and cosmetics industry relative to the pharmaceutical industry, this is noteworthy and signals no significant innovative efforts made in the field, neither in general (as a reaction to the new demand for health products), nor specifically in relation to the first foods and cosmetics companies that have entered the pharmacy market recently.

[1] Quantitative data on the German pharmaceutical industry and market and was provided by IMS Health and is used throughout the analysis. IMS Health® is a leading American market research institute, providing services and information technology for the healthcare industry.

[2] As the pharmaceutical industry holds a quasi monopoly on the pharmacy-market (pharmaceuticals and health products), while its activities are at the same time limited to the pharmacy, the market volume is representative of the industry's turnover. Changes in the market volume are therefore likely to reflect innovation dynamism of the industry in the market.

[3] The pharmacy-segment of the healthcare market as a whole (Rx-medicines, OTCs and health products) has been growing slightly, yet this is solely due to the growth of the Rx-segment (IMS).

Moreover, the monopoly of the pharmaceutical industry with respect to the pharmacy as their 'exclusive' chain of distribution has been damaged: the food or cosmetics industry start to compete with the pharmaceutical industry in the pharmacy. For instance, Innéov™, a food supplement developed by a joint venture of Nestlé and L'Oréal, has lately been the most prominent case of a health product innovation breaking into the pharmacy-market from the outside. Other examples are Nestlé Medical Nutrition or Wick™ (Proctor & Gamble). The involvement of the foods and cosmetics industries in the pharmacy-market for health products is minimal relative to the entire market, so that it can still be considered fully controlled by the pharmaceutical industry. However, it shows that the dynamics from the health products market starts entering the pharmacy, the traditional sphere of influence of the pharmaceutical industry. Outside the pharmacy — in the mass market — the pharmaceutical industry already left the field to other players, the food industry in particular (see figure 4). The question arises whether this represents a threat to the pharmaceutical industry.

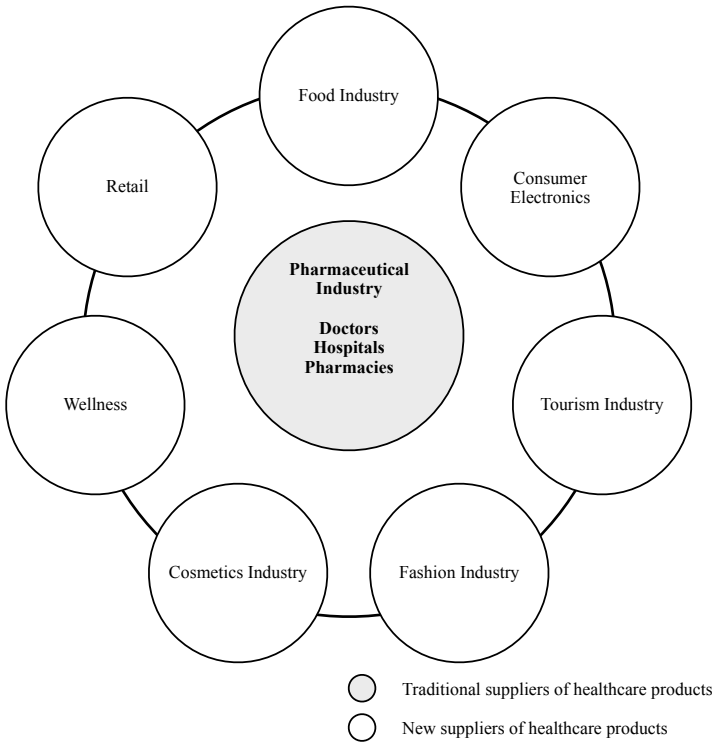

Figure 4: New players enter the healthcare market (own illustration, adapted from Sigrist 2006: 48).[4]

Also the German mass market for health products remains untouched by the pharmaceutical industry, as innovation activities are concentrated in the pharmacy.[5]

[4] Sigrist's conceptualization of the new players in the healthcare market is not limited to health products but considers all novel products and services offered in the field of healthcare.

[5] This is the case with the exception of very few large pharmaceutical firms who have historically grown ties to the mass market, operating a small segment in it (i.e., Klosterfrau Healthcare Group) and some small and medium firms, who are highly specialized niche player.

Even though the first healthcare market remains controlled by the pharmaceutical industry, numerous new players innovate in the various sub-areas of the second healthcare market. Industries such as the foods industry have established a new market for commodities with health benefits. As Pilzer (2007) argues, the classical pharmaceutical industry

> 'has very little to do with preventing illnesses or with making people feel stronger or healthier. On the other hand, the wellness industry includes products and services that promote wellness rather than respond to illness — this includes nutritional supplements, super foods and juices, personal trainers and "alternative care", such as chiropractic' (27).

The situation is noteworthy, as the mass market segment of the health products market has grown to half of the size of the pharmacy-segment over the last decade (IMS). Even though the segment showed no growth recently, its size relative to that of the pharmacy-segment underlines the strategic importance it should have for pharmaceutical firms. Functional Foods included, the extended health products market outweighs the volume of the pharmacy-segment by far: some Functional Foods brands alone (fortified yoghurt drinks for instance) represent revenues of a several hundreds of millions of Euros.

Also, the 'traditional' market for self medication (OTCs) in the pharmacy shows no significant growth that could be interpreted as the innovative response of the pharmaceutical industry to the changed conditions in the market. This can neither be observed with respect to revenues nor with respect to new products introduced to the market. Interestingly the market for freely marketed OTCs (those pharmaceuticals that are sold without prescription and outside pharmacies) has shrunk in size and innovative dynamics. This is noteworthy as it is this field where the pharmaceutical industry could, through innovations, compete with the health products face to face in a (relatively) open consumer market.

The pharmaceutical industry is confronted with several stimuli: demand for health products has developed and has been growing over the last decades; technological advancements made the production of sophisticated health products possible; demographic and social changes increased the importance of prevention and of a more holistic approach to health. Lastly, even if all those changes of the healthcare market were irrelevant, one stimulus would stay: the growing position of the foods and commodities industries in the health products mass market and their increasing know-how on health that comes with their activities. From a strategic viewpoint, this should also be a powerful stimulus for the pharmaceutical industry to strengthen its position with respect to the second healthcare market.

The situation outlined above provokes of course the question for the reasons for the industry's behavior. How come big pharma in Germany is — unanimously — acting very cautiously with respect to the market beyond pharmaceuticals, while the food and cosmetics industry seem to have absorbed the changes? What explains the rejection of the mass market and the noncommittal involvement in the pharmacy-

market for health products? Are the market changes — in terms of new product categories as well as new actors — not putting pressure on the pharmaceutical industry, forcing firms to act more dynamically with respect to innovations beyond classical OTCs and pharmaceuticals in general?

However, there is a second facet of the problem that merits consideration: interestingly, the homogeneous 'lethargy' of the pharmaceutical industry in Germany is not characteristic of the sector in general. Regarding the development and growth of the biotechnology sectors over the last decades, the industry has in fact shown strong dynamism and the ability to adapt to the changed conditions (see Gassmann et al. 2008; McKelvey and Orsenigo 2001). As Casper et al. (1999) outline,

> '[t]he 1980s and 1990s witnessed fundamental technological changes in both the pharmaceuticals and software industries. In pharmaceuticals, the emergence of new genetic engineering-based techniques for drug discovery and design have created scientific and organizational challenges that exceeded the capabilities of traditional large pharmaceutical companies. Leading-edge research in biotech required the inputs of smaller more dynamic biotech firms along with an extensive reorganization of the in-house R&D activities of large pharmaceutical firms.' (14)

They argue further that

> '[d]uring the 1980s very little start-up activity in biotechnology existed in Germany […]. In the past two years the climate for biotechnology in Germany has improved dramatically. Large German pharmaceutical firms are investing in new German-based biotechnology labs and forming alliances with German biotech start-ups. The climate for founding entrepreneurial start-up firms has also improved dramatically. […] . In order to keep track of developments in different research areas, large pharmaceutical firms have continued strategies of supporting large amounts of external research through alliances with small biotechnology firms.' (21)

The manner in which the pharmaceutical industry approached the biotechnology revolution underlines the relevance of exploring the reasons behind the industrial behavior regarding health products. Casper et al. (1999), among others, describe the process of fusion and concentration between the pharmaceutical and biotechnological sector that took place and contributed to the industry's competitiveness. Pharmaceutical firms made use of biotech start-ups that they co-founded and/or supported and bought once they surpassed a critical size (McKelvey and Orsenigo 2001: 28; see also Bührlen and Kickbusch 2008; Casper 2000; Casper et al. 1999; Gassmann et al. 2008), the aim being to exploit the new opportunities flowing from biotechnology R&D (Research & Development). As a result, biotechnology now plays a major role in the pharmaceutical industry, driving its growth. Realizing the potential of biotechnology for their future competitiveness, pharmaceutical firms adapted to it by innovating in the field.

This example adds another interesting aspect to the problem at hand, as it indicates that the pharmaceutical industry is in fact capable of adapting to changing conditions. As the successful integration of biotechnology into the dynamics of in-

novation shows, the industry can absorb environmental changes, exploit them and reorient accordingly. Put into context of the situation regarding health products, this indicates that change per se is not the problem — the industry can adapt to the market successfully. This is important to notice; it indicates that the problem at hand is not a general one but rather, the reaction to market changes appears to depend on the individual conditions. Why else would the pharmaceutical industry let new industrial actors profit from the considerable dynamism in the new healthcare market? And, perhaps even more importantly, why would the industry allow new actors to get so close to its traditional sphere of action? Are they not potential future competitors? After all, it is remarkable that an industry is — homogeneously — flexibly adapting to some environmental changes, exploiting the opportunities they provide, while it is — again without exception — largely insensitive to others.

1.3. Identification of the Research Gap

The literature provides no general studies on the systemic embeddedness of the pharmaceutical industry and its innovation activities. No major analyses are available dealing with questions of the underlying dynamics and the feasibility of an expansion of the pharmaceutical innovation activities from a broad perspective, beyond the traditional boundaries of pharmaceuticals.[6] Some works on the second healthcare market, such as those by Kartte (2008), Roland Berger (2009) or Sigrist (2006) point out the role over-the-counter drugs (OTCs) ought to play in the extended healthcare market, yet the potential extension of innovation activities to the market beyond pharmaceuticals is not discussed. The existing studies also fail to set up clear criteria allowing to distinguish the dynamics of innovation of the two markets that could be used for an analysis of the feasibility of extended OTC-innovations.

Those studies going beyond a general analysis focus on specific areas of the second healthcare market only and conduct no analysis of the role of the pharmaceutical industry in it. Those are for instance Gedrich et al. (2005), Goebel (2010), Menrad (2000, 2001, 2003, 2005), Mollet and Rowland (2002) or Roberfroid (1999, 2002) on Functional Foods and dietary supplements, or Draelos (2012) on cosmeceuticals. Similarly, the literature on OTC-innovations per se is rather limited. Even though the general issue of self medication is covered sufficiently from the social sciences and policy perspective, analyses of the dynamics of innovation of OTCs in the larger industrial context of the pharmaceutical industry are still missing. The only exception is a study by Santermans (2004), highlighting some challenges to OTCs that the changed healthcare market produces. It fails, however, to address the ques-

[6] Multiple studies exist, however, on the expansion of innovation activities to biotechnology and microbiology (see i.e. Bührlen and Kickbusch 2008; Casper 2000; Casper et al. 1999; Gassmann et al. 2008; McKelvey and Orsenigo 2001). Yet, the process of adaptation to the 'biotechnological revolution' has required no departure from the traditional pharmaceutical-dominated innovation trajectory.

tion of whether the pharmaceutical industry is able to cope with those new conditions.

The research aims at closing this gap by exploring the reasons for the industry's behavior and the dynamics underlying its innovation activities with regard to the second healthcare market.

In addition to this 'practical' problem, another interesting research gap is to be found in the theoretical concepts that explain patterns and dynamics of industrial change and adaptation. Over the last two to three decades, a variety of approaches have been developed, analyzing firms' innovation activities from a larger, systemic standpoint. Among those concepts, the theory of sectoral systems of innovation has established itself as a prominent approach to explaining dynamics of innovation from an industrial perspective, positioning processes of transformation and change at its centre (see Breschi and Malerba 1997; Malerba 2002, 2003, 2004, 2005a, 2005b, 2006; Malerba et al. 1999; Malerba and Montobbio 2000; Malerba and Orsenigo 1990, 1993, 1994, 1995, 1996, 1997, 2000).

The literature on sectoral systems of innovation sheds light on the collective behavior of industrial sectors and explains their transformation patterns. It describes sectoral dynamics from a multidimensional perspective, thereby creating an integral approach to innovation systems, including all network dynamics that shape the agents' behavior. Simply put, sectoral systems of innovation are sets of products and agents that are 'carrying out market and non-market interactions for the creation, production and sale of those products' (Malerba 2002: 247).

However, while taking into consideration the dynamics of the actors' interaction within the system, the literature on sectoral systems of innovation fails to address barriers to change that might — despite the systemic dynamism — be present. Based on evolutionary theory of growth and development, the literature assumes cycles of growth and development at the centre of sectoral systems of innovation. System boundaries are therefore never static or fixed but subject to co-evolutionary development processes (Malerba 2002: 250). Yet, if any aspect of the system can always change towards any direction, how can it happen that an industry does not adapt to multiple environmental changes that come about at once?

While incorporating the evolutionary principle of systems of innovation, the sectoral approach fails to discuss situations of drastic environmental change in depth. A discussion of scenarios regarding the clash of two sectoral systems of innovation, their potential bonding or separation and the real degree of adaptability that sectoral systems of innovation incorporate is absent in the literature. Malerba himself attests this shortcoming of his theoretical work:

> ‘a lot of empirical and theoretical work has to be done in order to understand the dynamics of sectoral systems and their basic co-evolutionary processes […]. Even more work is necessary when the transformation of sectors involves not just traditionally defined sectors […]. Here, the analysis of sectoral systems has to consider the integration and fusion of previously separated knowledge and technologies and the new relations and overall dynamics among different types of users and consumers, firms with different specialization and competencies, and non-firms organizations and institutions grounded in previously separated sectors (2002: 259).

Theory fails to conceptualize the potential inability of sectoral systems of innovation to change; instead the literature conceptualizes sectors as highly malleable and continuously adapting.

The dissertation is to contribute to closing the gap in the sectoral systems of innovation theory. Due to the prominent role of the institutions and regulation, the embeddedness of innovation activities in systemic network structures is particularly strong in the pharmaceutical industry.[7] With the growth of the second healthcare market, not only the dynamics of innovation of the pharmaceutical industry are challenged, but those of the entire system of innovation. An analysis from a sectoral perspective therefore suits the research particularly well, the assumption being that the observable lethargy of the pharmaceutical industry has systemic reasons that partly lie beyond the control of the individual pharmaceutical firm. Particular attention is paid to the patterns of change and the potential of adaptability of sectoral systems of innovation, as to explore how industries can — in dialogue with their systemic environment and the attached network structures — develop dynamics that make the extension of systemic boundaries to new markets impossible. The dynamics of innovation of the health products segment of the pharmaceutical industry is, after all, a function of the sector’s ability to stretch its boundaries towards new sources of growth and innovation.

1.4. Research Questions

From the observed phenomena and the research gaps stated above emerges the principal research question of the study, aiming at resolving what industrial dynamics are responsible for the behavior of the German pharmaceutical industry. The fact that the pharmaceutical industry is not adapting to the changed market conditions implies that dynamics are present on industrial — sectoral — level, that represent barriers to change. It leads to the assumption that the pharmaceutical industry suffers from certain sectoral structures and dynamics that produce insufficient adaptability to the changes in the second healthcare market.

[7] See Burr and Musil 2003 for an overview of institutional barriers to pharmaceutical innovation, as well as Gaiser et al. 2005 on the relation between regulations and market attractiveness for pharmaceuticals

The fundamental aim of the study is therefore to shed light on the industrial structures that guide the behavior of pharmaceutical firms in Germany in the face of the changing market. As discussed above, the study addresses the major research gap, which the question reflects. It aims at understanding the industrial dynamics of innovation with respect to their influence on the ability to transport environmental change into the pharmaceutical firms.

Naturally, additional research questions are flowing form the principal question, structuring the research. In order to understand why the pharmaceutical industry is acting as observable, it must be explored what guides their dynamics of innovation in general (subquestion 1). Secondly, it is to be examined in how far the industrial structures and dynamics impose limits to the innovation activities of pharmaceutical firms in Germany (subquestion 2). In a third step it needs to be investigated under what conditions those boundaries cannot change, making processes of adaptation to changed environmental conditions impossible (subquestion 3).

In the light of the shortcomings of the sectoral systems of innovation theory that were identified, the sectoral systems approach is extended. Otherwise, the theory neither has the explanatory power needed for the purpose of this research, nor can the gap in the theory be closed; by implementing the sectoral systems theory alone, analyzing the sectoral dynamics of innovation of the pharmaceutical industry with respect to the sources of inflexibility would be impossible.

Consequently, the notion of inflexibility and rigidity to change must be incorporated in the theoretical discussion in order to create an analytical tool that serves the purpose of the research. The sectoral systems of innovation discussion is therefore expanded by the theory of Incumbent or Organizational Inertia (see Freiling 2004; Gilbert 2005; Hannan and Freeman 1984; Leonard-Barton 1992; Liebermann and Montgomery 1987; Teece et al. 1997; Weiss and Ilgen 1985), aiming at integrating the concept of organizational rigidity into the sectoral discussion. Both approaches are combined towards a theoretical framework providing categories for the empirical analysis of the pharmaceutical industry.

The concept of organizational inertia is concerned with identifying organizational barriers to adaptation to change, flowing out of the historically grown stability-generating structures of the organization. It helps explore what industrial and organizational dynamics can lead to lock-ins that limit the space of action that a sector has, ultimately disabling the sectoral firms to respond to environmental changes and stimuli to innovate beyond their traditional boundaries.

Figure 5 gives an overview of the research questions and the theoretical concepts employed for approaching them. Subquestion 1 is approached by a discussion of the general theoretical background of systemic approaches to innovation, lying the basis for exploring the sectoral systems of innovation approach. A second analytical part complements this by presenting a more concrete analysis of the building blocks of sectoral systems of innovation as well as the dynamics of innovation that their in-

teraction produces. Subquestion 2 is addressed by a further analysis of the sectoral systems of innovation literature, exploring the systemic boundaries and their patterns of change, as conceptualized by theory. Finally, the third subquestion covers the theory of organizational inertia, as to explore under what conditions firms are unable to adapt to changing innovation conditions.

In a last step, a framework is deducted from the theoretical discussion that is to guide the empirical analysis of the pharmaceutical industry in Germany. It allows to integrate the notion of sectoral inflexibility into the sectoral systems of innovation approach, providing concrete categories for measuring it.

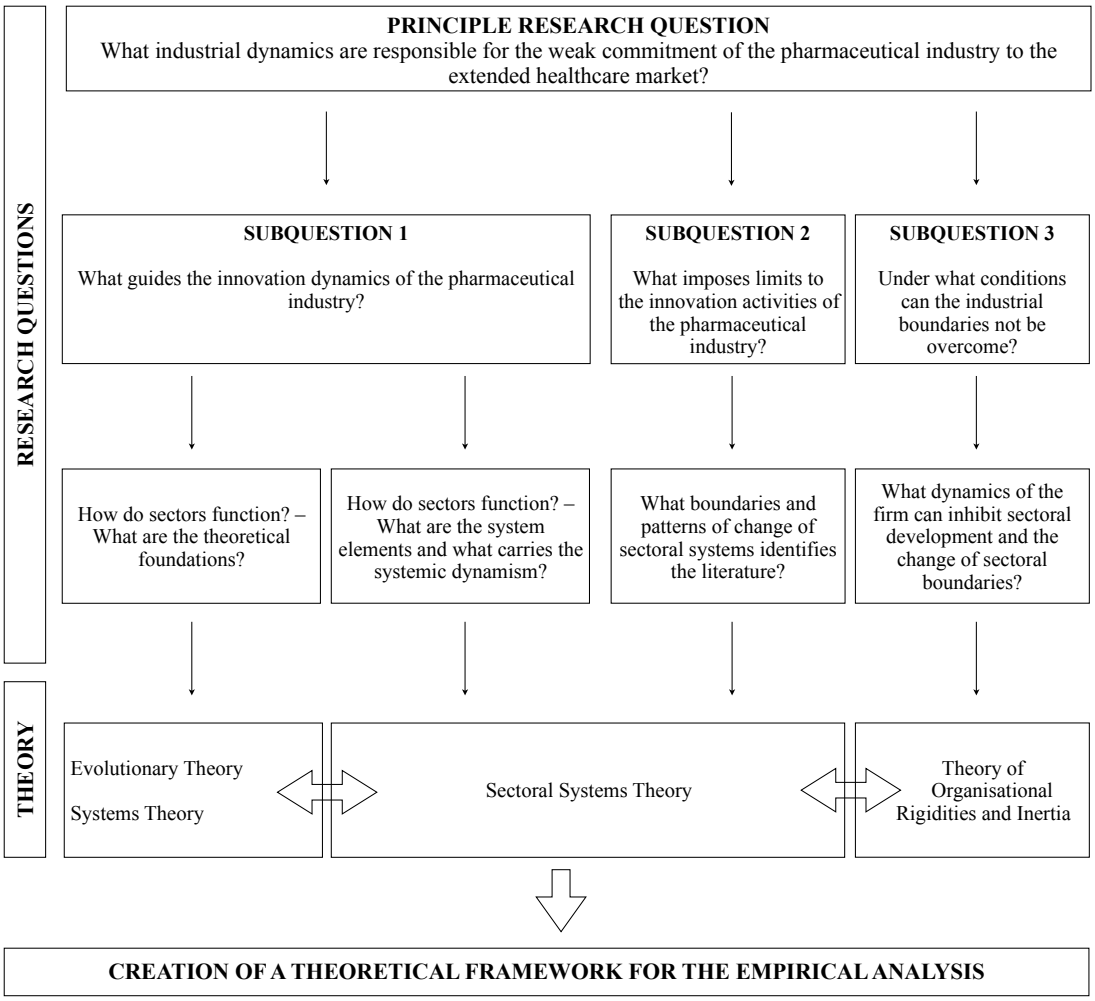

Figure 5: Research questions and structure of the research (own illustration)

The research questions aim at filling the research gaps described above. They approach the dynamics of innovation of the pharmaceutical industry in the sectoral context, while focusing on inertia and inflexibility in the system of innovation that might be responsible for what appears to be a lack of innovativeness regarding health products. The analysis is to contribute to the research on the pharmaceutical industry, as well as to innovation research and innovation systems theory in general. Therefore, in the light of the shortcomings of the literature on the pharmaceutical industry and its innovation patterns as well as on the conceptualization of boundaries and

change of sectoral systems of innovation, the study pursues three main objectives that are addressed through the basic research question and its three subquestions:

1. By answering the basic research question the dissertation is to contribute to the understanding of the dynamics of innovation of the pharmaceutical industry at its boundaries. The analysis of the pharmaceutical industry can generate knowledge regarding the perspective of the pharmaceutical industry on the second healthcare market and the motives to avoid innovating in it.
2. A second aim is to provide explanations for the interplay between systemic conditions and the flexibility of the industrial innovation activities, contributing to innovation research. Through the study of the pharmaceutical dynamics of innovation in light of the systemic contexts, the dissertation might be able to shed light on the influence that sectoral dynamics have on industrial behavior.
3. Finally, the empirical results allow to draw conclusions about the sectoral systems of innovation theory from them. Reflecting the empirical results onto the sectoral systems of innovation theory and the theoretical framework created for the empirical study might provide insights into the role of organizational inertia in sectoral systems of innovation. They would help to refine the theoretical conceptualizations of industrial dynamics and the ability of industries to change at the boundaries of their innovation activities.

1.5. Structure and Methods of the Research

The structure of the research follows the research questions presented above. Chapter two is dedicated to the theory of sectoral systems of innovation, which is employed as the theoretical approach to the research question. The chapter focuses on the issue of sectoral boundaries and patterns of change as conceptualized by the literature, discussing the concept's theoretical foundations and building blocks as well as the dynamics they entail. This is followed by the discussion of the theory of organizational inertia (chapter 3), representing the second stream of literature employed for the analysis of the dynamics of innovation of the pharmaceutical industry. The introduction of the concept of organizational inertia to the discussion is needed, as the sectoral systems of innovation literature provides no clear guidelines and categories for the expansion of systemic boundaries in times of environmental change. Chapter 3 combines the theories of sectoral systems of innovation and organizational inertia to a theoretical framework which provides categories along which barriers to sectoral change and flexibility can be measured for the pharmaceutical industry. It structures the analysis of incumbent inertia in the sectoral context along two major categories, each consisting of two sub-categories. Resource rigidities, comprising of the analysis of resource dependences and incumbent reinvestment incentives, address

the barriers to industrial change resulting out of the sectoral context in which the firms are embedded and the feedback mechanisms form their traditional markets. Secondly, routine rigidities, including the analysis of firm routines (search routines, routines of interaction, routines of combination and routines of diffusion are selected as categories), as well as organizational culture and managerial cognition, address inflexibility from the firm-internal perspective. The empirical findings are presented in chapter 5 and are further discussed in chapter 6. Finally, a summary of the study and conclusions that are drawn from it is presented in chapter 7.

Different amounts of literature are available to be drawn from for the empirical analysis of the pharmaceutical industry. While studies on the sectoral frame conditions (mostly the regulatory sphere) of pharmaceutical innovations and the market can be evaluated towards evidence for resource rigidity, no data whatsoever is available on organizational routines of pharmaceutical firms. Multiple methods are therefore employed to carry out the study along the theoretical framework (described in chapter 4). Following the logic that the research question determines the methods used, whereby a combination of different methods and data sources is legitimate (Edmondson and McManus 2007: 1158; Flyvbjerg 2006: 226), the empirical study draws on three data sources and methods of evaluation. Firstly, through an exploratory analysis of the literature on the dynamics of innovation of the pharmaceutical firms, evidence for resource dependences of the pharmaceutical industry is collected. This is combined with the analysis of quantitative data on the industrial activities and the core markets of the pharmaceutical industry.

Thirdly, routine rigidities are approached by 15 semi-structured expert interviews in nine major pharmaceutical firms in Germany. Qualitative studies provide complex descriptions of and explanations for human actions and their context (Miles & Huberman 1984: 9) and are therefore an attractive tool for unveiling organizational routines. The range of methods and data sources employed for the empirical analysis also allows to make use of the benefits of method and data triangulation, contributing to the validity of the empirical data collected (see Flick 1992, 2011). Based on the close interrelatedness of the aspects examined, the methodological triangulation allows to undertake ‘multiple levels of analysis and the reciprocal study of contexts and action in changing’ (Pettigrew et al. 2001: 709). Figure 6 illustrates the structure of the research.

The study of the pharmaceutical industry is limited to Germany and to research-intensive, globally acting pharmaceutical firms.[8] The geographical limitation is due to the fact that the pharmaceutical dynamics of innovation are highly regulated, while the degree of regulation differs significantly among countries. For the sake of feasibility, the research concentrates therefore on one country. Germany is of

[8] The literature on sectoral systems of innovation underlines that geographical boundaries may and sometimes must be assigned to sectors (see i.e. Malerba 2002: 260; 2005b: 68). Geographical boundaries can take any form: cross-national, national or regional. Similarly, Malerba underlines that boundaries are also legitimate with respect to certain parts of a sector that are to be analyzed.

particular interest, as it represents Europe's biggest pharmaceutical market, while the market for health products (in particular those in the mass market) is small in relation to other countries. The focus on the globally acting, R&D intensive pharmaceutical firms accounts for the fact that only those industry leaders have potentially the force to strategically reorient. Small niche-players in the industry are clearly driven by their own dynamics.

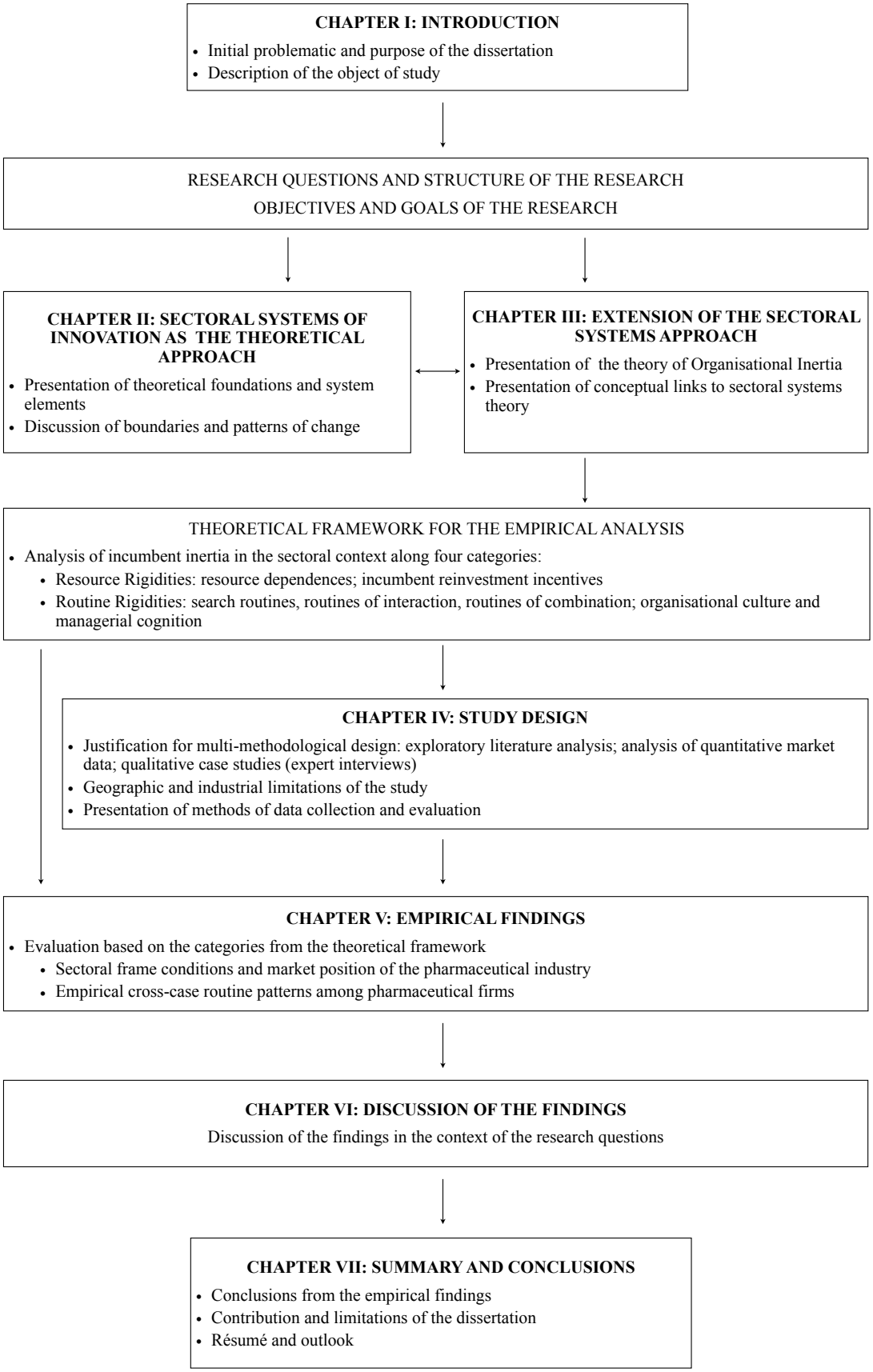

Figure 6: Structure of the research (own illustration)

2. The Sectoral Systems Approach

As stated above, this chapter explores the sectoral systems of innovation approach in order to understand the dynamics of sectoral change that the concept entails. Simply put,

> '[t]he sectoral system approach has emphasized a set of variables that affect the working, dynamics and performance of sectoral systems. These variables can be related to the structure of knowledge, agents and artifacts' (Malerba and Montobbio 2000: 2).

In other words, a sectoral system of innovation is a set of products and agents (organizations as well as individuals) that interact through market and non-market relations, aiming at creating innovations and selling products. This process is carried by 'a knowledge base, technologies, inputs and an existing, emergent and potential demand' (Malerba 2002: 250). The approach is based on the assumption that each industrial sector is characterized by a specific configuration and interplay of products, agents, knowledge and technologies and that each sector produces a collective outcome through co-evolution of those elements.

The approach shares similarities with technological systems of innovation as well as national and local systems of innovation, who also concentrate on networks of actors and institutions that lead to the emergence and diffusion of innovations within certain conceptual boundaries (Malerba 2002: 248, 2003: 331, 2005b: 64).[9] Yet, it is those conceptual boundaries that differentiate the technological and geographical approaches from the sectoral one, creating a gap that the concept of sectoral systems of innovation attempts to fill: while technological systems focus on technology-specific patterns of the generation and diffusion of new technologies and technological knowledge among technologically related clusters of firms, geographical approaches such as national and local systems of innovation are limited to the analysis of sets of actors and institutions within geographical boundaries. Even though the sectoral systems of innovation concept incorporates some aspect of those two schools (as discussed below), it goes a step further: sectoral systems of innovation try to conceptualize the dynamics within industries under the constraints that technology, geography, institutions and the relations between the actors and components put on them. Processes of competition, networking and co-operation are at the center of sectoral systems of innovation. This perspective allows to categorize industries and make predictions about their patterns of transformation and change (see Malerba 2002: 259, 2003: 331, 2005b: 68; Carlsson et al. 2002: 236);

[9] As the focus of this research lies exclusively on sectoral systems of innovation, those related concepts are not discussed in much detail. For more information on technological systems of innovation see i.e. Carlsson et al. 2002; Carlsson and Stankiewicz 1991. For national and sub-national innovation systems see i.e. Edquist 2005, 1997; Freeman 2002; Lundvall 1993, 1992; Lundvall et al. 2002.

> '[the sectoral systems of innovation approach] departs from the traditional concept of sector used in industrial economics because it examines other agents in addition to firms, it places a lot of emphasis on non-market as well as on market interactions, and focuses on the processes of transformation of the system; it does not consider sectoral boundaries as given and static.' (Malerba 2002: 250)

2.1. Theoretical Foundations

Before the discussion turns to a deeper exploration of the building blocks of sectoral systems of innovation, the approach's principal theoretical groundings must be discussed. They lay the basis for the dynamics of change and transformation of sectoral systems of innovation. Two major theories provide the basic logic according to which sectoral systems of innovation develop: first, the Evolutionary Theory of Economic Growth and 'the broader analyses of the long-term evolution of industries' (Malerba 2002: 249), as provided by Schumpeter and others and second, Innovation Systems Theory (see i.e. Malerba 2002: 248, 2003: 336-337, 2004, 2005a, 2005b: 64-65).

2.1.1. Evolutionary Theory of Economic Development and Growth

The Austrian economist Joseph Schumpeter is widely considered the forefather of the evolutionary school of growth and development. His major work *Capitalism, Socialism, and Democracy* (Schumpeter 1976)[10], introduces the idea 'that capitalism can only be understood as an evolutionary process of continuous innovation and "creative destruction" ' (Freeman 2009: 126). Schumpeter coins the concept of turbulence and destruction through innovation being the initiator of healthy processes of winnowing which force agents to evolve and keep innovating. Economic development, according to him, equals a gradual and self-reinforcing process of change (Rahmeyer 2005: 5). Of course, some players die in that race, whereas the surviving few can accumulate knowledge and undergo further processes of transformation and evolution (Canter and Hanusch 1998: 9).

Evolutionary theory following Schumpeter's work stands in sharp contrast to neoclassical theory. The neoclassical school assumes an economy in which rationally acting agents follow their aim of profit maximization. The external environment in which economic exchange takes place is stable, predictable and universally known to all agents; markets are continuously in an equilibrium of supply and demand (Nelson and Winter1974: 887). Evolutionary theory on the other hand assumes a much more complex world. Schumpeter's theory underlines that the aim of economic agents may of course be profit-maximization, yet what he rejects is the notion of well-defined and calculated sets of choices the agents are faced with. Instead, Schumpeter and the

[10] First published in 1942.

entire evolutionary school that has been flowing out of his theories claim that economic agents have to deal with permanent uncertainty and change: the 'selection environment' is considered dynamic rather than in equilibrium. Processes are key to evolution and innovation, not equilibria (see i.e. Campbell 1960: 381; Hodgson 2002: 698; Rahmeyer 2005: 12); even though short-run stability in the decision rules of economic agents can be assumed, in the long run uncertainty and turbulence persist, to which the firm must respond in order to survive (Nelson and Winter 1974: 892). In other words, evolutionary theory assumes that unpredictable, almost random events are continuously shaking the firms' exogenous environment, requiring them to reposition themselves constantly. This means not that this evolution is completely random, but neither can it be considered deterministic, as neoclassical theorists tend to underline (Nelson 1995: 55).

The literature is regularly drawing analogies to biology and the Darwinist theory of evolution, in order to stress this aspect: 'change "according to a plan" is usually not regarded as evolutionary. However, it is recognized widely that many random occurrences will affect the development of an embryo or a tree.' (Nelson 1995: 56). This aspect of 'continuous struggle and motion' and the resulting 'survival of the fittest' is a key characteristic of economic theory (Nelson and Winter 1974: 890).

Consequently, evolutionary theory is an inherently dynamic model of economic development. Agents have no other choice but to overcome their 'bounded rationality' and survive in the ever changing selection environment through constant learning, transformation and of course innovation. Embedded in the dynamic selection environment, firms are involved in 'search processes' that are supposed to lead to economic returns and eventually to growth. In any case, an evolution is always the result. This aspect makes evolutionary theory a 'behavioral approach' to the firm: it assumes that the actions of a firm are the product of its decision rules 'that link a domain of environmental stimuli to range of responses on the part of the firm' (Nelson 1974: 891). Certain search routines exist in each company that direct, in concordance with the firm's situation, its responses to the market reality. The interplay between these responses sent out and the markets' reaction to them then determines the direction of the firm's evolution: expansion or contraction. Based on this the firm starts a new search process and thereby the next cycle of transformation (Nelson 1995: 70). In short, this is the evolutionary processes any firm in an economy undergoes.

The concept of variation, selection and replication in evolutionary theory addresses this process in detail (see i.e. Nelson and Winter 1982). Borrowing the logic from natural history it is claimed that the evolution of firms and economies equals a process of knowledge-generating and -upgrading through the creation of various sets of solutions to economic problems, the filtering out of the weak ones and the preservation of the strong ones. Variation, selection and retention take place simultaneously and among groups of heterogeneous agents.

As a reaction to an unsatisfying economic performance, firms initiate changes, hoping that the following transformation alters the firm's position in the market. This results in a deviation from what the firm has done before; in biology this process would equal mutation (Nelson and Winter 1982: 142).[11] From an economic standpoint, evolutionary theory labels this phenomenon variation. It is stressed that the process of variation is driven by inter-firm heterogeneity in terms of firm properties like competences. This is to say that only if a set of heterogeneous actors exists, different offshoots can develop. Heterogeneity is unlikely to develop out of homogeneity. At the same time variation is of course also creating further heterogeneity. Variation occurs therefore out of heterogeneity and at the same time creates it (see Rahmeyer 2005: 13; Srholec and Verspagen 2008: 8).

Just like mutation of different species in nature, variation leads to increasing diversity among firms. Each firm possesses a priori individual means to deal with 'motion and struggle'; the nature and effectiveness of the search processes in terms of both, quantitative and qualitative growth of the firm, lies in the hands of the individual organization and is therefore 'the source of differential fitness' (Nelson 1995: 69) among them. Factors like different skills of individual workers or differences in firm size, experience or financial power, co-determine the nature and effectiveness of firms' activities and function therefore as sources of further heterogeneity (see i.e. Nelson and Winter 1982: 113). Firms are seen as complex learning organizations that develop different ways to operate successfully in their environment. This is the reason for their heterogeneity.

Yet this is not to say that firms innovate in perfect isolation. According to theory, firms cannot innovate totally detached from other agents and the general economic environment (Nelson 1994: 55, 1995: 54).[12] What evolutionary theory stresses is rather that heterogeneity exists but can never be perfect, as the individual search process of any firm of a sector or an industry is embedded in a shared, exogenous search environment. Of course this leads to shared sources of growth and to appropriability problems. Nelson analyses this well to the point:

> '[t]he firm, or rather the collection of firms in the industry [...] is viewed as operating within an exogenously determined environment. The profitability of any firm is determined by what it is doing, and what its competitors do, given the environment' (1995: 69).

Within the process of variation, evolutionary theory differentiates between blind and more intentional, deliberate variation. Blind variation describes an unconscious, or at least unplanned change in behavior (Volberda and Lewin 2003: 2116). Intentional variation on the other hand is a planned adaptation of behavior that is the

[11] As we will see throughout the discussion, the biological processes of evolution cannot simply be mirrored onto economic development processes but are rather a proxy for economic evolution. This is, as firms possess intelligence, allowing them to reinforce or counteract changes. This differentiates them from biological species who have little means to influence their developmental path.

[12] For more general overviews see also Nelson and Winter 1982 or Thelen 1999.

well-calculated reaction to anticipated changes in the firm's environment (Volberda and Lewin 2003: 2118). If for example the legal environment in which a firm is operating changes, the firm might be aware of it and initiate transformative steps that prepare it for the new challenges. In contrast, if the firm is taken by surprise the changes in the environment can act as an external shock to which blind variation can be the response. Yet even though the literature differentiates between those two causes for variation the transformation of firms or technologies cannot always be clearly traced back to one of them. As Vincenti (1994) illustrates, employing the example of the evolution of the airplane landing gear, the exact cause for an observed evolution can often not be traced back, as blind and intentional processes of variation can easily amalgamate in dynamic transformative processes. Also, one kind of variation can of course provoke the other, which can lead to simultaneous occurrence of both.

The second mechanism identified by evolutionary theory as a driving force behind the evolution of firms is selection. In a way, selection can be seen as the force that reduces the variety that the variation process creates. As Srholec and Verspagen (2003) put it, '[s]election will reward strategies that are associated to high competitiveness [...], and punish strategies that imply low competitiveness' (8), which means simply that only those firms that are competitive will survive in the market while those that are too weak will die. Metcalfe (1995) argues that '[a]ny framework in which agents interact in order to choose between competing patterns of behavior has selective properties' (469). The process of selection works therefore against heterogeneity; this is true, nor matter how much variety develops, as variation and selection are always simultaneously present in an economy. Yet, even though Metcalfe (1994) argues that 'selection destroys the measure of variety on which it depends, so that, for example, the variance of behavior is driven to zero by selection [...]' (330), heterogeneity is unlikely to vanish completely. This is plausible, because even though selection will for a while reduce variety, the surviving firms will nevertheless enter a new loop of variation and selection is to follow. So, variety in a world with selection processes is certainly smaller than in one where selection is absent, yet heterogeneity will always persist (see i.e. Srholec and Verspagen 2003).

Volberda and Lewin (2003) differentiate between 'managed' and 'naive' selection. While naive selection equals a 'pure market selection of existing initiatives', managed selection processes are directed by the top management of a firm. They are embedded in larger strategic considerations, selecting the 'promising initiatives' only (2115). Witt (1999, 2003) applies a similar concept, differentiating between external and internal selection. External selection processes in economies are similar to naive selection: 'selection effects that would be imposed on them from outside', resulting from 'developments which entail unfavorable consequences' (Witt 1999: 23). In contrast, internal selection is a managed process:

> 'They may deliberately try to change the course of action so as to avoid these consequences. Someone who supplies goods or services may thus respond to tendencies threatening to drive her/him out of the market by changing her/his offer before external selection takes place. This amounts to 'internal' selection and is subject to the individual's perceptions of situational factors, expectation formation, the current state of preferences, etc.' (23)

Logic suggests that the initiatives of any firm are, once they have gone through the internal selection processes, confronted with market realities. Here external selection processes can go on.

While processes of variation create diversity of capabilities among firms and processes of selection separate the competitive ones among them from the less competitive ones, the third process guiding industrial evolution is retention or replication. Again, the major logic of retention in evolutionary theory can be compared to evolution in biology (Rahmeyer 2005: 17: Witt 1999:23), where retention is usually labeled replication. According to Darwin, mutation, selection and replication govern evolution of organisms and species. - Organisms mutate to new forms, the strong ones survive the selection process and reproduce themselves, whereby their strengths are passed over to the next generation of species.

Evolutionary economic theory tries to reflect the processes of replication to industrial evolution; mutation (variation), selection and retention 'are an abstract reduction of the neo-Darwinian theory in evolutionary biology' (Witt 2003: 6). According to the evolutionary literature, retention processes are responsible for the duplication of those firm attributes that have proven to be superior. Retention can therefore arguably be seen as a refined selection process: in case certain competencies, routines or behaviors have survived the selection process, they might function as the 'dominant genes' which are transferred to and inherited by the next generation. This next generation of firms can then profit from the inheritance and create new variety until the most competitive among the varieties are selected and replicated again. Certain behaviors and competences are kept and reproduced through endogenous growth or the off-springing of new actors from those competences. In other words, retention is carried by the exploitation of what a firm owns on the one hand and the exploration of new attributes on the other (see Rahmeyer 2005: 13). Ironically, it is this aspect of stability that is partly responsible for the dynamism in the evolution patterns of firms and industries (Rahmeyer 2005: 9). Only if the dynamics within a firm or within an industry are stable in the short run, can variation and selection (both blind/intentional and external/internal) take place and only if that is the case can the strong firm properties be passed over to the next evolutionary cycle. Those entrepreneurial activities enable the firm to initiate change and they need not to be based on scientific novelty only. Often, it is the mere recombination of a firm's assets that can lead to innovation (Rahmeyer 2005: 5).

2.1.2. Innovation Systems

Innovation systems are defined as sets of components that are interrelated through relationships and characterized by certain sector-specific attributes. Components are the main actors in a system. They can be firms, individuals or organizations and groups like banks, research institutes, institutions or political bodies (see i.e. Carlsson et al. 2002: 234; Edquist 2005: 188). The relations between the components are responsible for a system's dynamism. Such relationships can be the transfer of knowledge (technology in particular) or any other market and non-market link among the actors in a system.

The attributes of a system represent the properties of the components and the relationships and determine the behavior, characteristics and, finally, the innovative potential of the system. Their configuration determines a system's ability to generate, diffuse and utilize products and technologies. As Hughes (1987: 52) puts it, the character of a system of innovation develops out of the interrelations between the components and therefore out of the system itself, rather than out of its external environment. Carlsson relates this discussion to the concept of economic competence (Carlsson et al. 2002: 235) that aims at measuring the system's ability to generate, diffuse and utilize technology that have an economic value. They define economic competence as the ability to identify, expand and exploit business opportunities, thereby creating innovations. This requires four types of capabilities: selective (strategic) capability, organizational (integrative or coordinating) capability, technical (functional) ability and finally learning (adaptive ability).

For the evolution of a firm and consequently for the functioning of a system, strategic and learning capability are certainly the most important. Selective capability in general is described as the ability to choose strategic paths with respect to markets, products, technologies or organizational structures; to obtain resources and competences; and to manage human resources successfully. Yet Carlsson and Eliasson (1994: 695) go further by stressing that the most important part of this is the ability to make the right selections, which they claim to be a question of absorptive capacity of decision makers. Carlsson et al. (2002) describe it as the

> 'ability to scan and monitor relevant technological and economic information, to identify technical and market opportunities, and to acquire knowledge, information, and skills needed to develop technologies' (235).

Innovations can only be born if a firm is able to recombine and create competences that open up new ways of economic activity. The firm must be able to communicate with the opportunity set; business opportunities must be detected and then be exploited. Carlsson and Eliasson claim that it is only this creativity – the ability and willingness to take risks and to expand the opportunity set without reacting to exogenous shocks – that really determines the strategic foresight and power of firms

(Carlsson and Eliasson 1994: 697). This includes of course the ability to see where the firm's capabilities reach their limits.

This ability of a firm is and must be supplemented by a second crucial 'adaptive ability': the capacity to learn. As Eliasson states, firms must be 'experimentally organized' in order to be able to learn (Eliasson 1991: 154). If firms want to generate innovations continuously they must be able to draw conclusions from the successes and failures that they experience during their evolution, to listen to market signals and to adapt accordingly. They must be able to use this knowledge to recombine capabilities, to generate new competences out of it and to acquire new knowledge in the market. Only then can the following economic activities and innovations overcome the mistakes made and yield the desired returns. 'This ability is essential for the long-term survival' (Carlsson et al. 2002: 235).

The other two capabilities are rather technical in nature (but certainly no less important for the functioning of a firm). Organizational capability is defined as the ability to combine and manage the firm's resources and organizational capabilities in a way that ensures that they can efficiently be employed to meet the firm's economic goals. Functional ability is described as the ability to execute the functions within a firm and to make sure that technological and organizational processes are working as planned.

The concept of economic competence, presented by Carlsson and Eliasson (1994) underlines the main dynamic within innovation systems: the generation of innovations and economic success out of the dynamics that stem from the nature of the components and their relationships. Those system attributes represent (in the ideal case) an economic competence that enables the system to generate change out of own strength and to respond adequately to a changing environment. New components can be generated as a response to the erosion of old ones; the relationships between firms and organizations can be changed so that economic success rises; or external threats and opportunities can be detected and dealt with. An innovation system is the more effective the further those abilities go.

This discussion highlights that the components of a system all depend highly on each other: each component's behavior and properties affect the entire system. This interrelation creates strong network dynamics, as it makes the components inseparable; the system is not only the sum of its components but a more complex entity. Consequently, as Hughes (1987: 51) argues, if a component of a system is dysfunctional or removed from it, a change of all other artifacts and components is to follow. Yet, this dynamism alone is insufficient to guarantee the survival of an innovation system. Only if the system is evolving in the right direction (through economic competence and innovation), can it stay healthy.

The concept of innovation systems is in many ways related to evolutionary theory; 'its development has been influenced by [...] evolutionary theories' (Edquist 2005: 5). The innovation systems approach assumes that any economy is driven by

ongoing processes of learning, searching and exploring, which result in new products, new technologies, forms of organization and markets (Malerba 2002: 249). Even though the uncontrollable forces from the external environment are not considered core components of an innovation system (see Hughes 1987: 53), they have of course an effect on the processes of change and transformation and are therefore a part of the concept.

Yet the systems approach goes beyond the classical evolutionary approach in some respects. It tries to put evolutionary processes in a frame that allows to draw boundaries and to relate the developments to certain domains in which innovations take place, such as regional, national or international innovation systems or technological and, last but not least, sectoral systems of innovation. This assigns a clear analytical framework to evolutionary processes. Also, it stresses and formally conceptualizes the argument that firms cannot innovate in isolation. Any innovation process is the result of cooperation on all levels of a system; 'interactivity paves the way for a systematic approach' (Edquist 2005: 5).

Another important feature of the innovation systems approach that goes beyond the focus of evolutionary theory is the importance assigned to institutions. Freeman (2002: 194) goes as far as to put institutions at the basis of any systemic process of innovation. Freeman (1987) argues that any kind of innovation system is 'a network of institutions in the public and private sectors whose activities and interactions initiate, import, modify and diffuse new technologies' (1). The firm's evolution is consequently dependent on the institutions surrounding it; organizations operate not in isolation but are 'embedded in a much wider socio-economic system [determining the] direction and relative success of all innovative activities' (Freeman 2002: 195). Lundvall and Carlsson/Stankiewicz take a more moderate position towards the importance of institutions but they also put them at a central place in their definitions of innovation systems. While Lundvall (1992: 12) argues that an innovation system contains 'all parts and aspects of the economic structure and the institutional set-up affecting learning as well as searching and exploring', Carlsson and Stankiewicz (1991) view an innovation system as a

> 'network of agents interacting in a specific economic/industrial area under a particular institutional infrastructure or set of infrastructures and involved in the generation, diffusion and utilization of technology' (93).

Already Karl Polanyi (1957) states that institutions are essential to the functioning of markets, regarding them as the basis of any modern capitalist economy. He sees innovation not simply as the outcome of an aggregation of individual behaviors of rational and profit-maximizing economic agents but rather as the result of an 'instituted processes', dependent on organs that communicate between the market, the firm and society.

As humans respond to much more than rational and economic motives, markets without institutions could not reproduce themselves. This dilemma makes the

presence of institutions as a regulatory force unavoidable; any 'mode of economic accumulation' must be supplemented by a 'mode of social regulation' that manages the interactions between the economy/market and society (see Boyer 1993) in order to generate a stable system that allows the returns needed for the economy to work. Institutions provide this regulatory framework; they 'make it possible for economic systems to survive and act in an uncertain world' (Lundvall 1992: 10). The way those institutions are set up determines the patterns of economies and consequently of corresponding systems of innovation; national economic for instance institutions represent a regulatory sphere that stands above the firm, is unavoidable for her and has therefore the power to affect the evolution of a national system of innovation.

Even though both concepts of economic development that have been outlined above stress the omnipresence of change, they also imply that learning and transformation of economic actors and networks is never random. Rather, economic evolution follows always some historically determined trajectory.

2.2. Building Blocks

It has been stated above that the sectoral system of innovation approach draws from evolutionary theory and the innovation systems approach. Consequently, the dynamics amongst the system components are per definitionem characterized by high multidimensionality and continuous change. The literature identifies five main building blocks that constitute the systemic environment in which agents operate and innovations develop (see for instance Carlsson et al. 2002: 234; Geels 2004: 898; Malerba 2002: 251, 2003: 332, 2005a: 387):

1. a knowledge base and learning processes,
2. technologies, inputs and demand and the related links and complementarities at those levels,
3. structures of interaction among the heterogeneous agents, firms and non-firm organizations,
4. institutions, and finally
5. mechanisms of competition and selection.

2.2.1. The Knowledge Base and Learning Processes

Knowledge and learning stand at the centre of any sectoral system of innovation. In line with evolutionary theory, sectoral systems of innovation theory claims that at the basis of a firm's success lies learning and the accumulation of knowledge, as only this can help the firm to overcome the constraints that the ever changing environment in which it operates puts on it. As Foss (1996) argues, only the inclusion of knowledge into the analysis of the firm can lead away from a purely 'contractual' view of the firm and attract the attention to

> 'its function as a repository of distinct productive (technological and organizational) knowledge, and as an entity that can learn — and grow — on the basis of this knowledge' (Foss 1996: 470).

The characteristics of the knowledge base are sector-specific and differ therefore across sectors. This is necessarily the case as the industry's knowledge stock develops out of the interaction with the environment and the resulting constraints to innovation that the sector must overcome; those conditions always differ across industries.

According to the sectoral systems of innovation literature the knowledge base of a sector is characterized by several variables whose configurations determine the nature of the sectoral knowledge and ultimately the innovative power that the respective sector has. Malerba and Orsenigo (2000) argue that knowledge must be conceptualized further beyond the distinction between tacit and codified knowledge (as most of the modern literature on the knowledge based firm and economy does) in order to have a 'deeper understanding of the relationship between knowledge and competencies on the one side, and the boundaries of firms on the other' (290). The dichotomy of tacit and codified knowledge already touches on the crucial point that knowledge is more than sheer information and that its degree of codification determines how easily it diffuses within the firm and consequently to what degree it is available to generate innovation. Concepts like Nonaka's Spiral of Knowledge have already dealt with the issue of how to codify as much of a firm's tacit knowledge, making it thereby readily available (see Nonaka 2007). Instead, Malerba argues, the discussion of knowledge should include finer measures of a firm's knowledge stock (see i.e. Malerba 2002: 251). These are:

- accessibility and opportunity conditions,
- cumulativeness,
- technological regimes and
- domains of knowledge.

2.2.1.1. Accessibility and Opportunity

Depending on the sector in question, knowledge can have different degrees of accessibility. The concept of accessibility describes the ease with which firms can obtain knowledge that is external to them (Malerba and Orsenigo 2000: 300, Malerba 2002: 251). The literature claims that the greater the accessibility of knowledge, the lower the concentration of an industry is, as great accessibility lowers appropriability (the ways of preventing competitors from copying an innovation).

The literature differentiates between internal and external accessibility. The ease with which competitors can gain sector-internal knowledge effects of course the appropriability conditions within the industry, as a high rate of knowledge diffusion within a sector enables competitors to copy each other's innovations. Consequently

concentration is likely to be low (Malerba 2002: 253). Similarly, great accessibility of sector-external knowledge effects the innovative activities as it allows firms to raise the level and sources of the technological and scientific opportunities. For example, human capital acquired from outside can bring new knowledge to the firm. Great accessibility of this source of knowledge leads to rising opportunities for innovation (see i.e. Malerba 2002: 253; Malerba and Orsenigo 1997: 98, 2000: 300).

Yet, the availability of external knowledge alone is only a sufficient condition for the emergence of scientific or technological opportunities to the industry. Whether or not accessible knowledge yields real opportunities for innovation depends on the specific sectoral conditions. Some sectors require major scientific breakthroughs, some profit from more incremental advancements in R&D or technologies and again others require external knowledge about users and product applications to undertake new innovative steps. (see i.e. Malerba and Orsenigo 2000: 300). Hence, only if a sector can easily access knowledge and transform this knowledge then into innovation without a significant integrative effort, innovations can occur. Depending on the integration capabilities of the firms and the degree to which the accessible external knowledge is spread amongst the sectoral firms, this availability of new knowledge can then attract numerous new entrants or lead to concentration and the dominance of the large incumbents that are able to integrate the information (Malerba and Orsenigo 2000: 300).

2.2.1.2. Cumulativeness

Another property of knowledge in the context of sectoral innovation activities is cumulativeness. The concept of cumulativeness describes the degree to which the emergence of new knowledge is contingent and builds on existing knowledge within the firm. Cumulativeness can have three sources (see Malerba 2002: 252; Malerba and Orsenigo 1997: 95, 2000: 301):

- learning processes and dynamic increasing returns at the technology level,
- organizational capabilities and
- feed-backs from the market.

The process of learning and the existing stock of knowledge codetermine cumulativeness as they can circumscribe the entry of new knowledge into the organization (knowledge takes time) but also be the basis for the efficient generation of new knowledge. Also, organizational capabilities have the power to affect continuity of knowledge generation, as they can indirectly filter the aspects that a firm can and wants to learn.

Finally, feed-backs from the market are a determinant for continuity of innovation activities. If the market response to a new product is positive, the firm will reinvest the returns into the continuation of the related R&D processes, thereby building up cumulativeness. This is carried by the logic that ‘success breeds success’: con-

tinuous positive feedbacks from the market are likely to lead to persistence where positive returns form innovation are reinvested in similar innovations which are expected to yield the same economic rent. Of course, this virtuous circle can easily turn into a vicious one, in case the firm fails to realize that the demand from the market changed, now mismatching its internal cumulativeness of knowledge.

Such cumulativeness can occur on the technological level, as well as on the firm and the local level. Firm level cumulativeness results in rather high appropriability conditions which might allow firms to gain first mover advantages and can eventually lead to concentration processes within the industry. On the industry level, high cumulativeness leads to the contrary: appropriability is lowered and high knowledge spillovers among the sectoral firms is the likely result. Usually this leads to turbulence and the entry of new agents. High cumulativeness at the local level can provoke low local appropriability conditions and knowledge spillovers within distinct geographical boundaries.

2.2.1.3. Technological Regimes

Malerba and others (Breschi and Malerba 1997; Malerba 2002; Malerba and Orsenigo 1993, 1997, 2000) expand and define the sectoral knowledge environment further by introducing the concept of Technological Regimes into the discussion. The idea stems, among others, from the works of Nelson and Winter. As Nelson (1995) states, Winter and her

> 'have used the concept of technological regime or paradigm to refer to the set of understandings about a particular broad technology that are shared by experts in a field, including understandings about what a firm needs to be doing to operate effectively in that regime' (79).[13]

The sectoral systems of innovation literature borrows this approach to describe the technological knowledge environment of a sector, in which accessibility and cumulativeness are two key aspects. Sectors differ significantly with respect to their technological base and as technology changes over time, it affects the nature and boundaries of sectors (Malerba and Orsenigo 1997: 94). Technological regimes mirror this influence of technology on sectoral innovation patterns; they represent 'a particular combination of some fundamental properties of technologies' (Malerba and Orsenigo 2000: 302) and reflect a concept that combines technology, knowledge and the environment of a sector in an analytical approach to sectoral innovation (similarly to be found in Breschi and Malerba 1997; Malerba and Orsenigo 1994, 1996, 1997). The properties of technologies captured in the concept of technological regimes are opportunity and appropriability conditions, the cumulativeness of techno-

[13] For more detail on the foundations of technological regimes see Nelson and Winter 1977, 1982 as well as Dosi 1982, 1988.

logical knowledge and the characteristics of the relevant knowledge base (Malerba 2002: 252; Malerba and Orsenigo 2000: 302).

As indicated above, (technological) opportunity describes the likelihood of successful innovation in case an investment into innovation activities is made.

> 'High opportunities provide powerful incentives to the undertaking of innovative activities and denote an economic environment that is not functionally constrained by scarcity' (Malerba 2002: 252).

Consequently, technological opportunity reflects the abundance of options for technological innovations that the firm faces. The greater those opportunities are, the more attractive (and easier) it is for firms to employ its technology successfully for innovations (Malerba 2002: 253). Thereby the success depends on the level of investment into the search process undertaken by the firm, as well as on the variety of possible technological solutions to the problem (the more the better) and the potential pervasiveness of the newly acquired technological knowledge amongst the other products of the firm. Finally, the technological knowledge required for innovation must be suited for effortless integration into the existing stock of knowledge (Malerba and Orsenigo 1993: 304, 1997: 99).

Appropriability conditions depend mostly on the means to protect the innovations that are at disposal to the firm. Such can be patents, contracts with cooperating organizations or special organizational policies. High appropriability denotes the availability of means to protect the firm's innovations (and ultimately its knowledge) from imitation by others so that the firm possessing the protected knowledge can extract relatively high profits from its technological innovations. On the other hand, low appropriability means that knowledge is circulating rather freely and spillovers occur on a regular basis (see i.e. Malerba 2002: 252). The availability and effectiveness of tools to ensure appropriability varies across industries.

Based on Pavitt's work (1984), Malerba (2002) argues that appropriability equals in no case technological barriers to entry. While barriers to entry apply to 'the ease of innovative entry into an industry by potential entrants' (Malerba 2002: 252), the notion of appropriability refers to all players, within as well as beyond the industry boundaries. However, a relation between barriers to entry and appropriability in a sector seems possible: the lower the appropriability conditions within and around an industry are, the more likely it seems that barriers to entry are (in this respect at least) rather low. On the other hand, it may be assumed that high appropriability heightens the barriers to entry as it leads to a dominance of the few large and established firms in a sector.

Thirdly, cumulativeness of technological knowledge corresponds, as already outlined above, to the presence of relevant continuities in the innovative activities of a firm and can arise on the technology level as well as on the level of the firm, the sector or the local environment.

The last building block of technological regimes is the knowledge base. It refers to those aspects of knowledge that (really) determine (the quality of the) innovative outcome. Here the literature differentiates between two spheres: the nature of the knowledge generated and the means of knowledge transmission. The nature of knowledge is characterized along four domains: depending on the sector, it must to varying degrees be tacit/codified and generic/specific to match with the relevant fields of application and yield innovative success. Further, the degree of complexity of technological knowledge with respect to the technological and organizational competencies needed to implement the knowledge play a role (Malerba 2002: 252; Malerba and Orsenigo 2000: 302). Also, the independence from larger contexts that the technological knowledge may possess varies amongst sectors and has a great effect on innovation.

With respect to the means of knowledge transmission it is underlined that the nature of the knowledge required for successful innovation in a sector strongly affects the way knowledge is transmitted among firms. In other words, it is the properties of the knowledge base that determine if and how effectively technological opportunities or cumulativeness are transmitted among and within firms (see i.e. Malerba and Orsenigo 2000: 302). Also, as Malerba and Orsenigo (2000: 302) stress, the mechanisms of knowledge transmissions between firms and actors in a sector are very sensible to distance between the firms; in case technological knowledge is tacit and unstable, informal means of knowledge transmission can play greater roles; on the other hand, when knowledge is highly codified, publications, licenses or patents can play a major role in the transmission process.

Malerba, Orsenigo and others justify the importance of technological regimes by the empirical observation that patterns of innovation can differ across sectors while nevertheless similarities across countries with respect to sectoral innovation patterns can persist. This leads them to claiming that the technological environment in which sectors operate must be a major determinant of its innovative activities. They conclude that

> ‘ ‘‘technological imperatives” and, more generally, broad factors related to specific ways of accumulating knowledge play a major role in determining the specific pattern of innovative activities in a technological class’ (Malerba and Orsenigo 1997: 94).

Based on this thesis, the literature (see i.e. Carlsson et al. 2002; Leiponen and Drejer 2007; Malerba 2002, 2003; Malerba and Orsenigo 1994, 1995, 1996, 1997, 2000) proposes several hypothesis about the interrelation between technological regimes and sectoral innovation patterns. First, the literature claims that industries where high technological opportunities are present are characterized by strong turbulence regarding technological entry, high hierarchical instability and a ‘tendency towards concentration’. This is the case, as on the one hand numerous firms enter the sector and on the other hand those that are successful lead waves of selection that

eliminate the small and less competitive players. In contrast, in case of low technological opportunities a sector is characterized by low innovative entry and growth; the hierarchies among the established firms are more stable and the sector is less concentrated.

Secondly, high technological appropriability allows firms to isolate their knowledge stock from others and gain profits on it exclusively. As a consequence those sectors usually show high concentration and a rather low number of innovators.

Thirdly, as indicated above, cumulativeness stands for persistence of innovative activities: this usually breeds high stability, a low number of entrants and incumbents and a selection environment that tends to favor experienced and established (large) leader firms. Cumulativeness can be the guarantee of continuity and ongoing success but can also act as a barrier to reforms that might be needed to face the future; in any case however, high cumulativeness creates high barriers to innovative entry to a sector.

The knowledge base, as it represents the most complex element of technological regimes, has a multifold influence on the sectoral patterns of innovation. The presence of highly tacit knowledge within a sector can lead to the emergence of mostly firm-internal means of communication, which makes the transfer of knowledge across firms (which would enable copying) harder (see i.e. Malerba and Orsenigo 1993: 51, 1997: 99). In contrast, highly codified knowledge may lead to specialization and means of a division of labor among firms (see i.e. Malerba and Orsenigo 1993: 68, 1997: 97).

Also the degree to which the sectoral technological knowledge is generic and applicable to more than one product or specific and therefore focused on one innovation only, has an effect on the sectoral innovation patterns. Pervasiveness might occur in case the technological knowledge is generic enough to serve more than one technological opportunity, while very specific technological knowledge may lead to a lack of pervasiveness and eventually to specialization of firm activities (Malerba and Orsenigo 1993: 48, 1997: 99).

Similarly, the degree of complexity of technological knowledge allows different scenarios for sectoral innovation activities. According to the literature, if a knowledge base is highly complex but separable and codified and combined with high opportunity and appropriability conditions, the sector's firms might form 'external networks composed of complementary specialist firms co-existing with system integrators' (Malerba and Orsenigo 1997: 99). On the other hand, if the knowledge is complex, highly tacit, separable and appropriable, firms are likely to innovate through long-term strategic alliances with other firms. Thirdly, knowledge can also be indivisible, highly tacit and only hardly appropriable. In that case, Malerba and Orsenigo (1997: 99) claim that firms tend to form strong mechanisms aiming at effective control and integration of that tacit knowledge and a strong internal culture of commu-

nication in order to be able to turn the tacit knowledge into innovation (see also Teece 1986: 292).

Malerba and others describe how the concept of technological regimes is partly able to explain the variance of the patterns of innovation that can be observed across sectors and technologies (see i.e. Malerba 2002; Malerba and Orsenigo 1990, 1993, 1994, 1997). This stream of literature mainly describes how the concept of technological regimes can be employed, for instance for explaining fundamental differences with respect to innovation activities such as described by Schumpeter's Mark I and Mark II stadium of sectoral innovative activities.

Schumpeter Mark I patterns of innovation are characterized by 'creative destruction' through the easy entry of new firms into the sector and the importance of the entrepreneur and young and dynamic firms. This is the phase where no dominant design has not yet developed and the industry is drastically changing. Schumpeter Mark II patterns of innovation on the other hand are characterized by 'creative accumulation', which denotes the presence of large firms and industrial R&D in the innovation process, implying that innovation activities at that stage are characterized by less turbulence, more stability, higher barriers to entry and usually higher industry concentration (Malerba 2002: 253; Malerba and Orsenigo 1994: 8, 1996: 452; see also Canter and Hanusch 1998: 276).

According to Malerba and Orsenigo (1995) the two 'patterns of innovation could be labeled also widening and deepening' (48), where a widening pattern of innovation is related to the periodic erosion of the technological advantage of the leading firms and a following enlargement of the industry through new entrants that attempt to fill this gap. In contrast, a deepening pattern of innovation is driven by the dominance of a few established firms that accumulate technological and innovative capabilities, thereby consolidating their position.

The literature on technological regimes and on sectoral systems of innovation underlines that technological systems allow to relate back to 'learning patterns of firms over time' (Malerba and Orsenigo 1994: 7). Technological regimes, as they represent a sort of ecosystem in which the firm is learning, function thereby as the vehicles that carry organizational learning. The taxonomy of technological regimes can be employed to categorize sectoral innovation activities (see i.e. Malerba and Orsenigo 1997: 90): sectors with a technological regime characterized by high opportunity and low appropriability conditions as well as low cumulativeness can be categorized as Schumpeter Mark I sectors. On the other hand, those sectors that show characteristics of Schumpeter Mark II patterns of innovation are usually marked by high cumulativeness and opportunity and appropriability conditions. This creates high barriers to entry, which incumbents can exploit to accumulate technological knowledge and innovative capabilities.

2.2.1.4. Domains of Knowledge

The last aspect of knowledge that the sectoral systems of innovation theory underlines as relevant for the innovation patterns of sectoral systems of innovation is the domains of knowledge. The domains of knowledge identified are science and technologies at the base of the sector, as well as applications, users and demand (see i.e. Malerba 2002: 251; Malerba and Orsenigo 2000: 305).

Similar to technological systems of innovation, where actors and institutions of an innovation system evolve around the technology at the centre of innovation activities (see i.e. Carlsson 2002), the sectoral systems of innovation literature claims that the technological conditions of each sector are responsible for varying degrees of complexity and different thresholds for innovation. This is on the one hand due to the technical limitations (technological facilities represent some sunk investment that cannot quickly be replaced by something new that meets the requirements of new innovations) but has at the same time a knowledge-related aspect. Over time, firms develop technology-specific competences that they employ for their innovation activities. As Patel and Pavitt (1994) claim, on a sectoral level the technological competences of the firms are rather homogeneous (Malerba takes this point up, see Malerba 2002: 254), as they are accumulated in a path-dependent manner over time, which is usually shared by all firms within the sectoral system of innovation.

However, technologies differ in their knowledge base, which is the reason why firms develop certain competences in concordance with the technological imperatives they face (Malerba and Orsenigo 2000: 305). Those technology-related competences represent self-reinforcing effects, as the learning process behind them provokes technological trajectories that in turn make the technology-specific capabilities even more necessary (see Malerba 1992: 857).

Similarly, applications, users and demand represent a domain of knowledge that determines the innovative activities of a sector. Over time, firms learn what consumers prefer, how the demand for their products is composed and what changes can be expected. The better a sector knows this factors and can handle them, the more effective the innovation activities are (Malerba 2002: 251).

As the preceding pages have shown, knowledge and learning are the key forces that keep a sectoral system of innovation alive and hold up a dynamism that is able to yield innovation. We will see later that the responsibility for the boundaries of sectoral systems of innovation as well as for their change rests also mainly with sectoral dynamics of knowledge, competences and learning processes. Yet, the other elements of sectoral systems of innovation must also be discussed as they contribute significantly to the nature of a sector and ultimately to its knowledge stock and its flexibility.

2.2.2. Basic Technologies, Input and Demand

As it has been indicated above, technology and demand are two major building blocks of sectoral systems of innovation that determine the stock of competences that a sector accumulates and that guide necessarily the innovation activities. Yet, demand and technology shape a sectoral system of innovation also on another level: they simply determine the behavior of a sector as a whole, as they constitute the problem that any sector faces: the need to create a profitable balance between what is desired by the market (demand) and what can be produced to satisfy this (technology). This interplay that reflects the very principle of any economic action is of course limiting the leeway sectors have in their activities; in other words,

> '[a] given technological environment or demand defines the nature of the problems firms have to solve in their innovative and production activities and the types of incentives and constraints to particular behavior and organizations' (Malerba 2002: 254).

As Malerba (2002) states, the technologies employed by a sector for the production of goods, shape a 'technology-product matrix' (254) that is unique for each sector; technology can be seen as a major distinguishing factor of sectoral systems of innovation.[14] The sector-specific employment of technologies defines therefore not only the nature of the sectoral innovation activities but sets also certain boundaries to the innovative ambitions a sectoral system of innovation might have. Depending on the sectoral technology-production matrix, technologies can to a varying degree be employed and re-combined as to realize innovations; yet, the technological trajectories of a sector that have developed over time represent certainly limits to this.

Similarly, firms within sectoral systems of innovation must adapt their strategies to the demand that they are facing, this is the aim of any innovation activity. Demand, according to the literature is made up of heterogeneous agents rather than just the sum of similar buyers (see i.e. Malerba 2002: 255). This includes consumers, suppliers, other firms and organizations that are each characterized by their own knowledge and learning processes, competences, social environments and institutions; together they form a pressure to deliver innovations that differs across sectors. Of course this demand has a great affect on the sectoral firms. It dictates where the innovation activities of the sectoral firms should lead and forms a main source of increasing returns and positive feedbacks that lead to lock-ins and the evolution of industries. Porter Five Forces concept underlines the importance of demand for the competitive strategy of firms: the power of buyers and of suppliers shapes the competition amongst competitors in an industry and consequently the innovative activities they undertake (Porter 2008: 81).[15]

[14] For more detail see Malerba and Orsenigo (1996), where empirical data is used to illustrate that across countries, technological classes show similar innovation patterns, which underlines the argument that technologies have an impact on sectoral innovation patterns.

[15] Porter's 2008 Harvard Business Review is an updated version of his original 1979 article *How Competitive Forces Shape Strategy* in which he first published the concept of Five Forces.

In summary it becomes clear that technology and demand are key determinants of the leeway for innovation activities that a sectoral system of innovation has. Consequently they contribute significantly to the nature of sectoral systems of innovation; technology and demand 'constitute major constraints on the full range of diversity in the behavior and organization of firms active in a sectoral system' (Malerba 2002: 255).

2.2.3. Heterogeneity and Interaction of Firm and Non-firm Actors

The sectoral systems of innovation literature sees sectors as composed of heterogeneous agents that can be organizations and individuals. Organizations can be firms as well as non firm organizations, sub-sections of lager firms or groups of firms and organizations (Malerba 2002: 255, 2005a: 391). Firms are the most important players in sectoral systems of innovation, as they are 'involved in the innovation, production and sale of sectoral products, and in the generation, adoption and use of new technologies' (Malerba 2002: 255). The literature underlines, however, that often the different parts of the firm carry different importance for the innovation outcome. The analysis of sectoral innovation patterns must account for that. For example, in some industries such as chemicals or biotechnology, firm-internal R&D is crucial and an analysis of those parts should be at the core of sectoral studies.

At the same time, however, other agents play a role in sectoral systems of innovation: non-firm organizations such as universities, governmental research agencies, financial institutions and other private or public bodies play into the system, affecting the nature of sectoral innovations (Carlsson et al. 2002: 234; Malerba 2002: 249, 2003: 233). As the preceding discussion of innovation systems theory has already outlined, those non-firm agents are important elements of the systemic networks as they direct and regulate the behavior of the key player — the firm — in relation to its environment.

Heterogeneity of firms plays an important role for sectoral innovation patterns. '[T]he firm as a social community whose productive knowledge defines a comparative advantage' (Kogut and Zander 1993: 626) draws its innovation potential from learning processes through interaction with the environment. This leads, as the discussion of evolutionary theory has already stressed, to firm-specific bundles of technological and commercial competences, knowledge and skills. The sectoral systems of innovation literature accounts for this by claiming that firms in sectoral systems of innovation

> 'are characterized by specific beliefs, expectations, competencies, and organization and are engaged in processes of learning and knowledge accumulation' (Malerba 2005a: 66; Malerba 2002: 255).

As Srholec and Verspagen (2008) stress in their discussion and empirical analysis of sectoral firm heterogeneity, firms in a sector show, even though they share a common selection environment, significant heterogeneity in their innovation patterns. It is claimed that generally the innovation strategy of a firm is made up by four 'ingredients', namely R&D, users, external influences and production issues. Each of those entails a number of organizational values and the weighting of the ingredients in each firm's innovation strategy differs. This is, according to Srholec and Verspagen, even the case in sectoral systems of innovation, which leads to the permanent presence of firm heterogeneity; 'a prosperous innovation system will resemble the variety of a rainforest rather than an Arctic wasteland' (Srholec and Verspagen 2008: 28). Srholec and Verspagen argue and empirically underpin that the shared sectoral selection environment is highly variable and the reaction to this variability differs across firms (i.e., in terms of speed of adaptation or strategic foresight). Also, selection processes never homogenize all aspects of a firm's innovation strategy, so that certain elements of the firm regularly bypass selection, develop and create further heterogeneity. Finally, due to the high instability of the environment, only a mixed firm strategy might be 'evolutionarily stable', which is another reason to believe that the sectoral selection processes cannot eliminate firm heterogeneity of a sectoral system of innovation entirely.[16]

Malerba and others (Malerba 2002, 2005a; Malerba and Orsenigo 1997) see the evolutionary processes of variation as the basis for the continuous development of heterogeneity within sectors. According to them, institutions, firms, technologies and other building blocks of sectoral systems of innovation change continuously; regularly even new aspects such as new institutions or behavioral patterns of firms emerge, thereby increasing the variety in the sector. Those 'processes of variety creation […] are related to several mechanisms: entry, R&D, innovation and so on' (Malerba 2002: 258). This means that out of new variety, new possibilities for the sectoral firms emerge: changes of the legal conditions might open up new niches for innovation, technology changes might enable firms to change their production patterns or, in return, some institutional change might exacerbate further innovations in a certain domain. In other words, the industry transforms those incentives for change into evolution and heterogeneity is necessarily the result. The role of the university in sectoral systems of innovation, for instance, can lead to processes similar to Etzkowitz's and Leydesdorff's 'knowledge-intensive network transitions' (Etzkowitz and Leydesdorff 2000: 113), where new knowledge generated in universities fuels innovative advancements within the sectoral firms. For sectors like chemicals, pharmaceuticals or biotechnology those chains of evolutionary incentives are crucial.

[16] For this argument Srholec and Verspagen draw from evolutionary game theory (Bergstrom and Godfrey-Smith 1998; Maynard-Smith 1982), claiming that an 'evolutionary stable strategy specifies is a strategy that cannot, at the population level, be successfully invaded by alternative strategies (and hence is a stable outcome of selection)' (Srholec and Verspagen 2008: 9). Theory assumes that those stable strategies tend to be mixed strategies, composed by numerous different strategic paths.

This means that variety creation in sectoral systems of innovation is responsible for much of the systemic dynamism that is observable; the emergence (or entry) of new firms introduces new knowledge into the sector that is shared and used for further innovation. However, the role of new firms in sectoral systems of innovation naturally differs from sector to sector: as the sectoral knowledge base, the diffusion of competences, the functioning of sectoral institutions and the presence of non-firm organizations are sector-specific, the sectoral conditions of firm entry must differ accordingly.

Yet, this is of course not to say that sectoral firms are characterized by perfect heterogeneity; if that was the case the umbrella-concept of sectors could not exist at all, as the sectoral framework per se implies some commonality between all actors. Srholec and Verspagen (2008: 9) identify certain 'typical innovation strategies' of sectoral firms that develop out of the selection environment that the firms have in common. Certain similarities with respect to firm organization, structure, knowledge and, ultimately, innovation outcome are therefore natural. The literature on sectoral systems of innovation identifies evolutionary selection processes as the sectoral mechanisms that are automatically reducing heterogeneity to a sector-specific level

> '[…] the learning, behavior and capabilities of agents is constrained and "bounded" by the technology, knowledge base and institutional context in which firms act. Heterogeneous firms facing similar technologies, searching around similar knowledge bases, undertaking similar production activities and "embedded" in the same institutional setting, share some common behavioral and organizational traits and develop a similar range of learning patterns, behavior and organizational forms.' (Malerba 2002: 250)

This selection may take place in any of the sector's domains, such as the firms itself, the products or the technologies and it can be governed by market and non-market forces. 'Firms try different things, the market selects upon them' (Malerba et al. 1999: 39), based on the firm's ability to adapt to altered environments and to uphold its competitiveness (see Malerba and Orsenigo 1994).

Non-market selection processes select independently of the competitiveness of firms but according to regulatory, institutional and governmental maxims. Prominent examples for sectors with powerful 'non-market selection processes' are therefore heavily regulated industries, such as are the military or the health sector (Malerba 2002: 258). Consequently, it is clear that the type and degree of selection processes, and therefore ultimately also the sectoral homogeneity, differ significantly across sectors:

> 'A higher or lower degree of agents heterogeneity in terms of types, beliefs, competencies, behavior and organizations may stem out of differences in a set of factors: the characteristics of the knowledge base, experience and learning processes, firms specific interaction with demand, the working of dynamic complementarities, firms' histories and differential rates and trajectories of innovation and growth.' (Malerba 2002: 255)

Depending on the sectoral conditions, selection processes effect both the growth and decline of agents and groups of agents as well as the sectoral diversity of behaviors (Malerba 2002: 258).

The sectoral systems of innovation literature includes suppliers and users into the definition of the firm (Malerba 2002: 255, 2003: 333, 2005b: 66; Malerba and Orsenigo 1997: 95). This reflects the importance of users and suppliers for innovation, as it has already been discussed by numerous other streams of literature. Von Hippel (1998, 2007) for instance underlines the importance of the user in the innovation process of firms as the user is ultimately the only beneficiary of any innovation. Von Hippel differentiates the innovation environment in the user and the manufacturer of innovation. Any entity that profits from the innovation is a user, the entity that produces the innovation is its manufacturer; '[i]nnovation user and innovation manufacturer are the two general functional relationships between innovator and innovation' (Von Hippel 2008: 294). Yet, he differentiates further between the type of user that is a supplier or vertically integrated firm benefiting indirectly from an innovation as they only use it to add value to their own products and the consumer, who benefits directly from an innovation.

Out of this relation between the user and the innovation emerge 'user networks' (see Von Hippel 2007) or 'user-producer networks' (see Lundvall 1985) with 'information transfer links' (see Von Hippel 2007) that lead to an interconnection between the user and the innovating firm. In other words, the users, represented by the demand for an innovation, have a significant impact on the innovation processes of the firm; as discussed above, demand is a key limiting factor for the diversity and direction of innovations. Viewed from a sectoral perspective this means that through the demand, the users of an innovation, all with their own preferences, competences and structures, are part of the sectoral system of innovation (see i.e. Malerba 2005b: 67, 2003: 334). It is underlined that due to the heterogeneity of types of users and consumers this demand is highly heterogeneous; 'demand is [...] composed by heterogeneous agents with specific attributes, knowledge and competencies who interact in various ways with producers' (Malerba 2002: 255).

Sectoral systems of innovation attribute a similar position to the suppliers to the innovating firm. Their competences, knowledge and preferences also affect the productivity, competitiveness and innovation activities firms. As Pavitt (1984: 356) illustrates, firms can under certain conditions be heavily influenced by their suppliers; supplier-dominated trajectories of firm development can develop and have finally of course an influence of the firm's innovation patterns, channeling the attributes and competences of those suppliers in the sectoral system of innovation. Yet, of course, the character of suppliers and their distance from and effect on the innovating firm differs of course across sectors (Malerba 2002: 255).

The sectoral agents are in close communication with one another; 'heterogeneous agents are connected in various ways through market and non-market relation-

ships' (Malerba 2002: 256). Malerba identifies several sorts of relations between the firms and their sectoral environment, that determine the sector's network structures. Firstly, 'processes of exchange, competition and command' as they exist in any network of vertically integrated firms regulates the relation between the sectoral agents. The sectoral systems of innovation approach follows thereby the theories of industrial organization, such as Pisano (1990) or Armour and Teece (1980), who claim that structures of vertical integration of several firms lead to shared knowledge and technology, thereby benefiting and facilitating innovation processes.

Secondly, means of formal co-operation and/or informal interaction between firms as well as between firms and other bodies of the sectoral system of innovation regulate the actor-networks of sectoral innovation systems.

Like all aspects of sectoral systems of innovation, also the types of interrelations between the agents are of course sector-specific, differing among industries; this is, as the knowledge base, the competences, learning processes, demand, technologies, links and complementarities differ across sectors. This is quite logical, as every industry is based on its own network structures that have grown over time and ensure the transfer of knowledge that is required for innovation activities. Networks of firm R&D and institutions for instance play an important role for institutionally regulated sectors such as the pharmaceutical industry, while the computer and microelectronics industries might rather rely on networks of globally dispersed sources of knowledge and innovation.

2.2.4. Links and Complementarities within and beyond a System

Links and complementarities between knowledge and technology within and beyond sectoral systems of innovation play an important role for the dynamics and ultimately for the growth of sectoral systems of innovation (see Breschi and Malerba 1997; Malerba 2002, 2004, 2005a, 2005b; see also Breschi et al. 2003 on the role of knowledge in expansion of a firm's innovation activities). Those links and complementarities can be static as well as dynamic: Static links are quantitative links, such as output-input links and dynamic links. On the other hand, '[d]ynamic complementarities take into account knowledge and technological interdependencies and feedbacks' (Malerba 2002: 254) that determine the firm's strategies and innovation activities.

Malerba (2002: 249; Malerba and Montobbio 2000: 3) links this logic to the concept of Development Blocks, introduced by Eric Dahmèn in the 1950 and widely employed since then (see Dahmèn 1988). The concept is concerned with knowledge or competence flows between several economic actors, that effect ultimately the strategy of a firm, its organization and performance as well as the network structures it is embedded in and the characteristics of technical change. 'Innovation-induced structural tensions' (Edquist and Hommen 1999: 76) let producers and users interact,

which leads to a process of interactive learning, where growth tends to be the outcome. Menrad describes development blocks as 'synergistic clusters of companies and technologies' or clusters of technologies within an industry (Menrad 2001: 332; see also Carlsson and Stankiewicz 1991: 105). Interestingly, the development of such a cluster requires some 'critical mass' of entrepreneurial activity: only if the agents are actively undertaking entrepreneurial activities without limiting them to responding to market signals can the complementarities between the actors develop (see Carlsson and Stankiewicz 1991: 107)

The concept implies that strategies, decisions and investments are seldom undertaken isolated from a larger context but that they are rather closely interrelated and span over different technologies or fields of knowledge and activities. Given a critical mass of entrepreneurial will, communication and interdependencies between the actors develop and during the process of economic development those interrelations can lead to cycles of exchange and growth;

> 'dynamic complementarities among artefacts and activities thus provide force and trigger mechanisms of growth and innovation; […] [l]inks and complementarities greatly affect firms' strategies, organization and performance, the rate and direction of technological change, the type of competition and the networks among firms and among firms and non-firms organizations' (Malerba and Montobbio 2000: 3; see also Malerba 2002: 255).

According to Malerba (2002: 255) links and complementarities can change over time and differ across sectors. This is logical as the different configurations allow only for sector-specific interrelations between knowledge, technology, demand and other factors of sectoral systems of innovation.

2.2.5. Institutions

It has already been indicated above that institutions play a crucial role in innovation systems, which is also reflected in the sectoral approach. As Lundvall (1992: 10) argues, it is 'the structure of production' and the 'institutional set-up' only, that 'jointly define a system of innovation'. Institutions regulate sectoral systems of innovation and vary across sectors; they are

> 'norms, routines, common habits, established practices, rules, laws, standards and so on, that shape agents cognition and action and affect the interactions among agents' (Malerba 2002: 257).

This perspective on institutions comes very close to the stand that the institutionalist industrial economics literature takes on them (see i.e. Edquist 1997, 2005; Edquist and Hommen 1999; Freeman 1987, 2002; Lundvall 1992, 1993); Edquist and Johnson (1997) for example describe them as

> 'sets of common habits, norms, routines, established practices, rules or laws that regulate the relations and interactions between individuals, groups, and organizations' (46; see also Edquist 2005: 188).

Institutions are consequently perceived as regulating bodies that ensure for instance the communication between different aspects of the firm or the industry, such as certain governmentally determined production and quality standards. Those institutional structures regulate and ensure a certain interrelation between a firm's scientific and technical or economic departments. The literature on sectoral systems of innovation underlines that institutions can take various forms; their form and function as 'the rules of the game' (Edquist 2005: 188) ranges from binding to non-binding and from formal to non-formal. Building on the work of Edquist and Johnson (1997) and Coriat and Weinstein (2002), Malerba (2002: 257) describes binding institutions as those that automatically impose restrictions on actors and less binding institutions as those that develop out of the individual interaction between actors (such as certain types of contracts). Formal institutions, are laws and regulations, whereas informal institutions can be traditions and non-codified habits.

Sectoral institutions are carrying the influence of the regional, global or international sphere into the sectoral system of innovation. As many institutions — such as governmental agencies or controlling organs — are national, they impact the innovation activities of an industry (see Lundvall et al. 2002). Clearly the nationally distinct institutional set-ups affect, through their impact on economic structures, also a nation's innovative capacity, which has necessarily an impact on any industry. As institutions determine what factors of production are available to the firm and how they can be used, they dictate what innovations the economy is capable of producing or, at least, in which economic domains the national industry may have comparative innovative advantages;[17] '[i]nnovations are rooted both in the production structure and the institutional set-up of the economy' (Lundvall 1992: 34). As Malerba (2002: 257) argues, this impact of the national regulatory sphere can make sectoral systems of innovation (to varying degrees) nationally distinct: national institutional conditions might favor certain sectors that match those characteristics. The matching sectors can then grow faster than those with attributes that are not supported by the national institutional set-up. Of course, institutions present in a sectoral system of innovation need not necessarily be national. Rather, inter- or supranational institutions, such as European regulatory bodies or regional institutions can play a role for sectoral innovation activities (see i.e. Malerba 2002: 261).

2.3. System Boundaries, Transformation and Change

So far, the discussion has focused on the theoretical roots of sectoral systems of innovation and on their elements and building blocks. Yet, to achieve the aim of this dissertation to explore the sectoral dynamics that can inhibit sectoral flexibility in

[17] Michael Porter (1990) explores this notion in his work The Competitive Advantage of Nations, where national institutions are seen as major determinants of the factor conditions, the relating and supporting structures and ultimately on the innovative potential of a national economy. In turn this implies of course that the institutions present on the sectoral level carry this national element in the industry-internal innovation patterns.

light of environmental changes, more aspects of sectoral innovation systems must be considered. This chapter is therefore dedicated to outlining the boundaries and patterns of change that can — from the perspective of the literature — be expected from sectoral systems of innovation. After all, it is per definitionem the change and transformation of innovation systems that constitute their dynamism and innovative capacity. Malerba describes the sectoral systems of innovation approach to innovation as one that

> 'does not consider sectoral boundaries as given and static, but it focuses on the process of transformation of the system' (2005b: 67).

Ignoring this aspect when conducting an analysis of industry behavior would mean that only a snapshot of the industrial conditions could be made. Rather, the patterns of change of sectors must be discussed, as to understand, how environmental alterations affect the innovation patterns of the sectoral firms.

The following discussion presents therefore the approaches to the boundaries and the patterns of change of industrial innovation activities as presented by the sectoral systems of innovation literature. It suggests that the sectoral systems approach is rather encompassing, perhaps even at the border of vagueness, as it presents sectoral change as a quasi automatic, permanent and omnipresent process, failing to take into consideration organizational and sectoral aspects retarding the pace and intensity of change.

This chapter discusses therefore the boundaries and patterns of change of sectoral systems of innovation, as the corresponding literature views them. The subsequent chapter relates to the discussion by presenting the concept of organizational inertia as to illustrate how, in addition to what the sectoral systems of innovation literature claims, the change and transformation of sectoral systems can be hampered, thereby limiting the possibilities of sectoral innovative expansion.

The notion of boundaries plays a crucial role in the theory of sectoral systems of innovation. The identification of the system elements alone would be insufficient to capture the innovative dynamism and potential of a sector. Malerba (2002) goes as far as to claim that one of the main advantages of the sectoral systems of innovation perspective 'can be identified in a better understanding of the structure and boundaries of a sector' (248). As the literature implies and the following discussion will show, the concept of sectoral boundaries resembles thereby something like the general framework conditions under which an industry is operating; they can be imagined as the boxing ring in which the sectoral firms compete with each other. Those competitors are heterogeneous but share a collective field of activity. At the same time however, the competitors are the basis of the entire game and represent the key players in sectoral systems of innovation. Their actions can affect the size of their boxing ring and they themselves should consequently be seen as elements of sectoral boundaries. The forces and dynamics that constitute the conditions for the firms' activities represent therefore this boxing ring, constituting the boundaries of a sector-

al system of innovation. Firms can undertake innovative activities within those boundaries; any innovation that requires input unavailable within the boundaries would require an extension of the sectoral limits, which would equal a transformation of the sector.

The boundaries of a system of innovation can consequently only be understood in the context of the system elements that have been discussed earlier. Knowledge, learning, technology, demand, institutions as well as links and complementarities among the system's actors have an effect on the innovation patterns of a sector as a whole. In line with evolutionary theory, the configuration of those system components is said to be a product of the environmental conditions and therefore sector-specific and differing significantly among sectors. Consequently, the system configuration has, depending on its characteristics, varying effects on the realm of possible innovation activities available to the sector (of course, no sector exists where the environment has no effect whatsoever on the limits of its innovation capacity); there are 'complex and relevant relationships between demand, technology, the knowledge base and the boundaries of firms', which effect of course the innovation patterns of the sector as a whole (Malerba 2002: 254; see also Bresnahan and Malerba 1997; Malerba et al. 1999). Further, Malerba names geographical aspects of sectors as well as the sectoral links and complementarities as additional elements of sectoral boundaries. The individual building blocks of sectoral systems of innovation and their effects on sectoral boundaries and adaptability are discussed below in more detail.

Yet even though the sectoral systems literature implies that boundaries are always present in the system elements, narrowing down the industrial innovation capacity to a varying degree, they are at the same time said to be highly flexible and changing over time;

> 'the notion of sectoral systems […] focuses on the process of transformation of the system and does not consider sectoral boundaries as given and static' (Malerba 2002: 250).

This positions the sectoral systems of innovation approach in contrast to the standard industrial economics literature that tends to perceive industrial boundaries as static, delimited and pre-determined and explains differences between sectors by formal analyses of technology, demand and sunk costs. Malerba and Orsenigo (1994: 2) describe those models of industrial economics as well as the structuralist approaches to economic growth of the 1960s and 1970s as having 'a static and equilibrium flavor', since not every industrial behavior can be due to some unexplained features of the production function or is the equilibrium outcome of strategic interactions (Malerba and Orsenigo 1994: 2). According to Malerba (2003: 363) sectoral systems of innovation are in this respect distinct from classical game theoretic models of strategic in-

teraction and cooperation or econometric industry studies:[18] non-firm organizations, knowledge, learning processes, institutions and inter- as well as intra-sectoral relations are included in the analysis of sectoral performance and boundaries. A focus lies on interactivity and evolutionary patterns of transformation and change; 'economic entities expand or contract their boundaries and undergo organizational change' (Malerba and Orsenigo 1994: 1).

This focus on change is a crucial feature of sectoral systems of innovation. In concordance with their evolutionary fundament, the sectoral systems of innovation approach puts a key emphasis on the processes of transformation, change and learning (see Malerba 2002, 2003, 2004, 2005a, 2005b; Malerba and Montobbio 2000; Malerba and Orsenigo 1990, 1994, 1997; Malerba et al. 2007). This is based on the assumption that over time, environmental conditions — such as the transformation of knowledge, convergence in demand, changes in the institutional landscape or in the structures of competition — do naturally change. Those dynamics affect of course the boundaries of sectors, which are in turn defined by the environmental conditions in which the industry operates. However, as Nelson (1994, 1995) emphasizes and as it has been discussed, this change can neither be called random nor deterministic. Rather, change and transformation are, in the evolutionary sense of the word, partly guided by the 'boundedly rational' actor, partly by random alterations to which firms must react in order to stay competitive. Ultimately, the dynamics lead then to adaptive processes within the sectoral systems of innovation and to changed innovation patterns and a qualitative evolution of the innovation activities;

> 'change is a distinctive feature of sectoral systems. However, change does not mean simply a quantitative growth of the variables of a sectoral systems. It means also transformation and evolution.' (Malerba 2002: 258)

At the same time, sectoral change is necessarily a co-evolutionary process. Malerba and Orsenigo (1994) present evidence, that the evolution and transformation of sectoral systems of innovation requires several processes of change to occur at once, where one process of change is closely linked to the other. Of course, this focus on co-evolutionary processes is a key feature of systems of innovations in general and of sectoral systems of innovation in particular. The closely tied network structures that make up the dynamism of a system make any change cause something like a domino effect among the network players, forcing them to adapt accordingly. The components of sectoral systems of innovation can be identified in a general analysis. Yet they cannot be fully separated and isolated from each other, as they are interwoven with one another, together constituting a system of innovation; if one component is removed from its systemic network or if its characteristics and nature are

[18] Malerba (2003) names 'the structure-conduct-performance tradition, the transaction costs approach, sunk cost models, game theoretic models of strategic interaction and cooperation, and econometric industry studies' (330) as models of industrial analysis that the sectoral systems of innovation approach contrasts.

altered, an adaptive change of the other system players must necessarily follow (Carlsson et al. 2002: 234; Malerba 2005b: 76).

Bresnahan and Malerba (1997:6) identify in their study of the evolution of the computer industry three major industry dynamics that characterize the co-evolution at the basis of sectoral change: change of firms' capabilities, their organization, strategy, and technology, change of the market structure, as well as of a corresponding change of the relationship between the industry, public policy and the respective national institutions. Interestingly, they show that in all three cases the initial 'shock' that caused the 'domino-effect' of co-evolutionary change was the introduction of a new technology. This underlines Malerba's (2002: 259) argument that due to the close connection amongst the elements of sectoral systems of innovation, broad systemic changes can be initiated by the alteration of just one element; any imbalance in sectoral system of innovation leads to a process of co-evolution.

Similarly, in another study of sectoral evolution, Malerba (2003: 354) identifies co-evolution as a 'process of fusion' that can create new industrial activities. In the case of the telecommunication industry, he argues, simultaneous advancements and changes in the information/communication technologies as well as in the audio-visual technologies have converged and fused into a new product category. Changed environmental conditions have come with it, such as new types of demand, and ultimately adaptations of the innovation activities. This shows that sectoral change does not come about along well defined lines where an innovation is just the logical outcome of the previous one. Rather, sectoral change is often driven by simultaneous changes of different system components. Even though these co-evolutionary processes dominate any process of change of sectoral systems of innovation, they differ across sectors and can include any aspect of the sectoral system of innovation (see Malerba (2003) on the patterns of coevolution of major industrial sectors; see also Nelson 1994: 50).

Malerba and Orsenigo (1994) suggest that at the basis of any analysis of industrial evolution must stand 'a sensible definition of the boundaries of an industry' (23). At its basis must be a definition of the industry itself as a construction of economic activity at a high level of aggregation, characterized by structural relations between actors and between the actors and the products produced by them. The products are naturally evolving and changing during the development of the industry, as they are subject to life cycles and evolutionary pressures from their environment. Yet, as Malerba and Orsenigo continue to argue, a focus on the products alone would miss out some important industry dynamics that shape boundaries and would not be sufficient to define the sectoral boundaries entirely; they suggest that instead larger industry boundaries must be applied to sectors as to include aspects like industrial shocks, the entry of new agents and knowledge or the possible 'industry rejuvenation' (23) through technological, structural or knowledge disruptions into the boundary analysis. This 'broader view of structural evolution' (23) includes all aspects of

sectoral systems of innovation. Malerba and Orsenigo (1994) claim that the firms remain the key element of sectoral boundaries;

> '[f]irms however have to be analyzed according to several dimensions at once: competence, innovative activities, productive specialization, boundaries, organizational structure and, finally, connections with other actors' (24)

Those 'connections with other actors' in turn include the relations between the firms and their suppliers and consumers, as they participate in the exchange of products, knowledge and people, that keeps the firm alive and co-determines the boundaries of an industry. Yet, precisely through the interaction with the firms, those actors are also involved in eventual processes of structural change and alterations of sectoral boundaries.

Additionally to the firms and their suppliers and consumers, Malerba and Orsenigo (1994) as well as Malerba (2002, 2003, 2005b) present institutions as a crucial determinant of sectoral boundaries and patterns of change, that must be considered in analyses of industrial evolution. As it has already been discussed earlier, it is institutions that exercise significant influence on boundaries and change of sectors, as they affect aspects like the external knowledge stock available for firms' innovation activities, the diffusion of knowledge and technology, the entry of new firms and the exit of incumbents as well as the speed and type of production and industrial co-operation. This clearly makes institutions a major force in the transformation and change of sectoral systems of innovation and their boundaries.

Unfortunately, the literature remains rather vague with respect to the individual elements of sectoral innovation systems and their role with respect to the boundaries and change of systems. The co-evolutionary aspect of the change processes makes it of course hard to isolate from each other the effects that single system elements exercise on boundaries and change; after all, sectoral dynamics resemble a closely tied net where multiple processes affect each other, making it impossible to undertake a formal cause-effect-analysis of change. Additionally, the literature allows the boundaries of sectoral systems of innovation to change with the goal of the analysis. For instance, national boundaries of sectoral systems of innovation may change according to the geographical limitations that the sectoral analysis has. The boundaries can therefore vary, depending on whether an industry is looked at on the regional or on the global level (Malerba 2002: 260). This makes a generally applicable differentiation of the mechanisms making up boundaries and driving change difficult if not impossible. Yet, some rudiments are presented by Malerba and others that shall be discussed here. According to those pieces of literature the boundaries as well as the main dynamisms of sectoral change lie in all of the key elements of sectoral systems of innovation: knowledge, learning and technology; links and complementarities among sectoral actors and sectoral systems of innovation; demand, institutions, as well as the geographical dimensions of industries and their innovation activities.

2.3.1. Knowledge, Technology and Learning

Knowledge, learning and technology are described by the literature as 'the core of any sector' (Malerba 2002, 2003), which is why those two aspects have probably the biggest impact on the boundaries of sectoral systems of innovation. Obviously this reasoning flows out of the evolutionary tendencies at the basis of the sectoral systems of innovation approach: firms are learning entities that survive by continuous processes of learning and the extension of their knowledge stock. '[T]he firm as a social community whose productive knowledge defines a comparative advantage' (Kogut and Zander 1993: 626) has no other choice but to keep on learning as otherwise its competitive position will weaken. Knowledge is therefore the core of its engine of development.

Yet also tendencies of the knowledge-based theory play into the sectoral concept. The major role that knowledge and learning play in sectoral systems of innovation positions knowledge not only as a key resource of the sectoral firm but as the ultimate basis of it. This goes beyond evolutionary theory; as Spender (1996) implies, evolutionary theory is good at conceptualizing the retention, variation and selection processes that shape the firm's actions but fails to come down to the ultimate origins of the firm, which are mainly its knowledge stock. In this sense, the sectoral systems of innovation literature seems to draw from the two schools to underline the importance of knowledge to functioning of sectoral systems of innovation. Firms are the product and developer of productive technological or organizational knowledge; they can learn and transform through their knowledge (see Foss 1996; Kogut and Zander 1993; Spender 1996).

Looking back at the preceding discussion of building blocks of sectoral systems of innovation, this seems logical: knowledge, learning processes and technologies are reflected in accessibility and opportunity conditions, domains of knowledge and the technological regime under which a sector is operating. Those forces represent a certain status quo that determines the knowledge environment in which a firm acts. Over time, the sectoral firms develop their knowledge stocks in relation to this environment and base their innovation activities on it.

In a dynamic way, the literature implies, the focus on knowledge and technology emphasizes therefore the real boundaries of the firm, as any innovation activity is rooted in and dependent on the technological possibilities and the knowledge stock currently at hand (see Malerba 2002, 2003, 2005b). Of course, behind this stands the reasoning that innovation is mostly a function of knowledge, which in turn is a function of history. The firm knowledge is therefore at the same time the biggest guarantor of and the highest barrier to innovation. Ergo, Malerba calls knowledge an essential part of sectoral boundaries. Having put the concept of technological regimes at the centre of sectoral knowledge and learning, Malerba argues that

> '[t]echnological regimes [as the description of the sectoral knowledge environment - A.N.] set the boundaries of what can be achieved in firms' problem solving activities and identify also the 'natural trajectories' along which solutions to these problems can be found' (Malerba 2005: 64).

Take for example an industry that has been innovating under high opportunity and low appropriability conditions as well as low cumulativeness (the knowledge environment that Malerba and Orsenigo would associate with a Schumpeter Mark I pattern of innovation). It is very unlikely that the (technological) knowledge accumulated under this regime allows successful innovations under the reverse conditions. As we will see later, a transformation is said to be possible but for the moment the sectoral knowledge represents a boundary to it. Malerba and Orsenigo (1997) argue that technological regimes can set boundaries to the innovative process as they define the trade-offs with respect to the technology, knowledge and the interplay between the two. Therefore '[t]he notion of technological regime also provides the basis of an explanation of the diversity in the patterns of innovation across sectors and technologies' (97).[19]

Yet, following the literature, knowledge and technologies at the basis of sectoral innovation activities can and do in fact always change. A basic assumption of sectoral systems of innovation is that the firm (and therefore also the sector, as a conglomerate of firms) is a learning organism that remains competitive through the continuous expansion of its knowledge stock. In other words, the knowledge base of a sector is the result of processes of adaptation to the ever-changing innovation environment. Consequently, any change in the firm environment must necessarily have an effect on the knowledge stock of the firm.

Among others, Malerba (2002: 258) presents two concrete scenarios for the change of technology and knowledge and the related sectoral evolution. The earlier discussion of the relation between technological regimes and Schumpeterian patterns of innovation in sectoral system of innovation is thereby expanded. As Malerba claims, technological regimes change naturally over time; the industry life-cycle dictates an evolution of any industry, including changes of technology, (technological) knowledge and the focus of innovation. Yet, at least two varieties of this change are possible: firstly, in concordance with the assumptions of the industry life cycle, Malerba argues, Schumpeter Mark I patterns of innovation may turn over time into Mark II patterns. This would equal a movement away from turbulence with respect to technology and innovation, towards a 'dominant design', where technological change follows well-defined trajectories and industrial learning curves are established. Growth and concentration of the leading firms and their knowledge stocks would be the result (Malerba 2003).

The second scenario would be the replacement of a Schumpeter Mark II innovation pattern by a Mark I (Malerba 2002: 258). This would be the case if major dis-

[19] For a discussion of the role of knowledge in organizations, see Breschi et al. (2003) on the knowledge-relatedness of firm diversification.

continuities, such as technological disruptions, occurred. Those periods of discontinuities tend to create turbulence, destroy knowledge and competences. This provokes, or rather forces the sectoral firms to undertake a 'drastic change' in order to remain competitive (see Malerba 2003: 335). Sectoral innovation activities must deal with the turbulence by changing their technological base or exploiting new demand.

Of course, those processes that cause changes of the knowledge base of an industry occur periodically. Malerba and Orsenigo (1994: 10) reason that technological discontinuities tend to appear regularly, creating turbulence, destroying knowledge and competences and forcing the industry to reorient itself. Those periods are often followed by times of stability and continuity, where new knowledge is collected. In any case, the sector is thought to be involved in a process of constant adaptation and change of knowledge. Clearly this affects the sectoral boundaries.

In the above discussions, the weight of knowledge and technology for the sectoral boundaries and change of innovation patterns has been emphasized more then once;

> 'the focus on knowledge and the technological domain places at the centre of analysis also the issue of sectoral boundaries, which usually are not fixed, but change over time' (Malerba 2003: 333).

This is supplemented by the literature's focus on the firm as the key player in sectoral systems of innovation and underlines the central role that the firm with its knowledge and technology plays in the sectoral process of innovation and evolution. This is certainly logical, as ultimately innovations are always born out of the technology and knowledge of the firm. Put differently: even in a situation of otherwise perfect conditions for sectoral innovation activities, a lack of knowledge or technological capacities makes innovation impossible.

On the other hand, knowledge, technology and the firm cannot be seen as a sectoral component that acts isolated from its environment. Contrarily, the effect of the other sectoral agents on it is significant. The concept of technological regimes exemplifies this strong connectivity inherent to sectoral systems of innovation: for instance, concepts like opportunity and appropriability conditions clearly carry in themselves institutional, geographic and regulatory components. This is the case, as the technological knowledge environment of sectoral firms is much more than the sheer combination of the technology in use and the static knowledge stocks of the firms. Rather, the knowledge environment is impacted by all other sectoral elements, thereby co-determining the sectoral knowledge base and consequently its patterns of change.

2.3.2. Links and Complementarities

One of those system elements that plays an influential role for sectoral knowledge, technologies and consequently the boundaries and change of innovation sys-

tems are the links and complementarities among system elements and across sectors. The earlier discussion of sectoral systems' components has addressed their importance already: it can be thought of those links and complementarities as flows of knowledge and competences between all kinds of actors within and across sectoral systems of innovation that help to bridge certain tensions and deficits in the innovation process. They are therefore carrying new knowledge into systems, thereby pushing (in the ideal case) growth and development. The intensity and quality of communication between actors and sectors determines the speed and quality of change, learning and consequently innovation.

However, this differs across sectors, so the development through links and complementarities is not possible to the same across sectors. This is why Malerba claims that 'interdependencies and complementarities define the real boundaries of a sectoral system of innovation' (Malerba 2002: 250; see also Malerba 2003: 333). Those links and complementarities include of course the impact of suppliers and users, as they are an integral part of the sectoral system of innovation. They therefore play into the boundaries as well (Malerba 2003: 343). Important linkages and complementarities can for instance develop out of investments of one sectors in another. Obligations and knowledge exchange are the result, which impacts the strategy, structure and organization of sectoral firms, can create tensions or boost cooperative innovations (see Bresnahan and Malerba (1999) on sectoral cooperation and knowledge-generation in the world computer industry). Clearly this all effects the limits of innovations the sectoral system of innovation can generate.

All in all, links and complementarities feed the knowledge stock of the sectoral firm, thereby helping sectors to expand their innovation activities. Depending on the type, degree and quality of the links and complementarities, which differs across sectors (see Malerba 2002: 255), they facilitate innovation activities to varying degrees and act as a source of transformation and change of sectoral systems of innovation;

> 'dynamic complementarities among artifacts and activities are a major source of transformation and growth of sectoral systems, and may set in motion virtuous cycles of innovation and change' (Malerba 2002: 254).

At the same time, links and complementarities can also change. Take for example drastic changes in the institutional landscape. This might shake the links and complementarities of the sector, as the interaction among agents might be heavily dependent on institutions. Hence the links and complementarities would have to adapt, which in turn would impact the sectoral innovation patterns and boundaries. Malerba (2002: 255) employs the example of the computer industry to underline his argument that links and complementarities impact the transformation and development of sectoral systems of innovation: he claims that until the 1980s dynamic links and complementarities held software and hardware in a very close relation to each other; knowledge flows and interdependencies between the two disciplines ensured simultaneous innovation and advancements of the two but no specialization. Yet later

on, standard interfaces developed and those complementarities lost some of their strength. This represented a shift of technology and knowledge that allowed the sector to evolve.

2.3.3. Demand

Another element of sectoral systems of innovation that is boundary-setting is demand. As the previous discussion of the architecture of sectoral systems of innovation has shown, demand can be thought of as the representation of the problems that firms have to solve through innovation; demand is a major source of impetus, inspiration and (in the extreme case) pressure for innovation. The role that demand plays for the boundaries of sectoral systems of innovation seems therefore logical. In a way, demand contains and directs the innovation activities of an industry. It can function as the door-opener to innovation as well as barrier to innovative change:

> 'demand […] is a major factor in the redefinition of the boundaries of a sectoral system, stimulus for innovation, factor shaping the organization of innovative and production activity' (Malerba 2003: 343).

In Five Competitive Forces that Shape Strategy, Porter (2006) underlines the effect that demand has on the structure, organization and finally on the innovation patterns of industries. A strategy-shaping force Porter calls 'bargaining power of buyers' reflects demand for a product; Porter illustrates that firms adjust their activities to a substantial degree to this element of their competitive environment. Also Mowery and Rosenberg (1979) reason that market demand has a 'governing influence' on the innovation process, 'innovations are in some sense "called forth" or "triggered" in response to demands for the satisfaction of certain classes of "needs" ' (104).[20]

At the same time it must be kept in mind that the sectoral literature conceptualizes demand as much more than only the sum of final consumers. Rather, it is composed of heterogeneous (groups of) agents and preferences. This calls into play the effect that other system elements have on demand and vice versa; those actors shape demand and consequently the boundaries of the innovation system. Strong relations between demand and knowledge for instance, or between demand and technologies or sectoral links and complementarities can be present in sectoral systems of innovation (see Malerba 2002). So again, this element of sectoral systems of innovation is co-determining the systemic innovation boundaries both directly and indirectly, through the mere consumer pressure on innovation activities and through indirect links to other boundary-setting aspects of the innovation system.

[20] Bresnahan and Malerba (1999) or Malerba et al. (1999) conduct empirical studies on the computer industry, illustrating the correlation between demand and innovation: they identify the growth in demand for computers and the related electronic devices as the major source for the industry's boom. Bresnahan and Malerba (1999) show that even different types of demand for computers can together provoke intensive innovation activities within the industry, thereby expanding the sectoral boundaries significantly.

Demand plays also a role in the change processes of sectoral innovation activities. Clearly, no demand is continuous but rather subject to regular discontinuities. As the sectoral systems of innovation literature conceptualizes demand as a very heterogeneous system element, its change can have various sources (i.e., technological breakthroughs, or altered institutional influence on the market structure). Broadly speaking, demand discontinuities can affect the market structure and hence also the selection processes: it can alter the ease of entry and exit as well as the survival rate of the incumbent firms (Malerba 2003: 335; Malerba and Orsenigo 2000: 306). Malerba and Orsenigo argue that while technological discontinuities can usually be absorbed by the industry leaders with ease, demand discontinuities tend to have a stronger impact on the sectoral configuration. They argue that the lock-in of existing customers to the 'old' technology can help firms to absorb the effects of technological discontinuities on their innovation patterns. Yet, with demand discontinuities, they argue, major technological changes come along that force sectoral firms to acquire new knowledge. This causes significant turbulence, entry and exit patterns change and the sector is likely to transform. Malerba et al. (2007) present experimental and lead users as groups whose demand for innovation (often based on new technologies) regularly creates turbulence, shaking sectoral innovation patterns. They show that new firms and technologies that cause sectoral turbulence and change are often successful when there are 'fringe markets which the old technology does not serve well, or experimental users, or both' (371).

Also, Malerba et al. (2007) argue, that it is not necessarily technological trajectories but can also be demand that is the major force behind the gradual development of a dominant design (which represents another type of sectoral development/ transformation). Demand can create lock-ins or be locked-in (i.e., to existing technologies), which prevents the entry of new knowledge or players into the sectoral system of innovation (384).

2.3.4. Institutions

Institutional regulation can also impose boundaries on the innovation activities of sectoral systems of innovation. Innovation systems in general put a lot of emphasis on the role of institutions as co-determinants of innovation (see i.e. Edquist 2005; Lundvall et al. 2002), which is also reflected at the sectoral level. Innovations always occur in interaction between institutional and organizational spheres; an interactive process between firms and the wider institutional context creates innovation. Of course, the institutional influence is omnipresent in any level of this learning process (see Edquist 1997; Lundvall 1992; Morgan 1997). Nelson and Nelson (2002) differentiate between two dominating forces in the innovation process: physical technologies on the one hand and 'institutions as social technologies' (269) on the other. According to them, physical technologies can be seen as a general 'recipe' for innova-

tion that functions independently of the regimes of division of labor or the mode of coordination that surround them. In contrast, institutions represent a 'social technology', as they provide guidelines for a division of labor and a mode of coordination for innovation activities. The concept underlines that institutions and technologies are equally important in the innovation process. Institutions can of course be constraints to development, yet they can also function as boosters to innovation. Expressed differently, innovation without institutions is impossible, their presence is as essential for innovation as that of technology;

> '[t]o view institutions as "constraints" on behavior is analogous to seeing prevailing physical technologies as constraints. A productive social technology (an institution) or a physical technology is like a paved road across a swamp. To say that the location of the prevailing road is a constraint on getting across is basically to miss the point. Without a road, getting across would be impossible, or at least much harder.' (Nelson and Nelson 2002: 269)

As it has been highlighted in the previous chapter the sectoral systems of innovation literature is well aware of this importance of institutions. This is reflected in the discussion of the sectoral boundaries: 'institutions may constraint the development or innovations in specific sectors' (Malerba 2002: 257). A key issue the literature addressed in the context of boundaries is the relation between international, national or regional institutions and the sectoral systems of innovation (see i.e. Breschi and Malerba 1997; Malerba 2002). Clearly, national institutions (as the most prominent type of institutions in sectoral systems of innovation) have a great affect on the sectoral system of innovation and can facilitate as well as hamper the functioning of sectors and their innovation activities. The health sector is a good example: being heavily regulated, the market is only open for those pharmaceutical innovations that have been approved of by the responsible state authorities — clearly a case where national institutions set boundaries to sectoral innovation activities.

Of course, institutions include much more than national regulatory bodies and can therefore set various forms of boundaries to sectoral systems of innovation. By impacting links and complementarities between actors and sectors or by influencing technological progress, norms and routines, they play into all aspects of sectoral systems of innovation and influence the innovation boundaries.[21]

This interconnectedness shapes also the incentives for sectoral change that institutions can represent. As the sectoral systems of innovation literature claims and as it has been discussed above, institutions that affect sectoral systems of innovation can be very heterogeneous, varying from informal contracts between firms to national or supranational regulatory organs. Any change of those institutional bodies is of course

[21] It is important to note here that Malerba (2002) is aware of research-deficits with respect to the interplay between institutions and sectoral innovation activities; 'a key issue to be addressed by current research refers to the emergence of sectoral institutions. […] Another major topic to be examined in-depth is the relationship between national institutions and sectoral systems' (257). However, no significant advancements of the academic debate on this field have so far been made.

translated to the sectoral system of innovation and changing the boundaries of innovation there. Apple Inc. for instance owes most of its success in the music business to contracts with the music industry that enables them to sell music online for a standard price per track. This institutional check can be said to have changed not only Apple but its entire sector.

2.3.5. Geography

A last aspect of system boundaries that the literature discusses is the geographical domain — 'in sectoral systems the national, the local and the global dimensions coexist.' (Malerba 2003: 348). Clearly, national and regional factors play into sectoral systems of innovation (through the effect of national/regional institutions or of geographical knowledge-concentration on sectors) and contribute thereby to their boundaries. For instance, the boundaries of a sector such as the Californian microelectronics industry that is based on the specialization of the area of Silicon Valley carry a significant geographical component; the industry and the region profit from one another, which is (besides all advantages) clearly a boundary to further innovation activities for the sectoral system of innovation (Malerba 2002: 260, 2005b: 68).

2.4. Critique and Discussion

Upon reflection, the approach of the sectoral systems of innovation literature to boundaries and transformation of sectoral systems of innovation leave a number of questions unanswered. It is the purpose of this chapter to discuss those open points in order to prepare the grounds for an extension of the sectoral systems of innovation approach. As discussed in chapter 1 already, the aim is to create a theoretical framework for the empirical analysis, combining the theories of sectoral systems of innovation and organizational inertia.

Due to the strong evolutionary and systemic tendencies of the concept, the sectoral systems of innovation approach views the composition and character of the system elements as a function of the environment. In turn, sectoral boundaries are a function of the system building blocks: the characteristics of the search environment that shape the sectoral agents are transmitted through the agents to the sectoral boundaries. Put differently, sectoral systems of innovation and their limits develop as a reaction to the environment. Within the realm of what the environment allows them to do, actors position themselves and innovate.

The close network structures in sectoral systems of innovation lead to co-evolutionary structures when it comes to changes in the environment. Classical evolutionary theory assumes that economic actors adjust themselves to changing conditions; sectoral systems of innovation theory claims that this process of adjustment to changes is carried by and automatically transferred through the system. This re-

sembles a logic that could be labeled 'chain of transformative effects': when it comes to several simultaneous changes — a co-evolution of several system aspects — the changes are translated into an according change of all system actors. Only if this transformation is working, the sectoral firms can remain competitive and survive the processes of selection.

At the same time, the sectoral boundaries are conceptualized as never fixed or static, while their existence is never contested by the literature (after all, any system element directs the innovation activities of firms in one direction instead of the other). Put differently, the scenario that a sector is — despite a multitude of environmental changes that should bring about co-evolutionary cycles of change — not adapting to a new sectoral reality is not considered by the literature. Instead, what the literature implies is permanent change of the system, driven by the systemic dynamics among the actors.

This permanent readiness for change is the crucial aspect. Of course, evolutionary theory claims that processes of variation, selection and retention are unforeseeable, omnipresent and therefore able to transform any industry according to the environmental forces and pressures. Yet, the evolutionary selective processes change firms and industries not exclusively through transformation but also through elimination of organizations. It can be argued that the elimination of an economic actor is necessarily the result of an incongruity between the environmental requirements and the organizational abilities: the boundaries of the firm.

So, from a systemic view, where are the innovative boundaries of industries? Under what conditions does an industry such as the pharmaceutical industry not adapt to external pressure to innovate? Quite naturally, Malerba and others name the general environmental and systemic conditions as bounding the innovative freedom of industries. Geography, technology or institutions, to name just a few bounding influences, necessarily impose limits to the innovative freedom of a system; ultimately, any system element and dynamic represents a barrier to change. This is, however, true for any system of innovation. Alternative approaches to innovation system go a step further. National systems of innovation for instance are, as discussed earlier, bound by the national institutional frameworks; technological systems develop along technological trajectories. Both systems can only develop in accordance with those trajectories on which their competitiveness is dependent. One could argue that those approaches entail a conditional notion of economic growth and development: the economic system cannot change if there are no changes on the national/technological level. Those spheres represent the systemic boundaries.

Yet, the sectoral systems of innovation literature entails such conditional elements only marginally. Whereas other approaches present the national or technological sphere as the core element of systems, the sectoral systems of innovation theory sees the firm at the system's heart. At the same time, it is not discussed how the firm can bound the industrial development. Rather, an automatism of change is implied by

stating that co-evolutionary processes of adaptation and change occur. The question about possible obstacles to such change remains open. It is implied that the sectoral firms are 'experimentally organized' (Eliasson 1991: 154), up to a degree that makes any transformation possible.

This dissertation intends not to argue that sectors cannot change whatsoever. In the long run, of course, the assumptions of the sectoral systems of innovation theory are right: change somehow occurs. Yet, it must be assumed that this 'automatism' can — in the short and medium run at least — be dysfunctional or rigid. The situation of the pharmaceutical industry suggests that even in cases of drastic environmental changes, industrial adaptation is not necessarily following. If it was, the observable lethargy of the pharmaceutical industry would be absent; pharmaceutical companies would react to the numerous stimuli from the market and invest heavily in health product innovations. The fact that this is happening very cautiously and slowly (or not at all) connotes that the sectoral firms are somehow inhibited to incur the market deferrals and transform accordingly. Boundary-setting sectoral dynamics must be present that cannot be overcome and hinder 'chains of transformative effects' to occur.

It is therefore crucial to screen the sectoral dynamics and the effects they have on the behavior of the firm, in order to understand how and at what point sectors can be rigid to change. Ultimately, it is in any case the firm that must carry the sectoral deferrals and transform in order to stay competitive. At the same time the firm is in many respects a product of its sectoral environment. For the sake of analyzing the reasons for inflexibility in times of change, the behavior of the firm, which Malerba calls the 'core player' of any sectoral system of innovation, must be understood in the sectoral context. After all, the notion of path dependence and the importance of history for the development of economic actors represents one of the main pillars of evolutionary theory, innovation systems and finally sectoral systems of innovation theory. The approaches to sectoral change and transformation the sectoral systems of innovation literature has developed seem to ignore this by assuming that environmental changes can always and automatically be incorporated by the firm, who is then adapting its innovation activities to them. The fact that sectoral systems of innovation are influenced by their development, producing inert systemic structures is addressed by the literature, yet marginally or indirectly only (Geels 2004: 899; Malerba 2002: 249, 2005b: 69).[22] Most of the times the issue is worth a marginal note only or is just implicitly included the discussion of sectoral boundaries and change.

It is precisely this lack of clarity regarding the system dynamics in times of change that represents a shortcoming of the sectoral systems of innovation literature.

[22] For discussions of sectoral systems of innovation that treat the issue of systemic boundaries and inertia implicitly only, see i.e. Carlsson et al. 2002; Malerba 1992, 2003; Malerba and Montobbio 2000; Malerba and Orsenigo 1995, 1993.

The literature describes the sectoral firm as coined by its own competences, organizational structures, corporate culture, hierarchies and beliefs. Those organizational key properties and the systemic environment are constantly impacting each other. They interact with each other and with the external systemic environment, producing systemic dynamics and ultimately innovations. At the same time, following the logic of the concept, stagnation is impossible and change can always occur. This illustrates the contradictions that the approach entails.

It remains unclear whether and how in turn those dynamics also influence the functioning of the sectoral innovation activities. Should it not be assumed that firms cannot always adapt to changing systemic conditions, that a firm may be subject to inert structures that develop over time as a reaction to path-creating forces in the system? After all, inertia is a natural by-product of organizational development, as any firm seeks stability. Stability in turn incorporates inflexibility. Also, the system dynamics in which the firms are embedded and that carry the system must necessarily produce rigidities in some way. Logic implies that any structure producing dynamics in one direction blocks the system with respect to another.

The sectoral systems of innovation literature is inconsistent with respect to the ability of systems to adapt flexibly to changes. Firms are conceptualized as possessing individual competences and routines, while their actions are at the same time considered to be driven by the system. This is in deed counterintuitive as the two dynamics can hardly coexist and maintain a system that is open to co-evolutionary processes of change. How can the firm as 'a dynamic, evolving, quasi-autonomous system of knowledge production and application' (Spender 1996: 59) at the same time be directed by a system that is constantly evolving? And even more importantly: how can boundaries be overcome easily in such a situation? This underlines the qualms with respect to the automatic, co-evolutionary processes of sectoral change, as presented by the literature.

It would in deed be wrong to view sectoral firms as organisms that always can quickly and easily adapt to changing environmental conditions, thereby carrying any alteration of their sectoral surrounding to the market. Certainly, firms are not flexible enough to adapt their innovation patterns unlimitedly. Nelson and Winter rightly state that

> 'it is quite inappropriate to conceive of firm behavior in terms of deliberate choice from a broad menu of alternatives that some outside observer considers to be "available" to the organization. The menu is not broad, it is narrow and idiosyncratic […]; highly flexible adaptation to change is not likely to characterize the behavior of individual firms' (134).

Firms enter into and grow along developmental paths that determine their nature, guide their innovation behavior and eventually lock them into an inert pattern of behavior. In times of environmental change, which may demand from firms to break their paths and transform, environmental change cannot always and automatically be absorbed and implemented by the organizational structures that have grown.

Sørensen (2002), among others, argues that the ability of firms to leave their developmental paths, to overcome inertia and to change depends on the relative strength of the firm's structural and cultural inertia in relation to the changes in its environment.

The following chapter therefore extends the theoretical discussion by the concept of organizational inertia, aiming at combining the sectoral perspective on market change with one of organizational rigidity. As outlined earlier, this is to close the gap in the sectoral systems of innovation theory in order to prepare the grounds for a consistent empirical analysis.

3. Extension of the Conceptualization of Sectoral Change

3.1. Organizational Inertia

The concept of organizational inertia, often also labeled 'incumbent inertia', addresses the tensions emerging between established industry actors and their environment in situations where environmental conditions change and the actors are unable to adapt at the same speed. It is primarily interested in proving the presence of obstacles to change or — in other words — lock-in and the resulting inert structures that firms can suffer from. Gilbert (2005) argues that in any industry, situations of 'discontinuous change' can occur, where external changes 'require internal adaptation along a path that is nonlinear relative to a firm's traditional innovation trajectory' (742). In such situations, the firm's ability to react appropriately is naturally reduced by inertia, which Gilbert defines as 'the inability to enact internal change in the face of significant external change' (741). Of course, this is not to say that firms and industries are completely unable to change; rather, as Hannan and Freeman (1984) put it, it means 'that organizations respond relatively slowly to the occurrence of threats and opportunities in their environment' (151).

But how does inertia develop? What aspects of the firm provoke lock-ins that have the power to prevent flexibility of innovation activities in times of environmental change? Hannan and Freeman (1984) disagree with the assumption of classical evolutionary theory 'that selection processes invariably favor adaptable forms of life'. Instead, they argue 'that selection processes tend to favor organizations whose structures are difficult to change' (149). This is, as they stress, because a firm's structure and development are shaped by two influences: internal firm arrangements and the external environment. Over time, the firm asserts itself in this situation. Adapting to the requirements of the external environment (institutional landscape, demand, etc.), bundles of resources are accumulated that are internally tied together by money, time, commitment and entrepreneurial talent of the firm. In other words, in order to meet the market requirements the firm develops matching internal (structural and technological) arrangements.

The underlying logic is simple. Accumulated resources as well as the processes of their development are a function of the organizational history: certain structures and behavior are benefited by the external conditions of innovation and yield therefore self-reinforcing effects to the firm. It is per definitionem that those effects accelerate the developmental process of a firm in the direction predetermined by 'history'; over time, they are 'progressively eliminating the scope of decision making' (Sydow et al. 2009: 702). What this underlines is the inseparability of the organizational resources and the organizational development. The allocation of resources and the evolutionary path of an organization are mutually dependent, which is why a clear distinction is impossible.

Hannan and Freeman (1984: 152) provide a rather 'pragmatic' explanation for organizational inertia: they see the financial value of the physical assets accumulated during a firm's history as one major building block of inertia. Its accumulated assets are the firm's main capital, source of experience and are of high financial value. – It is never in the interest of a firm to destroy them in times of environmental change. Following Hannan and Freeman, processes of adaptation and transformation as a reaction to changed sectoral circumstances for innovation are therefore often actively avoided (in cases of resource investments at stake) or simply impossible. Liebermann and Montgomery (1987: 12) compare this logic to the concept of cannibalization avoidance: naturally (and often unconsciously), incumbent firms are tempted to 'harvest' the rents from their sunk investments, rather than transforming themselves radically, which could force them to cannibalize some of the rents of existing products.[23] MacMillan (1983: 21) argues similarly that whether a firm adapts to new conditions or exploits the old assets depends on how costly it is to transform and convert the existing assets to a new use. Often, the loss or reduction of the self-reinforcing effects keeping the firm in its path represent that cost.

According to the literature, incumbent inertia is often a 'rational, profit-maximizing response' (Liebermann and Montgomery 1987: 13) to the organizational environment, even if this leads to organizational decline in times of radical change. However, it seems unlikely that the persistence of organizational structure is always a function of the organizational preferences and fears, as MacMillan and others imply. The self-reinforcing effects that can constitute path dependence and hold firms in their traditional paths are certainly too complex to be controllable at all their stages.

Gilbert (2005) provides a two-layer-model of inertia that focuses on the sources of self-reinforcing effects and lock-ins. He argues that two distinct types of organizational rigidities determine the firm dynamics that constitute organizational inertia: resource rigidity and routine rigidity. Both, a firm's resources and its routines can yield self-reinforcing effects that lock the firm into inert practices. The analytical differentiation between routine rigidities and resource rigidities as two sources of organizational inertia provides clear categories for measuring inertia, which will serve the theoretical framework that will guide the empirical analysis of the pharmaceutical industry.

3.1.1. Resource Rigidity

Resources are at the basis of organizational success; as Freiling (2004) points out, they are the 'result of successful asset refinement processes' (30). They represent the basic assets at disposal for a firm, employed to create economic rents and a competitive advantage. They can be material and immaterial, including physical, human and organizational capital and ranging from factors like production plants or infra-

[23] For more detail and empirical observations on the issue see i.e. Bresnahan 1985 or Reinganum 1983.

structure to established distribution channels or experience in certain markets (Barney 1991: 101). As Grant (1991) stresses, resources are the basis of firms' long term strategic evolution. This is, as they constitute the firm's basic identity (supplemented by competences and routines, as discussed hereafter) and thereby 'provide the basic direction for a firm's strategy' (Grant 1991: 116). Also, when integrated into the organization's competences, resources are the main source of profits generated by the firm, ensuring its survival, success and competitive advantage. Those two dynamics together allow firms to evolve and plan strategically.

As this already indicates, organizational resources heavily shape the firm's innovation activities (any innovation must follow the resources available to the firm) and consequently its strategic planning. Naturally, this makes resources a potential source of inertia: the company employs different resources as to attain new goals, yet those resources may turn into a rigidity when facing change. Gilbert's (2005) concept of resource rigidity as one component of organizational inertia addresses this issue. He claims that two main dynamics drive behind resource rigidity.

Firstly, similar to the argument of Lieberman and Montgomery presented above, Gilbert argues resource dependency to be often the reason why firms invest insufficiently in discontinuous change. Following the work of Pfeffer and Salancik (1978) on the controlling influence of the environment on organizations, Gilbert outlines that external resource providers — capital and customer markets for instance — can be of such importance to firms that they affect their strategic choices (Gilbert 2005: 742). He leaves it unclear, how widely the term 'resource provider' should be interpreted. The argument, however, indicates that the term describes all external market influences, such as sources of firm resources and determinants of their development under the influence of self-reinforcing effects. As Pfeffer and Salancik put it:

> 'Organizations engage in exchanges and transactions with other groups or […] organizations. The exchanges may involve monetary or physical resources, information, or social legitimacy. Because organizations are not self-contained or self-sufficient, the environment must be relied upon to provide support. For continuing to provide what the organization needs, the external groups or organizations may demand certain actions from the organization in return. It is the fact of the organization's dependence on the environment that makes the external constraint and control of organizational behavior both possible and almost inevitable.' (43)

Noda and Bower (1996), for instance, describe the hampering influence on changes in business models and organizational architecture that public equity markets can exercise. They illustrate that the market conditions as they are at the time a business is founded can impact the resource configuration of the firm to such a degree that change at a later point in time becomes difficult. A similar example would be institutionally set performance or quality standards through institutions that put self-reinforcing effects and the development of corresponding resources in motion, which become at one point unchangeable. The idea to switch resource providers, which would be necessary to flexibly react to external change, is therefore often rejected by

firms due to this dependence or can — due to the power of the resource provider — simply not be realized.

The second aspect of resource dependence relates to firm-internal rigidities, shifting the focus from the external environment as the provider of rigidity to the firm-internal sphere (Gilbert 2005: 742). The differentiation between firm-external and firm-internal sources of resource rigidity is also taken up by Hannan and Freeman (1984):

> 'Some of the factors that generate structural inertia are internal to organizations: these include sunk costs in plant, equipment, and personnel, the dynamics of political coalitions, and the tendency for precedents to become normative standards. Others are external. There are legal and other barriers to entry and exit from realms of activity.' (149)

Gilbert claims further that generally, successful and well-established firms (in terms of technology and/or products in the market) are very unlikely to invest largely in discontinuous change, as it could threaten their stable and strong current position. The better a firm is positioned in the market, the less likely 'incumbent reinvestment incentives' are to develop (Gilbert 2005: 742). The reason is simple: firms tend to exploit their position and the benefits from it (produced by self-reinforcing effects and positive feedback from the market) as long as possible, rather than taking the risk of changing. For instance, empirical observations suggest that in cases where access to a new technology is blocked, firms tend to invest in their current technology, rather than trying to find ways to engage in the new one (see Gilbert and Newberry 1982). Incumbent firms who dominate the 'post-innovation market' are unlikely to take the risk of innovation in a domain other than their core business (Reinganum 1983). 'An incumbent firm conducts fewer parallel projects than would a challenger' (741) who enters the market, simply because the incumbent firm lives off the returns form the investments it has made in their core market which naturally reduces the incentives (i.e., the mere financial need) to invest somewhere else. Those investments include the resources allocated, which generate the returns from the core market. As Reinganum underlines, this follows the simple logic that from the perspective of the firm who is successful in its core market and enjoys high market power in it, 'more drastic innovations may also be subject to greater uncertainty' (746). This naturally reduces the incentive to invest in discontinuous change. In turn, however, the exploitation of the positive feedback from the current position in the market strengthens dependences on it, which again reinforces the rigidity it creates.

As Gilbert puts it,

> 'whether constraints stem form the desire to preserve market power or from blinders created by resource dependence, they represent powerful inertial forces blocking incumbent investment in discontinuous change.' (742)

The situation of dependence (with respect to resources and/or the position in the market) that Gilbert describes can have various sources, as all firm resources develop and manifest themselves in accordance with the innovation environment. In other words, the dependence of firms on external resource providers is the logical consequence of structures that have grown under the influence of the self-reinforcing effects they bring about. Firms adapt to the conditions by building stable and reliable structures and resources. Naturally, this produces dependences from the resource providers to which they adapt. The more intensive or numerous the self-reinforcing effects are, the stronger is the resulting dependence. The same logic applies to the tendency of firms to create resource rigidity by preserving their market power. Following Meyer and Schubert (2005), 'history' infiltrates any element of the firm and remains there, nourished by self-reinforcing effects. Self-reinforcing effects are causing over time a certain taken-for-grantedness that things have to be done in a certain way as history has shown that it just works that way. There is some variety in the effects it can take, ranging from technologies, customers, demand and markets to organizational structures, hierarchies and processes. All those domains of the firm represent resources that are crucial for the innovation process. If they are highly dependent on self-reinforcing effects, they can easily turn into barriers to organizational change and adaptation.

Theory claims that at the same time, change can neither be fully excluded as an option; yet inertia cannot always be broken, once the firm is locked-in to a status-quo, held up by self-reinforcing effects (such as the dependence on resource suppliers and channels of distribution or the efficiency of competences). How and how quickly an organization can in fact change depends on numerous factors, among which are the development of the organization, its degree of adaptation to the 'old' environmental conditions, its economic success and, most importantly, the domains in which the inertia lies. According to Sydow et al. (2009), '[t]he chance of actually restoring choice depends on the character of the self-reinforcing dynamics and the possibility of creating a new advantageous situation' (703).

Gilbert (2005) analyses the print newspaper industry regarding its self-reinforcing effects and inert structures, that came to light when trends started to move towards online media. The new technological opportunities changed of course the innovation conditions of the industry, which in the beginning failed to pick up this trend. Gilbert's study shows that it was actually the industry's high dependence on the demand of its traditional customer base that made it impossible for it to change to online media.

> 'Much of the initial resource rigidity stemmed from resource dependencies related to the demands of the established print newspaper customers — both advertisers and readers. […] Even when money was provided, operating attention could be equally difficult to secure. An online sales representative at the Beacon A recalled this: "Print reps could sell the online product, but with varying degrees of success. Their margins were higher on other products that were easier for them to sell." ' (746)

Two dynamics become apparent here: the installed customer base that had been developing over time locked the industry into a position that it can hardly leave. Consumer preferences functioned as self-reinforcing effects, ensuring the industry's success, thereby giving no incentive to the industry to leave the strategic path of print media. At one point in time, this eventually created a lock-in and inertia, which, in times of environmental change, complicates a strategic repositioning.

The fact that margins of other products on sale are higher than the ones on online media reflects another self-reinforcing effect that is at work here. It shows again how the dependence on resources — money in this case — can hamper the industry's ambitions and ability to change and how different self-reinforcing effects can overlap.[24]

The example illustrates one of Gilbert's main points: abstractly interpreted, resource rigidity is the inability (sometimes perhaps even a certain unwillingness) of a firm to invest in discontinuous change. The resources allocated over time can cause a lack of motivation to respond to environmental changes, which manifests itself as inertia. Clearly, grown firm resources provide stability and generate therefore no such motivation; the firm could only break the inertia at extremely high costs. This can go as far as to a certain 'blindness' of the actors with respect to their situation; as Ghemawat (1991) puts it:

> 'they frequently fail to understand, and therefore to exploit, opportunities to sustain their positions by making their own products obsolete' (164).

Of course, it must also be noted that an important byproduct of resource development within firms is experience. Organizational resources include not only physical assets, but also immaterial aspects of the firm that codetermine the organization's character, innovation profile and competitiveness. '[T]he whole technical system is greater than the sum of its parts. This knowledge constitutes both information […] and procedures.' (Leonard-Barton 1992: 113), which are immaterial resources such as experience and competences. Whenever resources are employed and used to generate strategic and competitive advantages, experience and competences play in as

[24] Path Dependence theory stresses that usually more than one self-reinforcing effect leads to lock-in, as the combination of different trajectories determine the path-creation and the point where the firm loses its strategic flexibility. At the same time, the notion of lock-in itself must rather be seen as a phase, that is terminated with the organization's loss of its strategic elbowroom, than as a concrete point in time where the path suddenly stagnates; path dependence is a 'time-based theoretical concept differentiating between different states of flexibility/choice and stability/determinism, respectively. The dynamic eventually flips over into rigidity. At their heart, such processes can be explained by one or a combination of several self-reinforcing social mechanisms.' (Sydow et al. 2009: 698; see Beyer 2005; Meyer and Schubert 2005, accordingly).

well. The dependence of a firm on its assets and resources is therefore not limited to their physical attributes but span also the experience that goes with them.

Following Gilbert, among others, the relation between experience/competences and organizational inertia merits a separate discussion. Even though competences and, more precisely, organizational routines, are an aspect of the firm's resources, they can — as it is described below — develop dynamics that determine the firm's strategies and developmental paths differently than the physical assets. Even if the firm invests in its resource portfolio to change paths (such as a switch of technology or markets), there may still be routines and competences that — born out of the resources allocated over time — narrow the leeway for organizational change.

3.1.2. Routine Rigidity

Even though resources are the major input into the production process and the basic unit of analysis of organizational innovative activities, they are only productive and create an economic value if they are coordinated and combined (Grant 1991). Firms therefore need to use, recombine and transform their resources actively and efficiently in order to generate returns on them and innovate. The literature refers to this ability of a firm to employ its resources as competence or capability.

In the literature, the two terms are often used interchangeably, referring to the same crucial organizational abilities. A major aspect of both concepts is their role as the guarantor of the firm's competitive advantage. While Grant (1991) for instance states that a firm's 'capabilities are the main source of its competitive advantage' (119), Leonard-Barton (1992) presents a definition of 'core capability as the knowledge set that distinguishes and provides a competitive advantage' (113). A more encompassing, yet similar definition is given in Freiling (2004), where a competence is the

> 'ability to sustain the coordinated deployment of assets and resources enabling the firm to reach and defend the state of competitiveness and to reach the goals' (30).

Teece et al. (1997) underline the same dynamic, systemic and holistic elements of the concept when they talk about organizational capabilities as the firm's ability of 'adapting, integrating, and reconfiguring internal and external organizational skills, resources, and functional competences' (Teece et al. 1997: 515; see also Teece and Pisano 1994). Often, the literature labels competences and capabilities also core capabilities/core competences. Prahalad and Hamel (1990) for instance outline three properties that an organizational core competence should have: it should firstly enable the firm to access a wide variety of markets; secondly, 'a core competence should make a significant contribution to the perceived customer benefits of the end product' (281) and thirdly a core competence is not easily imitable for competitors. Yet, this definition is almost congruent with that of 'ordinary' capabilities and com-

petences, which is why the differentiation can surely be ignored. As Leonard-Barton puts it,

> 'capabilities are considered core if they differentiate a company strategically. The concept is not new. Various authors have called them […] core or organizational competencies' (111).

The focus of competence-based theory on the ability of organizational competences to uphold the firm's competitiveness and ensure that the strategic goals are reached underlines the process-oriented stand that it takes. Competences are the result of the firm's ability to employ its resources to generate economic rents out of them. They are sequences of action that create efficiency through cooperation and coordination; competences are reinforced and strengthened as they are applied and shared (Prahalad and Hamel 1990: 279). This must be learned over time and through repetition; 'the aspect of repetition constitutes the "anatomy" of organizational capabilities' (Grant 1991: 122).

It is this aspect of organizational competences that is mirrored by the theory of organizational routines (see i.e. Becker 2004, 2005a, 2005b). Following Grant, an organizational competence is a routine or a group of routines, as it is the aspect of repetition and recurrence that characterizes competences, and ultimately routines. Any competence is nourished and 'operationalized' by a range of routines that are stored, codified and socialized to a degree sufficient for the reliable reproduction of organizational abilities (Freiling 2004). 'The organization itself is a huge network of routines' (Grant 1991: 122), which includes all aspects of and processes within the firm.

The literature defines routines therefore as reoccurring, collective and repetitive patterns of action (see i.e. Becker 2005b: 250; Freiling et al. 2006: 47). Nelson and Winter (1982), who have contributed significantly to the concept, define 'organizational routines' as the combination of various knowledge-based abilities of a firm which constitute together behavioral patterns or patterns of reaction that are performed regularly and are burnt into the 'organizational memory' and therefore automatically employed by all actors in the firm. As Gersick and Hackman (1990) outline, routines can be perceived as 'organizational habits' (65), that develop as a reaction to recurring questions. [25]

It is this aspect of routines that can ensure a high degree of reproducibility and stability of the organizational activities. Gersick and Hackman underline that any social system aims at developing routines in order to get work done in a predictable (and therefore stable) manner (68). Standardization of group activities necessarily facilitates activities. This underlines once again the difference between competences and routines, however at the same time, why the two need each other to maintain efficiency. While it can be thought of competences as the concrete organizational abil-

[25] The stand that Gersick and Hackman take on routines is based on the works of Barnard, Simon and Stene. For more detail, see Barnard (1976), Simon (1945) and Stene (1940).

ities and skills, routines stand for the automatisms of their employment and stress rather the aspect of repetition and organizational behavior in response to environmental stimuli.

Yet, the question is how organizational competences and routines can inhibit the change of sectors. Organizational competences and capabilities are a part and a function of the developmental paths of the firm, making organizational routines inseparable from the organizational history;

> 'choices about domains of competence are influenced by past choices. At any given point in time, firms must follow a certain trajectory or path of competence development. This path not only defines what choices are open to the firm today, but it also puts bounds around what its internal repertoire is likely to be in the future. Thus, firms, at various points in time, make long-term, quasi-irreversible commitments to certain domains of competence' (Teece et al. 1997: 515).

Of course, this does not mean that historical trajectories allow firms and industries no change whatsoever. What Teece et al., among others, rather try to express is the fact that history must not be ignored when evaluating the options of change firms have and their ability to adapt to new situations; organizational routines develop along path dependent learning processes (Piening 2011: 72; Teece at al. 1997: 523). However, as Sydow et al. (2009: 703) point out, whenever learning effects are involved, change and transformation is particularly difficult: learning effects naturally occur in specific fields of practice, only. They generate codified, but also tacit streams of knowledge. Transmitting those effects to other (new) domains is often impossible and certainly always very costly. In any case, it would force the economic actors to destroy knowledge.

Precisely in organizational routines a lot of learning is involved, which is naturally dependent from the organizational development. What firms therefore usually face, when their sectoral environment changes, is 'a gap between current environmental requirements and a corporation's core capabilities' (Leonard-Barton 1992: 118); routinized behavior regarding values, skills and managerial systems that have proven to be core capabilities and sources of competitive advantage in the past can, in the light of this new or altered environment, easily turn into rigidity and constraints to change and further innovation:

> '[o]rganizational routines shape a firm's development by engendering path dependence. Specifying the path along which organizations will develop rigidity does in itself make an important contribution to understanding the behavior of an organization. Identifying path dependence engendered by organizational routines, however, also highlights tensions between, for instance, different parts of the firm learning to do different things well; it can also lead to competence traps and other biases (March 1994) and to interferences between interdependent parts (such as departments of a firm).' (Becker et al. 2005: 778)

Yet, how do those inert forces of routines develop? A broad discussion of the relation between organizational inertia and routines can be found in the work of

Hannan and Freeman (1984). It argues that modern economies require firms to develop very high degrees of accountability and reliability and that to obtain this, firms need to create organizational structures that are highly reproducible. Two means serve them to attain high reproducibility of structure: processes of institutionalization and the establishment of standardized organizational routines.[26] Of course, institutionalization of organizational structures facilitates reproduction processes, as it 'lowers the cost of collective action by giving an organization a taken-for-granted character' (Hannan and Freeman 1984: 154), reinforcing authorities and hierarchies within the organization.

Similarly, organizational routines can function as 'source of continuity in the behavioral patterns of organizations' (Nelson and Winter 1982: 96), as they can be what Hannan and Freeman call 'organizational memory': what has been done already can, thanks to the routinized behavior, always be reproduced. Routines function as 'procedural instructions' for the fulfillment of organizational tasks (Piening 2011: 62).

> 'The vast majority of what happens within an organization can be explained by either habitual execution of well-known routines or by routinized impulse reactions to recognized stimuli' (Winter 1987: 163)

Just like in the case of firm resources, it is the trade-off between exploration and exploitation of the firm environment that routines bring about. As Gersick (2005) emphasizes, the structural embeddedness of organizational competences and the routines of their use, that develop out of them, create

> 'organizational processes that are tightly aligned with one environment and can be difficult to change because they are self-reinforcing and are not built to adapt to discontinuities' (742)

Weiss and Ilgen (1985) claim that most firms are not actively monitoring their environments, scanning markets for opportunities and innovative niches. Rather their behavior is driven by 'habitual responses to familiar situations' (57). As any firm is naturally facing known situations and circumstances more often than novel ones, an automatism develops, letting the firm respond to the situation in a routinized, almost standardized way. Over time, the firm develops a pattern of routinized behavior for each type of situation and environmental stimulus. When applied, those routinized behavioral patterns are not compared to alternative solutions; instead, the routines are applied almost 'blindly', without considering alternatives (see Gersick and Hackman 1985: 69; Weiss and Ilgen 1985: 57).[27]

[26] In fact the argument of organizational hyper-stability through structures that ensure reproducibility applies to the entire concept of organizational inertia.

[27] Weiss and Ilgen (1985) underline that this is not to say that no alternatives are considered whatsoever. Yet, if acting according to routinized patterns of behavior, firms reduce the depth of their analysis of alternative actions considerably. This reduction varies with the type of routine, the degree to which it is established and the depth of its integration in the organizational activities.

Such well-established and stability-creating structures are hard to change. In times of structural and environmental changes, those aspects of the organization inhibit processes of adaptation to the altered conditions. Hence, routines can develop their own dynamics and be a major determinant of organizational behavior. The logic of this argument is similar to that of resource dependence. Nevertheless, within the organization, it functions independently from resource rigidity, as competences and routines have their own loops of self-reinforcement. As the analysis of Gilbert (2005) implies, this is shown by the fact that in order to overcome inertia, the self-reinforcing effects that drive resource rigidity must be broken, before the effects of it can also break routine rigidity. Yet, even if technological or institutional core aspects of the firm are adapted, the according change of routines stays out, as the firm has not yet recognized the new situation and developed a response to it.

Clearly, the advantage of routinized behavior is increased efficiency; 'the more routinized a firm's activities are, the more effective it can use the capabilities employed by the routines' (Grant 1991: 122). This is obvious, as routinized responses to standard situations require the actors within the firm to think less about alternative activities and allows them to concentrate on other issues while the routinized patterns of behavior are set in motion. Ergo, the firm's resources and capabilities can be used more effectively.

The downside of it is what organizational inertia points at: routines, or 'standard operating procedures' as Weiss and Ilgen (1985) call them,

> 'unfold relatively automatically, constrain exploration and direct attention toward restricted aspects of the environment which justify routine applications of the procedure' (57).

Following Langer (1978) and Leibenstein (1978), Weiss and Ilgen argue further that firms' 'rules' of behavior tend to be guided by something between a state of full awareness of their innovation environment and one of total unconsciousness; 'people behave according to well learned "scripts" rather than on the basis of new information' (Weiss and Ilgen 1985: 57). This habituation of reacting to environmental stimuli in a certain manner only, creates what Leibenstein (1978) conceptualizes as 'inert areas' that have two major properties: first, they are difficult to change and second, they inhibit the firm from scanning its environment intensively. Clearly, this leads to a reduced 'environmental awareness' and the inability of the firm to detect environmental changes and to adapt accordingly;

> '[t]he more older, more complex, more sophisticated and more 'tested' a routine is, the more uncertainty is reduced and confidence about the correctness of the routinized decision for the known situation develops. New information, environmental scans appear decreasingly important to the actors and ultimately environmental awareness decreases accordingly'(Weiss and Ilgen 1985: 59).

Firms can become locked in their standard operations, their core capabilities. Those can thereby easily turn into core rigidities (Piening 2011: 75).

Similarly, Gersick and Hackman (1990: 69) identify major 'dysfunctional consequences' that habitual routines can cause. First, firms' performance can decrease significantly because of 'miscoding of situations' as a result of habitual routines. They argue that groups and organizations tend to see only those parts of their environments that they know already how to respond to. Consequently it can happen that organizations are faced with novel situations but are unable to categorize them as such. Instead, only the known elements of the circumstances are detected and the organization reacts with the routine designated for those stimuli. The result is that new situations that would require new types of reaction are overseen by the firm and dealt with by employing a routine not fitting the context. According to Gersick and Hackman, this problem can occur in any organizational setting. Interestingly however, they stress that this process is most prominent in firms and industries that have historically been very successful (72). Firms automatically routinize their activities if they lead to economic success (the self-reinforcing effects that carry the success accelerate this process). Starbuck and Hedberg (1977) refer to this process as 'success breeds failure': the more successfully a firm masters over time a specific recurring situation, the quicker it develops heuristics for dealing with it, the aim being to be able to reproduce the success as efficiently as possible. According to Whetton (1980), the crux of the success-breeds-failure dilemma is an increasing insensitivity of the firm towards the environment. Firms tend to just reemploy the formerly successful routines to desired the utility they got used to, even when the situation has already dramatically changed and the old routines are of no use anymore. This effect is of course particularly intense in industries that have operated under highly stable institutional or technological conditions (335; see also Weiss and Ilgen 1984: 64).

The second dysfunctional consequence of habitual routines that Gersick and Hackman identify is a tendency towards reduced innovation, or a reduced innovation potential: 'the likelihood of innovation […] may be reduced by habitual routines because the group's behavioral repertoire is not changing or expanding' (Gersick and Hackman 1990: 72). The reasoning behind this assumption is that in organizations whose activities and decision processes are highly routinized, processes of 'productive dissent and disagreement' among the agents in the organization are reduced to a level that allows no or only little creative input and change. The result can be a lack of innovative activities; instead over time, the motivation and the mechanisms for learning can decrease, reducing the organizational innovation activity.

3.1.2.1. Innovation Routines as Sources of Rigidity

Based on a discussion of the path dependence of routines and their role in innovation processes, Piening (2001) reviews the empirical evidence on organizational routines that are relevant for efficient innovation processes, emphasizing the importance of routines as dynamic capabilities of organizational renewal and consequently

of innovation.[28] Piening argues that in contrast to operating routines, dynamic routines are responsible for finding new solutions to new problems and (in the best case) adjusting the existing firm routines accordingly (67). Zollo and Winter (2002) define dynamic capabilities, which are at the basis of dynamic routines, as

> ' […] a learned and stable pattern of collective activity through which the organization systematically generates and modifies its operating routines in pursuit of improved effectiveness.' (340)

Based on the discussion of the role of dynamic routines in the innovation process of organization, Piening categorizes relevant organizational routines along four domains: search routines, routines of interaction, routines of combination and routines of diffusion (table 1).

Routine Type	Function
Search Routines	Alliances, networks, acquisitions
	Other search mechanisms (i.e. market research)
Routines of Interaction	Communication
	Coordination
	Decision making
Routines of Combination	Integration
	Learning
Routines of Diffusion	Codification of knowledge
	Knowledge and information transfer

Table 1: Categorization of innovation routines (adapted from Piening 2011: 84)

Search Routines

In the ideal case every firm possesses search routines that help scanning the environment and efficiently exploring new resources as well as exploiting and recombining the existing ones; 'the deliberative processes of the firm, those that involve searching for better ways of doing things, […] are viewed as guided by routines' (Nelson 1995: 69). Search routines ultimately determine the firm's reaction to the environment and consequently also to changes in it (Piening 2011: 86). The literature identifies concrete characteristics of search routines that can be used to measure them. One of them is market research and the careful observation of com-

[28] In contrast to dynamic routines Zollo and Winter (2002), among others, define operating routines, which are responsible for the 'operational functions of the firm' and the functionality of the everyday tasks of the firm, rather than for adaptation processes.

petitive changes. Firms who monitor the development of their market can avoid the situation of a 'Capability–Rigidity Paradox' (see Atuahene-Gima 2005) where they are unaware of new market and product opportunities and therefore unable to exploit and recombine their core capabilities for innovations:

> 'market orientation can prevent a firm from becoming operationally efficient but strategically inefficient by simultaneously engendering competence exploitation and exploration' (Atuahene-Gima 2005: 61).

Building 'knowledge-sharing routines' through alliances or networks of firms (see Dyer and Nobeoka 2000) can also function as routinized behavior triggering learning, the renewal and recombination of resources and consequently the capacity to innovate in new niches and markets. Inter-organizational knowledge transfers through alliances, for instance, can establish stable channels of knowledge diffusion, facilitating innovation (Zollo et al. 2002: 345). This can also be established by acquisitions of firms and the successful integration of their resources into the existing structures (Piening 2011: 86).

Routines of Interaction

Routines of interaction guide processes of interexchange between the actors in an organization (Piening 2011: 85). In that sense they are complementary to search routines as new knowledge acquired externally is transported into and communicated within the organization. Piening identifies three sub-categories of routines of interaction: routines of communication, of coordination and those related to decision making. As Homburg and Pflesser (2000: 451) underline, routinized informal and formal communication and coordination within organizations are crucial for efficient information flows between the players in a firm. Routines of communication direct informal information flows, while formalized coordination (i.e., regular interdisciplinary meetings of representatives of different departments) help upholding constant communication between the different specialized entities of the firm, the aim being to combine their activities to a final product or service. As Dougherty (1992) emphasizes, by analyzing the negative impact 'departmental thought worlds' and 'organizational product routines' have on a firm's ability to link technology and market opportunities, without such coordination among the members of the firm, their specialization would be trapped and unable to yield innovatory results. More concretely, communication and coordination in an organization ensure — ideally — that the channels of communication are constantly open and that all departments and hierarchical levels of the firm contribute to the exchange of information (see also Homburg and Pflesser 2000).

Decision making routines are closely related to this issue. They determine the complexity of decision making processes in an organization, as they regulate what considerations and principles of decision makers are integrated into the decision process. In other words, they are the script along which managers decide about whether

and how to approach and implement an innovation project. No organization can approach situations that require decision making without learned behavioral patterns. Otherwise, decision making would be far too time-consuming and complex. Instead, decision makers structure decision making according to established routines that reduce the possible outcomes of the process to some tested and approved alternatives. Dougherty and Hardy (1996) point out that

> '[a]n organization should have structures and processes designed to make decisions continually, to follow through on problems, and to bring new issues to the ongoing agenda.' (1123)

This comprises communication structures contributing to the decision making process about new innovation projects. Open communication and coordination (vertically and horizontally) ensure efficient decision making processes (Lichtenthaler 2004: 334).

The degree of centralization of decision structures heavily impact the dynamics of innovation of a firm too. Centralized decision making routines naturally safe costs. In contrast, decentralized, 'democratic' decision making routines ensure more openness of innovation decisions and consequently more autonomy of the individual business units when it comes to the assessment of innovation projects (see Pavitt 2002).

Routines of Combination

Following Piening (2011), routines of combination describe the processes of recombining and reusing resources for innovations. Piening breaks the concept down into routines of integration and routines of learning: the former represent the capability of combining resources form different sources to solve a problem, while the latter is concerned with the ability to learn experimentally in order to experimentally recombine existing ideas and knowledge as well as to enable new knowledge to enter the organization (86). Lichtenthaler (2009) presents a similar categorization: 'transformative learning' comprises the ability to maintain and reactivate resources for problem solving, while 'exploitative learning' is the ability to scan the environment for new knowledge and combine it with the existing knowledge (825).

Routines of combination can, for instance, manifest themselves in interdisciplinary team structures, ensuring that knowledge is exchanged and transported to the different parts of the organization on a regular basis (Piening 2011: 86). Such a process of integration makes sure that knowledge is finally available to those who need it for problem solving tasks. Learning routines on the other hand make sure that the company remains 'curious', constantly trying out new combinations of their knowledge and resources for problem solving. This includes the recognition of the need of new knowledge for future problems. Such learning routines can be institutionalized R&D activities or mechanisms that allow teams and individual employees to undertake experiments that might lead to new knowledge (Piening 2011: 86). As Zollo and

Winter (2002) underline, organizational routines that determine dynamics of innovation are necessarily the result of learning processes that the actors in an organization undergo, this is the centre of the concept of routines. Naturally, learning is crucial for ensuring constant renewal of routines and ultimately processes of internal change. Zollo and Winter (2002) emphasize the importance of learning routines as dynamic capabilities in times of change:

> 'In a relatively static environment, a single learning episode may suffice to endow an organization with operating routines that are adequate, or even a source of advantage, for an extended period. Incremental improvements can be accomplished through the tacit accumulation of experience and sporadic acts of creativity. Dynamic capabilities are unnecessary, and if developed may prove too costly to maintain. But in a context where technological, regulatory, and competitive conditions are subject to rapid change, persistence in the same operating routines quickly becomes hazardous. Systematic change efforts are needed to track the environmental change; both superiority and viability will prove transient for an organization that has no dynamic capabilities. Such capabilities must themselves be developed through learning.' (341)

Learning routines in a dynamic sense are therefore closely related to search routines, as the inflow of new knowledge into the firm must be accompanied by routines that scan the environment, unveiling new opportunities.

Routines of Diffusion

Routines of diffusion are those routines that influence the diffusion of knowledge within the firm. In contrast to routines of integration, they are less concerned with the mechanisms of integration of knowledge in the organization's segments but rather with the mechanisms that make knowledge available for all actors. As Piening (2011) argues, the likelihood of new ideas and innovations of a company increases with the accessibility of the corporate knowledge stock. Piening splits routines of diffusion further into routines of codification of knowledge and routines directed at the transfer of knowledge and information. The former can for instance be databases where the corporate knowledge is constantly collected, updated and made available to the employees. The knowledge is codified in a certain manner that all actors understand and can therefore be employed for innovation processes by everybody (87). Zollo and Winter (2002) refer to this as the third and most sophisticated level of organizational learning mechanisms (arguing that after all, every dynamic capability of the firm is a learning capability). 'Knowledge codification' enables the collected knowledge to be shared and employed repeatedly, transforming it into a 'recyclable' resource. Knowledge that is collected but not codified (in Zollo's and Winter's concept the firm then conducted the stages of experience accumulation and knowledge articulation only) is not sustainable, as it cannot be retrieved at a later point in time for new problem solutions (342).

Routines that ensure the transfer of knowledge and information among the members of the firm connect to routines of codification, as they ensure that the stocked knowledge is really distributed among all employees. Piening (2011) names two major means of distributing the knowledge: firstly, vertical information flows through newsletters or other institutionalized channels of 'education' and secondly, qualification measures for employees. Advanced training increases the receptivity of employees, contributing to their ability to employ knowledge for innovations (87).

Piening's catalogue of dynamic innovation routines provides categories for measuring routines and their influence on the dynamics of innovation of an organization It will be employed for the theoretical framework that is to guide the empirical analysis of routine rigidities. However, as the literature underlines, routines per se are never dysfunctional or underdeveloped, they always match the organizational process and the environment in which the organization operates. Yet, in times of change, the stability-generating characteristics of routines can turn into dysfunctionalities when they allow for no appropriate adaptation processes. In other words, a routine can never be a barrier to innovation on its own, but it is the context that can turn it into one.

Of course the categorization of routines is not static. In fact, innovation processes never rely on one type of routines only but rather on 'bundles of routines' of different kinds that together enable the organization to innovate (Piening 2011: 60). Clearly, efficient routines of communication for instance are insufficient for product development if the organization is unable to scan the environment for opportunities.

The concept of routine rigidity addresses all of the above categories of routines. The tendency of routinized processes to lock the firm into lethargy has been addressed in length above and applies also to the routine categories listed here. They can lock firms in to 'competence traps' and the resulting exploitation of existing resources at the cost of exploration of the environment. Similarly, routines can create the tendency to reduce decision making processes to standardized reactions to external stimuli. Established routines of communication and cooperation and hierarchical, centralized decision making processes for instance can be the reason for the absence of 'productive dissent and disagreement among the actors in an organization', that Gersick and Hackman (1990: 72) view as a major reason for routine rigidity of organizations. Search routines can be underdeveloped or narrowly applied only, so that environmental changes are overlooked by the organization. In the case of the pharmaceutical industry, dysfunctional search routines could make the industry unaware of the potential of the second healthcare market and would consequently hinder the recombination of the industry's core capabilities - namely expertise on health, fundamental research and adequate production - to explore the market. Similarly, learning routines can be dysfunctional, leading to an organizational inability to act experimentally as to approach new situations.

According to Gilbert (2005), a second level of routine rigidity exists that bestows firms in times of change with inflexibility. This second building block of routine rigidity is organizational cognition and culture.

3.1.2.2. Organizational Cognition and Culture

Gilbert (2005) argues that routinized behavior of the firm is not only a function of the learned routines but also of the deeper thinking, identity and nature of the firm. This includes the cognition and culture of the organization and influences the routinized behavior of the firm on an even deeper level than the actual routines only. Following Gilbert,

> 'the original motivation for designing an organizational routine can be separated from the people executing the routine […]. The underlying logic pervades the thinking of the organization, often manifesting as deeply ingrained cognition.' (742)

This underlines that the routinized behavior of organizations can be anchored deeply in the organizational cognition, which exists independently of the managers directing the dynamics of innovation, as a deeper layer of learned behavior. Prahalad and Bettis (1986) address this aspect of organizational inertia: among decision makers in an organization, 'a shared dominant management logic' can develop, based on a 'representation of the world' that guides 'the way in which managers conceptualize the business and make critical resource allocation decisions' (490). Those mindsets develop out of the experience the decision makers have gained over time and is coined by the core business of the firm that has historically dominated the innovation activities.

> 'The characteristics of the core business, often the source of top managers, […] tend to cause managers to define problems in certain ways and develop familiarity with, and facility in the use of, those administrative tools that are particularly useful in accomplishing the critical tasks of the core business.' (491)

In other words, decision makers in firms tend to behave according to a Weltanschauung guiding their problem-solving processes. In times of environmental change, Prahalad and Bettis argue, those learned scripts can easily turn into rigidities; 'it is difficult for a top management group to be effective in managing a new business by learning and using a new dominant logic' (492). The result is 'cognitive biases' (Prahalad and Bettis 1986) that hamper learning processes, as they limit the decision making of management:

> '[…] the psychology of cognitive biases is the study of how people in making decisions sometimes make systematic (and often severe) errors […]. When dealing with uncertain and complex tasks people often rely on a limited number of heuristic principles which greatly simplify the decision process. In general these heuristics are useful, but on some occasions they can result in significant errors.' (494)

It can therefore happen that a strategic shift of a company fails to come about even if the decision makers know of its necessity, only because the changes are incompatible with their view of the business and its innovative focus. Tripsas and Gavetti (2000) find a relation between organizational capabilities, cognition and inertia. Managerial cognition produces 'strategic beliefs' that guide the search and learning processes and ultimately the ability to develop new capabilities that would be required to adapt to environmental changes. Put differently: managerial cognition produces inertia.

The literature argues further that the shared strategic beliefs of decision makers in an organization entail 'high morality rates' that impact the inability to reorient strategically (Tripsas and Gavetti 2000: 1159). Also, Tripsas and Gavetti present evidence that organizational hierarchy plays a role in managerial cognition: within organizations, 'profound cognitive differences across hierarchical levels', as well as 'differences in cognitive adaptability across hierarchical levels' can be found (1159). Those hierarchical tensions can impact organizational inertia further.

The discussion of the relation between cognition and inertia as 'the inability to enact internal change in the face of significant external change' (Gilbert 2005: 741) is also taken up by the literature on organizational culture. Sørensen (2002) argues that 'organizational cultures reflect the imprinting of a firm's early environmental conditions and that they are subject to inertial pressures' (74). In times of environmental change, organizational culture can produce organizational inertia.

The literature provides numerous definitions of organizational culture, the broadest probably being: 'that's the way we do things around here' (see i.e. Martins and Terblanche 2003). Other define organizational cultures as 'a set of norm and values that are widely shared and strongly held throughout the organization' (O'Reilly and Chatman 1996: 166). Schein (1990) defines culture as 'what a group learns over a period of time as that group solves its problems of survival in an external environment and its problems of integral integration' (111). Schein views an organization's 'values, norms, ideologies, charters, and philosophies' (112) as central to organizational culture (see also O'Reilly 1989); firms develop a 'mission and vision' of the firm (see Martins and Terblanche 2003). Problems are evaluated and understood against this background. Such routinized behavior includes the organization's norms, values, philosophy and — more abstractly — its understanding of 'the rules of the game'. The more successful or established (old) a company is, the stronger are the shared strategic beliefs and cultural norms among decision makers (see Martins and Terblanche 2003; Teece et al. 1994; March 1991).

Consequently, Sørensen (2002) argues that the stronger organizational culture is, the stronger are the tendencies that inhibit the adaption of organizational activities to environmental changes, the reason being that strong shared norms, values and beliefs make actors struggle with realizing the need to change.

> 'Because members of strong-culture organizations have a greater commitment to a particular understanding of the world than weak culture organizations, they may be slower to detect fundamental changes in environmental conditions.' (Sørensen 2002: 76)

Sørensen works out a relation between organizational inertia and the corporate culture, arguing that strong cultures affect organizational learning processes negatively, which impacts the ability of the firm to adapt its routines to changing environmental conditions. 'Strong-culture organizations will, in general, be ill-suited to exploratory learning' (76), as they tend to exploit the world along their cultural understanding of it. Yet, it is precisely the quality of exploratory learning processes in an organization — 'the nature of change in organizational routines in response to experience' (74) — that ensures innovation and performance reliability in times of change.

Of course culture and cognition can enhance organizational creativity (through the cultural support of internal and external communication and search routines, for instance), yet it can also hinder the emergence of creative problem-solving approaches. Total creativity is never possible, as even the simplest form of institutionalized innovation involves physical assets and support mechanisms that automatically direct the organizational culture in one direction instead of the other. Routinized cultural behavior automatically developing on top of that only reinforces the limits to creativity of innovation. Concretely, Terblanche and Martins (2002) name the organizational vision and mission and the resulting feeling for 'purposefulness' of certain innovations emergent from this as major determinants of the creativity of innovations (69). Depending on the organizational mission, different degrees of flexibility and support enter the routinized approach towards innovations. They determine the way in which ideas are generated and, most importantly, change is handled.

Hence, the values, norms and beliefs of an organization, converging into an 'organizational code of received truth' (March 1991: 74), are conceptualized as underlying deep structure of organizational routines. The dynamics of organizational culture and routines are, however, closely related. One affects the other, as routines are

> 'the forms, rules, procedures, conventions, strategies, and technologies around which organizations are constructed and through which they operate. It also includes the structure of beliefs, frameworks, paradigms, codes, cultures and knowledge that buttress, elaborate, and contradict the formal routine.' (Levitt and March 1988: 320)

Search and learning processes and the corresponding routines that are crucial for innovation can only be effective if they are supported by a matching organizational culture and a set of strategic beliefs among decision makers; 'routine behavior, norms, values, philosophy, rules of the game and feelings all form part of organizational culture.' (Martins and Terblanche 2003: 65). Organizational creativity with respect to problem-solving is highly dependent on the willingness of a company to

learn, which in turn is affected by culturally perceived 'purposefulness' of ideas (Martins and Terblanche 2003).

Schein (1990) presents a three-level model of analyzing organizational culture, He argues that at the first level, organizational culture manifests itself in 'observable artifacts'. Those artefacts are

> 'everything from the physical layout […] to the more permanent archival manifestations such as company records, products, statements of philosophy, and annual reports.' (111)

Schein argues that artefacts provide the researcher first indicators of the culture of the organization.[29] Organizational values — 'norms, ideologies, charters, and philosophies' (Schein 1990: 112) — are identified by Schein as the second level of organizational culture. He argues that it is ultimately the values of an organization that determine why things are handled in one way instead of the other. Lastly, the third level of culture is 'basic underlying assumptions' that direct the behavior of the firm. The assumptions of decision makers in the organization are reflected by 'perceptions, thought processes, feelings, and behavior' (112) of the agents in the firm, guiding their actions.[30] They constitute the cognitive reality of the firm and can contribute to organizational inertia.

3.2. Organizational Inertia and Path Dependence

The concept of organizational inertia is in some respects closely related to the theory of path dependence and was mentioned implicitly on some occasions in the preceding discussion. A short discussion of the similarities and differences is therefore needed.

David (1985) describes path dependence as a process where an inferior technology in use cannot be removed from its place because of certain lock-ins that make it extremely hard if not impossible to switch to another technology or even to move back to the beginning of the search process for a technological solution to a given problem.[31] Similarly to organizational inertia, the concept aims at explaining why during dynamic processes of development sub-optimal solutions may be chosen by firms. Path-dependent processes can be characterized by (a) sub-optimality of solutions, as alternative paths could have lead to a more advantageous development, (b)

[29] However, Schein underlines that organizational artefacts are relatively weak indicators for culture as their meaning depends significantly on how they are recognized and evaluated by the researcher; 'one of the flaws of studying organizational symbols, stories, myths, and other such artifacts is that we may make incorrect inferences from them if we do not know how they connect to the underlying assumptions.' (112). Also, evaluating an artefact isolated from the impact it has on the employees and the cultural meaning they see it can lead to false conclusions.

[30] Schein emphasizes that the assumptions of decision makers in the company represent the highest level of culture and that the issue is usually best approached through intensive observation of members of the company.

[31] Observations of economic history (i.e., David 2000; David 1992) constitute the birth of the concept of path dependence. The example of QWERTY (David 1985) has shown that inferior technologies can succeed in the market, even in case better alternatives are available.

inflexibility of the firm due to lock-ins, and (c) ex ante unpredictability (see Arthur 1989; Bassanini and Dosi 1999; Sydow et al. 2009).

The key element in the reasoning of path dependence is the assumption that 'history matters' (see i.e. Bassanini and Dosi 1999; David 2000, 1992, 1985; Koch 2009; Teece et al. 1994; Thelen 1999). No development process is a priori predetermined. Yet, over time the circumstances under which a firm develops (more abstractly called 'history') have an impact on the direction that the evolution takes, pressing agents into developmental paths. Logic suggests, quite simply, that another history than the one that took place would always have led to different developments.[32]

The development of a path is carried by increasing returns.[33] Their presence determines whether a decision taken by an organization leads to the formation of paths (Sydow et al. 2009); decisions that have no recurring positive effect on the organization are unable to shape the firm's developmental path. Those returns are self-reinforcing effects and positive feedbacks that occur during the development of a firm as a response to its actions.[34] In other words, firms

> 'are drawn into the neighbourhoods of one or another of several possible "attractors" [which equal increasing returns - A/N], selections among the latter being made, typically, by the persisting consequences of some aleatory and transient conditions that prevailed early in the history of the process' (David 1994: 208).

The process of path-creation and the emergence of path-dependency can roughly be divided into three phases (see i.e. Koch 2009; Sydow et al. 2009). During Phase I - the 'Preformation Phase' - a firm usually follows an erratic, undirected processes of development where in general any direction can still be taken and no patterns of behavior are yet established. However, during this phase some decisions are always made, setting off self-reinforcing effects (see Sydow et al. 2009: 691). The literature refers to this as the 'critical juncture': an historic event, followed by the first occurrence of some kind of increasing returns. Usually more than one of the

[32] Teece et al. (1992) bring this well down to the point: 'a firm's previous investments and its repertoire of routines (its 'history') constraints its future behavior. This follows because learning tends to be local. That is, opportunities for successful new developments will be 'close in' to previous activities [...]' (17).

[33] Self-reinforcing effects describe 'processes with increasing benefits', where the increase of a variable is repetitively rewarded by a further increase of the same variable eventually leading to an increasing irreversibility of actions, particularly when the investments and risks or the success that the decisions yield are very high (Sydow et al. 2009).

[34] There are several types of self-reinforcing effects and positive feedbacks that can be sources of increasing returns affecting the path-development. In the technological domain this can be (a) returns to scale and experience, (b) direct and indirect network externalities, or (c) learning processes of consumers; with respect to institutions the literature identifies (d) institutional learning, (e) effects of institutional coordination and (f) effects of institutional complementarities; also, (g) expectations and the corresponding behavior — with respect to technologies and institutions — can be the source of increasing returns (Koch 2009). However, as Sydow et al. (2009) argue, this rather technological view of path dependence captures reality only insufficiently. According to an institutional and organizational perspective on path dependence, 'soft' forces, such as (h) emotional reactions like uncertainty avoidance, (i) cognitive biases like selective perception or (j) political motivations can also have a great effect on firm activities, thereby contributing to the emergence of paths. Consequently, not only 'changes in the public knowledge base' (Teece et al. 1992: 21) that create increasing returns are responsible for the eventual lock-in.

forces described above act simultaneously and it may be rather 'small events' (Arthur 1989) whose occurrence cannot be anticipated by the actors (therefore the reminiscence to history as the driving dynamic);

> 'increasing returns can cause the economy gradually to lock itself in to an outcome not necessarily superior to alternatives, not easily altered, and not entirely predictable in advance' (Arthur 1989: 128).

Once self-reinforcing effects start to be present, in Phase II ('Formation Phase' (Sydow et al. 2009: 691)) the dynamics of the reinforcing effects start to kick in. Certain action patterns develop, which causes the available potions to narrow down and to make the firm's actions increasingly irreversible. This is simply, as over time, one pattern becomes just more probable/higher frequented than another (i.e., certain institutional standards start to prevail). Out of this, routines, habits and patterns of behavior develop in the firm, that are replicated and integrated. Yet, this is still not deterministic. Despite the increasing returns that start to sketch a path, decision processes have still not converged to one irreversible pattern of behavior (David 1992: 184).

Yet eventually it comes to a 'lock-in', which is the moment where some technology, habit or rule has come out on top, so that the firm's search process is ended. Decision patterns that were rewarded by increasing returns in Phase II become now deterministic and more or less irreversible. At that point the path is determined and the firm enters Phase III ('Lock in Phase'), which is the further development along the predetermined route. David (2000) describes the phenomenon of lock-ins as

> 'the entry of a system into a trapping region — the basin of attraction that surrounds a locally (or globally) stable equilibrium. When a dynamic economic system enters such a region, it cannot escape except through the intervention of some external force, or shock, that alters its configuration or transforms the underlying structural relationships among the agents. Path dependent systems — which have a multiplicity of possible equilibria among which event-contingent selections can occur — may thus become locked in to attractors that are optimal, or that are just as good as any others in the feasible set, or that take paths leading to places everyone would wish to have been able to avoid, once they have arrived there.' (10).

In deed, once a firm is locked into a pattern of behavior it is very hard to escape from it. Monopolistic market structures for example, that can emerge as the result of path dependence are often almost impossible to overcome for economic players and even new ones must obey to the conditions that have emerged over time. Similarly, in other situations switching costs and sunk costs that have accumulated

over time can be just too high to be ignored for the sake of a new strategic direction. In such cases, developmental paths have a deterministic nature.[35]

The theories of path dependence and inertia are somewhat similar, as both create a link between the conditions of firms' innovation activities and the resulting organizational structures. While organizations develop along trajectories, certain developmental paths can emerge that eventually lead to a lock-in. The lock-in equals an inert organizational structure and an inability of firms to conduct radical changes when confronted with environmental transformation or even threats. Self-reinforcing feedback mechanisms play a role in both perceptions of organizational development, as without them the firm would be able to break out of the status quo easily.

The theories of path dependence and inertia describe the same problematic, yet they focus on different aspects of it. While path dependence theory emphasizes the process by which the organization's innovation environment can over time shape the strategic paths of the firm and limit its 'elbowroom' with respect to its innovations (i.e. through 'historic events', such as the rule of certain regulatory regimes or market restrictions), the concept of inertia assumes an automatic process of organizational adaptation to the external environment conditions and puts the processes' results at the centre of the analysis. Organizational inertia assumes that with growing size and age, a firm adapts increasingly to the conditions under which it operates, as to hold up stability and reproducibility of its structure and innovation activities. Once the firm faces external changes, however, stability can turn into rigidity and inertia. The argument of the theory of inertia implies that the firm has no other choice but to adapt to the systemic conditions if it wants to benefit from self-reinforcing effects and survive. Inertia is therefore the natural result of organizational evolution and is present in any firm. Yet, it can vary, as different innovation systems show different degrees of turbulence to which the firms have to adapt and differ with respect to the strength and complexity of networks that limit the firms' strategic leeway.

Sydow et al. (2009) argue that despite the relatedness of the concepts of organizational path dependence and inertia, organizational inertia is meant to be an almost natural byproduct of firm development. They interpret it as a must for the success of the firm, as otherwise adaptation to the environment (and consequently survival and success) would be impossible;

[35] Yet, from a more organizational standpoint it can be argued that some limited 'scope for variation' (Sydow et al. 2009: 690) always persists, that lock-ins represent often only a quasi-immobility of firms. This argument holds since after all organizations are social entities that are, even if they are locked into a path, able to interpret that path, whereby they can gain some variation of action to change and can never live up to a state of full determinacy. Sydow et al. (2009) therefore propose to think of the path a firm is locked into rather as a 'corridor' that reduces the options of actions drastically while leaving some space for variation to the 'knowledgable agent'. Yet, even though this is true in theory it is not to say that firms are always able to mobilize the remaining threshold of section for breaking out of their path.

> ‘structural inertia — the hyper-stability of organizational arrangements in spite of environmental change — is a universal organizational feature that develops in the course of structuring the organization. Routinizing and institutionalizing organizational activities are seen as imperative in order to guarantee stakeholders reliability, accountability, and, finally, survival in competitive environments. Inertia is considered a precondition for effective organizational acting but, paradoxically enough, eventually threatens the organization's survival, because it is likely to bring about a mismatch with changing environmental conditions‘ (697).

The authors argue further that the presence and intensity of path dependence is more conditioned, as not all firms and industries necessarily develop the same path-dependent trajectories, if any.

This deterministic interpretation of organizational inertia, however, seems misleading, as in comparison, firms (and industries) show neither the same degrees of path dependence nor of organizational inertia. Yet they all have — according to both theoretical schools — the tendency, to develop towards increasing ‘congruence’ between the organizational behavior and the external innovation conditions.

In the end both approaches come to the same conclusion, namely that firms can have trouble to adapt to changing environments because over time structures have grown that turn out to be sub-optimal for dealing with the new conditions. Routines and resources creating inertia are naturally the product of the organizational path of development and are held together by self-reinforcing effects, which makes the ides of path dependence and inertia inseparable

However, there are substantial differences: path dependence theory argues that historic events set into motion loops of such self-reinforcing mechanisms that drive the firm into irreversible developmental paths. This process is not automatic and does not take place in all firms and to the same degree (Sydow et al. 2009: 690). Organizational inertia, on the other hand, assumes the almost natural presence of self-reinforcing effects that grow out of the adaptation of the organizational structures to the environmental conditions; self-reinforcing effects and positive feedback mechanisms hold up inertia. The organization survives by stability, reliability and the institutionalization of its actions, which naturally limits flexibility (Sydow et al. 2009: 697). The result is a state of stability and reproducible success, yet at the expense of organizational flexibility. – As soon as it comes to changes in the environment, organizational change is hard and might even be impossible in the short and medium run. At the basis of both logics is the idea of paths as ‘learning ranges’ (see Teece et al. 1997), even though it is interpreted differently.

A distinctive feature of organizational inertia is the fact that it focuses not on the process that leads to organizational lock-in, but more on the lock-in per se, when it comes to environmental change. As Sydow et al. (2009) put it:

> ‘[p]ath dependence, however, is supposed to mean more than the mere existence of timeworn routines, cognitive rigidities, or structural inertia. It is, first of all, a process. Its distinguishing features need elaboration.’ (Sydow et al. 2009: 690)

In fact, the model of resource rigidity and routine rigidity presented above highlights that difference. Gilbert's (2005) model is not concerned with the path an organization took to inertia, but rather focuses on the phase after the lock-on; the emphasis lies on unveiling the dynamics that generate hyper-stability, when change occurs. The theory conceptualizes 'history' as the environmental conditions under which the firm has simply learned to operate efficiently. The analytical focus lies on understanding the moment after the lock-in, when the organization faces environmental pressure to change. This is precisely what is of interest to this research, as the aim is to understand the systemic dynamics that hold the pharmaceutical industry in its position. The concept of organizational inertia focuses on the formative impact that the organizational environment naturally has on the firm. Inertia is not interested in the process by which an organization became what it is, analyzing the forces impacting its direction of development. In contrast, path dependence is a process-analysis of 'singular historical events' and 'avalanchelike processes' leading to lock-in (Sydow 2009: 697).

3.3. Translation into a Framework for Empirical Analysis

For the aim of this research the concept of incumbent inertia discussed above must be reflected in the empirical analysis to follow. In order to understand the situation we find the pharmaceutical industry in, the analysis aims at unveiling the inert structures that function as obstacles to organizational advancement. This segment functions as a transition between the theoretical discussion and the empirical analysis. The goal is to integrate the theoretical findings into a conceptual framework, allowing to explore the reasons for the behavior of the pharmaceutical industry. The conceptual framework is to function as a basis to mirror reality; it allows to give empirical answers to the basic research question with which this work has set out.

In order to create a bridge between the theoretical discussion and the empirical analysis, the research questions and their evolution during the discussion are shortly revisited (figure 7). The discussion started out with the principal research question:

> *What industrial dynamics are responsible for the weak commitment of the pharmaceutical industry to the extended healthcare market?*

To approach the basic research question, it was subdivided into three streams of theoretical analysis, representing the three subquestions to the main research question. The first one was represented by subquestion 1:

> *What guides the dynamics of innovation of the pharmaceutical industry?*

In order to prepare the ground for answering that question, the literature on sectoral systems of innovation was selected as the theoretical approach. The theoretical

foundations, elements and dynamics of the sectoral systems of innovation approach were discussed, aiming at laying out the basic logic according to which industrial dynamics of innovation function. Based on a short discussion of the theoretical groundings of the sectoral systems of innovation theory, the basic building blocks of sectoral innovation systems and their patterns of interaction were presented. Very high degrees of interaction between systemic players as well as evolutionary patterns of system growth turned out to be main characteristics of the sectoral approach to industrial innovation activities.

Based on those insights, the discussion subsequently turned towards the second stream of analysis: theoretical concepts of patterns of change and the potential limits to industrial innovation activities. This was first approached by subquestion 2, aiming at clarifying the literature's stand towards the limits and boundaries that might be affect the situation of the pharmaceutical industry:

> *What imposes limits to the innovation activities of the pharmaceutical industry?*

Subquestion 2 discussed the standpoint of the sectoral systems of innovation literature towards sectoral boundaries and change. It became clear that the sectoral systems of innovation approach conceptualizes sectoral change as omnipotent and omnipresent. As the literature points out, sectoral boundaries are never fixed or static and sectoral change can therefore occur. Co-evolutionary relations between the system elements are therefore thought be responsible for chains of change, once a system element alters.

This part of the discussion unveiled an obvious weakness of the sectoral systems of innovation approach: sectoral boundaries are said to be present in any industry (no firm or industry can be free of boundaries, of course); yet at the same time the logic of the concept implies that sectors are almost automatically transmitting any environmental change and can therefore adapt to new innovation conditions. As the situation of the pharmaceutical industry at hand signals that such automatisms are not necessarily present, the discussion merited a deeper discussion of boundaries to industrial innovation. Subquestion 3 dealt therefore with the limits to sectoral change that can — despite the co-evolutionary processes that coin sectoral systems of innovation in the very long run — make the adaptation to changed environmental conditions impossible:

> *Under what conditions can the industrial boundaries not be overcome?*

The discussion related to subquestion 3 pointed to organizational inertia and rigidity, making organizational change and reorientation nearly impossible. It was discussed what dynamics can inhibit an industry from adapting its innovation activities to a changed innovation environment. It came to the conclusion that the sectoral systems

of innovation approach alone might grasp reality only partially and that instead, the interrelation between industries and their innovation environment may produce inert organizational structures, characterized by (hyper-)stability rather than flexibility.

Against this background the initial research question must be reformulated; it must incorporate the findings from the theoretical discussion in order to provide the basis for the empirical analysis to follow:

> *In how far does inertia present in the pharmaceutical industry hinder the sectoral firms from extending their boundaries and adapt their innovation activities further to the extended healthcare market?*

This restated principal research question reflects the evolution that the theoretical discussion experienced. It incorporates the different streams of theory — the sectoral systems of innovation approach on the one hand and the theory of inertia on the other — brought together during the theoretical discussion in order to approach an explanation for the situation at hand.

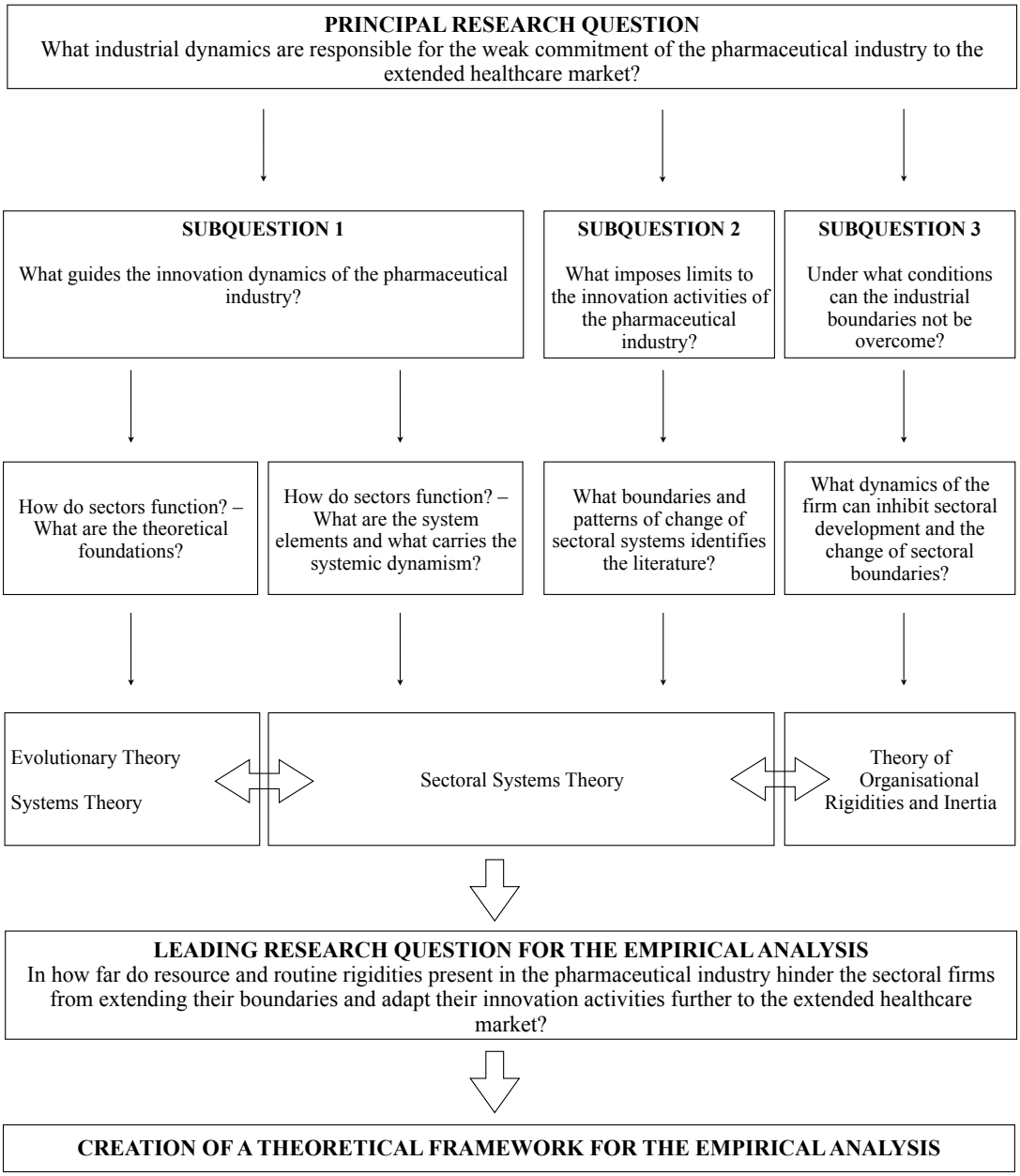

Figure 7: Evolution of the basic research question (own illustration)

This new perspective onto the basic research question must enter the conceptual framework guiding the empirical analysis. The direction and methods of research are to be defined. The framework must be able to unveil dependences and lock-ins of the pharmaceutical industry that are — despite the high degree of interaction and evolutionary dynamics present in the system — responsible for industrial inertia. After all, it is the goal of the empirical analysis to test whether a sectoral system of innovation can be stuck in a status-quo that retards reorientation or change; the aim is to visualize how the systemic conditions under which the pharmaceutical industry operates have created rigidities responsible for the situation at hand. The question comes up how to operationalize this leading research question for the empirical analysis.

For that purpose, the theories of sectoral systems of innovation and incumbent inertia are combined in order to create a framework allowing to measure barriers to sectoral change. The discussion of sectoral systems of innovation showed that the notion of rigidity is present in the model only implicitly and that it is of importance for explaining sectoral behavior under pressure to change. The theory of organizational inertia can complement the sectoral systems of innovation approach at this point, providing a theoretical basis for explaining the behavior of the pharmaceutical industry in Germany.

The conceptual integration of the idea of organizational inertia into the sectoral systems of innovation theory is possible as the theory of organizational inertia reflects the dynamics of sectoral systems of innovation. The sectoral innovation literature conceptualizes innovation systems as networks of actors, with the firm (as the innovating organ) at its centre. Systemic innovation activities are on the one hand determined by the interactions between the system players, as they are creating the sector-specific 'ecosystem', to which the firm adapts its innovation activities. On the other hand, the firm itself impacts the system dynamics through its internal characteristics. Organizational competences, routines and behavior impact the innovation activities of the firm and consequently of the entire system. Sectoral systems of innovation theory highlights the strength of the interdependences between the firms and the larger system; the nature of the dynamics and the dialogue between the firm and its systemic environment impacts and coins the dynamics of innovation of the system.

When searching for organizational inertia, it is therefore necessary to concentrate on the firm as the major source of rigidities to change. At the same time the firm must not be analyzed separately from its systemic environment as the another source of rigidity, supplanting the firm-internal inert structures.

Gilbert's (2005) concept of incumbent inertia addresses organizational rigidities along those two levels of analysis and is therefore applicable to the analysis of sectoral dynamics of innovation. Being initially conceptualized for firm-level analyses, its concern for the firm-external environment allows it to be applied to the sectoral analysis. Resource dependence addresses rigidity flowing from the relations between the firm and the systemic environment: firms develop dependences on external resource providers who deliver the key resources for innovations. In times of environmental changes, those dependences hamper the firm's adaptability, producing inertia. The second aspect of resource rigidity — the presence and nature of incumbent reinvestment incentives — relates to the firm's market power, the firm-internal resource compositions grown accordingly and the attempt to preserve this position. A strong market position can create a lack of incumbent reinvestment incentives, leading to inertia. The aspect addresses the firm-internal aspects of resource rigidity mostly. Firms are more likely to exploit their current strengths than to build up new resources and capabilities. This remains the case even in times of environmental

change. Yet, the market power is also a product of the firm-external environment, addressing the rigidities flowing from it. As figure 8 illustrates, the aspect of incumbent reinvestment activities is therefore positioned in between firm-external and -firm-internal sources of inertia.

In contrast, routine rigidity addresses firm-internal rigidities only. Firm routines can cause inflexibility as they are closely attached to an existing environment and hamper the firm's ability to change and explore discontinuities. The second aspect of routine rigidity targets managerial cognition and values that members of a firm share and that rigidifies firm routines independently from the managers executing them. This represents the second layer of routine rigidity.

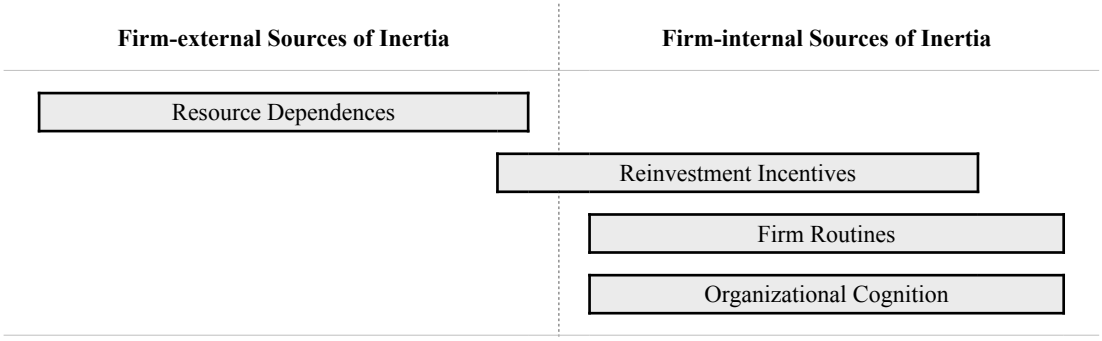

Figure 8: Resource and routine rigidities from the sectoral perspective (own illustration)

As the theoretical analysis has shown, regarding their dynamics and overcoming, routine rigidities and resource rigidities function independently from each other. However, they are at the same time connected: all four aspects of incumbent inertia are mutually highly dependent and causally interwoven. The distinction between firm-external and firm-internal sources of inertia can therefore sometimes be difficult, as for example, the resource dependences of the firm co-determine its organizational routines, which in turn themselves impact the firm's ability to answer to resource dependences. Nevertheless the theoretical differentiation is important here as it allows the influences of the sectoral system of innovation to enter into the firm analysis.

The empirical analysis must therefore answer to four specific subquestions to the general research question guiding the empirical analysis. They emerge out of the discussion of incumbent inertia in relation to sectoral systems of innovation. The analysis of inertia in the pharmaceutical industry to follow is structured along those four questions.

1. In how far is resource dependence affecting the dynamics of innovation of the pharmaceutical industry regarding the health products market?
2. In how far is a lack of incumbent reinvestment incentives affecting the dynamics of innovation of the pharmaceutical industry regarding the health products market?

3. In how far are organizational routines affecting the dynamics of innovation of the pharmaceutical industry regarding the health products market?
4. In how far are organizational cognition and culture affecting the dynamics of innovation of the pharmaceutical industry regarding the health products market?

The concept of incumbent inertia, applied to the sectoral level and addressed in four phases, constitutes therefore the theoretical framework for the analysis of the pharmaceutical industry in terms of its dynamics of innovation and the barriers to change that they might entail (see figure 9). It provides the categories needed for empirically addressing the four subquestions to the general research question, laying the basis for putting the research into action.

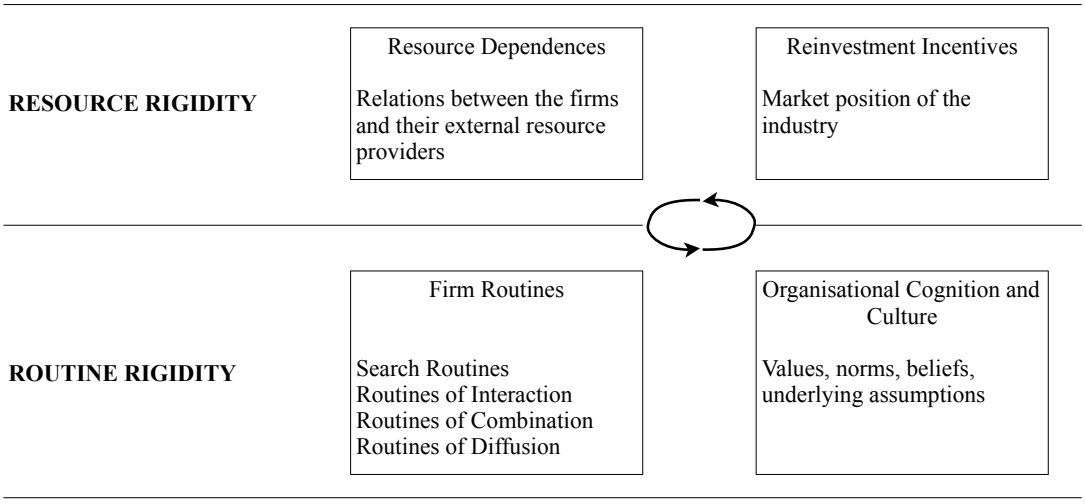

Figure 9: Theoretical framework for the empirical analysis (own illustration)

4. Study Design: A multi-methodological Approach

The study is to address the four aspects of incumbent inertia, aiming at drawing a picture of the sectoral dynamics of the pharmaceutical industry that determine the industrial behavior towards health products. Due to different types and amounts of data on the four aspects of inertia, a study design comprising multiple methods has been selected, which is described hereafter.

4.1. Justification of the selected Research Strategy

As indicated already, the aim is to shed light onto the inability of sectors to naturally follow virtuous circles of evolutionary development, adapting their dynamics of innovation to changes in their environment. The situation of the pharmaceutical industry and the rapidly growing second healthcare market suggests that the automatism the literature claims sectors to have is dysfunctional or absent. One would assume that if it worked as conceptualized in theory, the industry would alter its dynamics of innovation and get involved into the market for health products by either adapting its OTC business to the new market or by intensifying the innovation efforts regarding health products.

So far, the literature has failed to address this issue directly. Literature on the pharmaceutical industry, the markets and the systemic interrelations and regulatory regimes exists, yet it focuses on the traditional pharmaceutical innovations, ignoring the dynamics of innovation of the pharmaceutical industry in the extended healthcare market as well as the more general issue of innovative and strategic change towards non-pharmaceuticals. The issue of organizational routines in the pharmaceutical industry is not covered, neither on a general level, nor regarding rigidity and change. No literature exists yet that puts health products in the larger context of the pharmaceutical industry, relating the industrial innovation activities in the field to the overall dynamics of innovation.

The research employs three data sources: the literature, quantitative market and industry data and qualitative case studies. This approach allows to make use of the information on the pharmaceutical industry that is (indirectly) already available through the literature, while it also generates primary data where necessary. This is the case for routines, which are approached through interviews in the context of a qualitative case study.

The research consists of two major phases: the analysis of resource rigidities and that of routine rigidities to be found in the pharmaceutical industry. Both phases are divided along the theory of inertia, representing the four specific research questions that were identified above and are guiding the analysis. Even though they are highly interconnected, the phases are driven by different research methods: the exploratory literature review and the analysis of quantitative market and industry data mainly serve the analysis of resource dependences, while the case study interviews

aim at unveiling rigidities from organizational routines and cognition in pharmaceutical firms.

The usage of multiple methods for approaching a research problem whose facts are researched to different degrees already is justified in the literature. Edmondson and McManus (2007) comment on methods of 'developing sensible connections to prior work' that address a research problem, arguing that

> 'when a topic of interest has been studied extensively, researchers can use prior literature to identify critical independent, dependent, and control variables and to explain general mechanisms underlying the phenomenon. Leveraging prior work allows a new study to address issues that refine the field's knowledge, such as identifying moderators or mediators that affect a documented casual relationship.' (1159)

Further, Edmondson and McManus present a concept of 'methodological fit' for different stages of research. They categorize the 'state of prior theory and research' along three stages — nascent, intermediate and mature — and suggest research methods for each of those stages. The methodological approach to a research problem is therefore dependent on the characteristics of the topic (table 2). Leonard-Barton (1990) argues similarly that '[t]he phenomenon being researched always dictates to some extent the terms of its own dissection and exploration' (249). Flyvbjerg (2006: 242) also points out that the methodological approach to answering a research question is to be determined by the research problem itself, rather than by merely theoretical considerations; every research problem needs its individual methodological approach.

State or Prior Theory and Research	Nascent	Intermediate	Mature
Research questions	Open-ended inquiry about a phenomenon of interest	Proposed relationships between new and established constructs	Focused questions and/or hypotheses relating existing constructs
Type of data collected	Qualitative, initially open-ended date that need to be interpreted for meaning	Hybrid (both qualitative and quantitative)	Quantitative data; focused measures where extent or amount is meaningful
Illustrative methods for collecting data	Interviews; observations; obtaining documents or other material from field studies relevant to the phenomena of interest	Interviews; observations; surveys; obtaining material from field sites relevant tot he phenomena of interest	Surveys; interviews or observations designed to be systematically coded and quantifies; obtaining data from field sites that measure the extent or amount of salient constructs
Constructs and measures	Typically new constructs, few formal measures	Typically one or more new constructs and/or new measures	Typically relying heavily on existing constructs and measures
Goal of data analysis	Pattern identification	Preliminary or exploratory testing of new propositions and/or new constructs	Formal hypothesis testing
Data analysis methods	Thematic content analysis coding for evidence of constructs	Content analysis, exploratory statistics, and preliminary tests	Statistical inference, standard statistical analyses
Theoretical contribution	A suggestive theory, often an invitation for further work on the issue or set of issues opened up by the study	A provisional theory, often one that integrates previously separate bodies of work	A supported theory that may add specificity, new mechanisms, or new boundaries to existing theories

Table 2: Archetypes of methodological fit in field research (Edmondson and McManus 2007: 1160)

The general state of research on the dynamics of innovation of the pharmaceutical industry can — following the logic of Edmondson and McManus — therefore be categorized as 'intermediate'. Even though the existing literature on the pharmaceutical industry analyses the industry from a static standpoint, ignoring dynamics of change and adaptation as well as the pressure from the extended healthcare market, it contributes (indirectly) to understanding inertia, as it discloses the general systemic dynamics. An exploratory analysis of the literature can unveil new relations between the industrial dynamics, inertia and the systemic dimension.

As Edmondson and McManus indicate, research in context of an intermediate overall state of research on the topic may require the use of a hybrid tool of data collection, including qualitative and quantitative material. The exploratory literature analysis is therefore extended and supplanted by the evaluation of quantitative market and industry data, provided to the author by German pharmaceutical associations[36] and IMS Health, a leading market research institute.

Finally, the state of the research on routine rigidities in the pharmaceutical industry can be called 'nascent', which is why — in accordance with table 2 — semi-

[36] These are the Bundesverband der Arzneimittelhersteller (BAH) and the Bundesverband der Pharmazeutischen Industrie (BPI), two of the three major German associations of the pharmaceutical industry.

structured expert interviews are conducted, as to explore the presence of organizational routines that produce rigidities. The aim is the identification of cross-company routine patterns that help generating theory.

The multiple method approach to the empirical study question reflects the current state of research on innovation activities at the boundaries of the action scope of the pharmaceutical industry. Yet, besides this pragmatic aspect, the approach bestows the study with a sufficient degree of triangulation of data collection and analysis. Triangulation in general is the combination of methods for the analysis of a phenomenon. This requires looking at a research topic from different perspectives, through different data sources and/or theories and methods (Flick 2010: 280). The theoretical framework for this analysis already lays the basis for the multi-method approach. While the analysis of the regulatory and market conditions requires a context analysis, the study of routine rigidities demands a deeper look inside the organizational structures. Qualitative studies provide complex descriptions of and explanations for human actions and their context (Miles & Huberman 1984: 15; see also Hoffmeyer-Zlotnik 1992) and are therefore an attractive tool for unveiling organizational routines. Based on the close interrelatedness of the aspects examined, the methodological triangulation allows to undertake an analysis 'of contexts and action in changing' (Pettigrew et al. 2001: 709) where a high validity of data-interpretation is ensured. A systematic triangulation of perspectives thereby helps obtaining valid interpretations of qualitative data (Flick 1992: 16).

4.2. Phases of the Study

The empirical study is structured along two phases that address the four specific research question successively (figure 10). First, resource dependences are addressed, aiming at unveiling the 'external constraint and control of organizational behavior' (Pfeffer and Salancik 1978: 43) that the system components can exercise and that can lead to inertia when changes occur. This is followed by the analysis of the market position of the industry, searching for a potential lack of incumbent reinvestment incentives. The second phase consists of the analysis of routine rigidity (addressing research questions 3 and 4). The phases of the analysis are highly interactive and sometimes overlapping; they are characterized by iterative processes of theory generation (see Eisenhardt 1989).

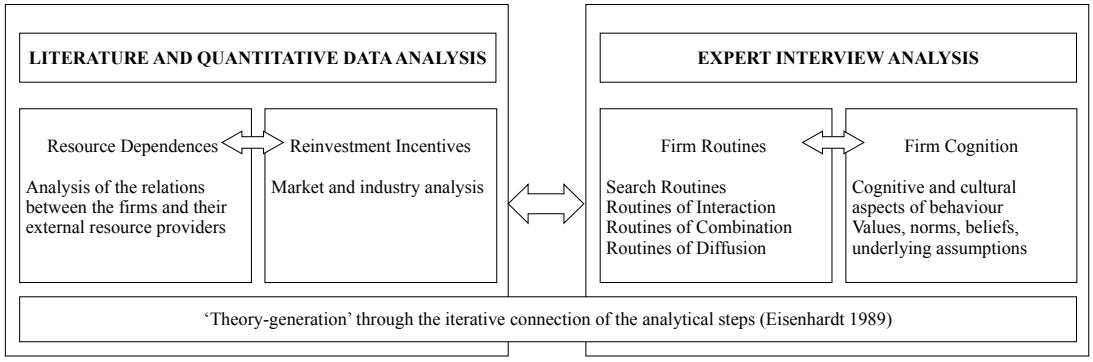

Figure 10: Phases of the study (own illustration)

Even though the research is targeted at industrial inertia with respect to health products and the extended healthcare market, the analysis considers the pharmaceuticals and non-pharmaceuticals departments of the pharmaceutical industry across all phases. The picture of the industry dynamics — and consequently the evidence of inertia deducted from it — would be incomplete without the evaluation of the industrial dynamics of innovation regarding pharmaceuticals. As the analysis is to show, the innovation activities of the pharmaceutical industry are dominated by pharmaceuticals, while non-pharmaceuticals play a minor role only. This affects the dynamics of innovation significantly, as the dynamics and rigidities that determine the direction of pharmaceutical innovations impact the behavior in relation to health products. The search for inertia must therefore consider the entire industry and all fields of activity. In the following passages the methods of data collection and evaluation are described in more detail.

4.3. Data Collection and Evaluation

4.3.1. Limitations of the Analysis

As discussed earlier, according to the theory of sectoral systems of innovation, sectoral analyses naturally need to work with pre-determined geographic and industrial limits, as to allow the analysis to focus on the aspect of the sectoral system of interest. As Malerba (2002: 260) suggests, those limits are necessary in some cases in order to make the analysis feasible. Imposing limits on the analysis regarding the geography of the sector and the focus on certain players in the system accounts for the fact that sectoral systems of innovation are a priori unlimited by national or industrial boundaries; they can span over numerous countries and industrial (sub-)branches. With respect to the geographic size of sectors, Malerba (2002) emphasizes that

> 'geographical boundaries are an important element to be considered in most analyses of sectoral systems. Not always national boundaries are the most appropriate ones for an examination of the structure, agents and dynamics of these systems. Often a sectoral system is highly localized and frequently defines the specialization of the whole local area (as in the case of machinery, some traditional industries, and even information technology).' (260)

In order to approach the pharmaceutical system of innovation, those limits regarding the geographic scope and the industrial branches need to be set, as otherwise the analysis would be imprecise.

4.3.1.1. Geographic Boundaries

Even though the market for pharmaceuticals is global (with the big multinational corporations at its centre), the national differences with respect to the legal and institutional framework structures are still significant (see i.e. Casper and Matraves 2003). Therefore, one can hardly speak of a global pharmaceutical innovation system, not even of a homogeneous global market for pharmaceuticals. – Even though the product market spans over the entire globe, it is only the sum of many nationally distinct markets. Accordingly, the underlying pharmaceutical innovation system is dominated by globally acting firms, yet fragmented along national boundaries. The fact that marketing authorizations for pharmaceuticals are still managed on the national level illustrates this well.

The European Union is in some respects an exception, as it tries to gradually homogenize the national drug laws, in order to facilitate European innovation processes and ease the barriers of access to new markets. However, this process is still far from being completed; the marketing authorization process on the European level is still extremely complex. Additionally, due to legal differences, not all medicaments can be marketed all over Europe. The segment of self medication illustrates this particularly well: the regulations on selling pharmaceuticals without prescription in the UK, for instance, are much more liberal than those in Germany; the German drug law permits fewer substances to be marketed as self medication (see Casper and Matraves 2003). Obviously this ultimately affects the national dynamics of innovation.

Consequently, the empirical analysis is limited to national boundaries. It analyses — whenever possible — the dynamics of innovation of the pharmaceutical industry from the German perspective. The German market for pharmaceuticals is the largest in Europe (AESGP 2011), making it an exemplary market in Europe in terms of dynamics of innovation and market development. Also, the German market is amongst the best researched in Europe, which clearly produces some practical reasons to analyze it.

In case European regulations are in place they are treated as superior to German legislation. This is justifiable as otherwise the sectoral system of innovation in which OTC-innovations are generated could not clearly be identified; national differ-

ences would make it impossible to define a robust set of systemic conditions and to draw conclusions from it.

4.3.1.2. Industry Boundaries

Even though the analysis focuses, for the sake of feasibility, on the German pharmaceutical market and the corresponding systemic conditions, a different focus is applied to the industry itself. Three industrial sub-groups act in the German pharmaceutical market: big globally acting, R&D-based pharmaceutical corporations, producers of generics and a high number of small and medium-sized (family run) businesses. The analysis will, whenever possible, focus exclusively on the first group of industrial actors. A major reason for that restriction of the search area lies in the potential for innovations that the different groups of actors have. Producers of generics generate no innovation at all, as they manufacture products that were already marketed under the protection of a patent for at least twenty years. The small and medium-sized companies are relatively innovative, yet their innovation activities focus on incremental advancements in competitive niches of high specialization (Casper and Matraves 2003: 1874; Sigrist 2006: 95). Only the global corporations are today still able to finance entire innovation and product development cycles that yield 'blockbusters' and open up new markets (see i.e. Thierolf 2008).

Consequently, when thinking about fundamental changes and strategic reorientation of the large trends in pharma towards a new market, one ought to focus on the big players in the industry. This shall not imply that small and medium-sized pharmaceutical companies are unable to change or reorient per se. However, only the big players may be considered capable of absorbing the challenges that the growing extended healthcare market represents; they are the only players in the system that would be capable of transforming the industrial dynamics of innovation towards health products-innovations. The analysis will therefore focus on them, whenever going beyond aggregate systemic analyses.

Of course, while the small and medium companies are German (they are considered the backbone of the German pharmaceutical industry and its innovation capacity, the big corporations are mostly foreign, Bayer, Böhringer Ingelheim and Merck Darmstadt, being the only exceptions. This means that the analysis will focus on the German pharmaceutical market and innovation system, while at the same time it will not be restricted to German firms. The systemic perspective of the analysis makes this possible: no matter what nationality a pharmaceutical firm has, it may only innovate in the German market if it can overcome the various systemic boundaries. The 'rules of the game' are the same for all companies, which makes them comparable. Also industrial inertia can be analyzed independently of the company's nationality as the logic of inertia as the result of adaptation processes and dependencies is true for any company that operates in Germany.

4.3.2. Data Sources

As the discussion of the research methods and the phases of the studies already highlighted, the selection of data sources for the analysis is guided by the availability of information and the state of the research on the various aspects of the analysis. Three data sources are exploited that are presented hereafter: the exiting literature on the pharmaceutical industry, quantitative data on the German pharmaceutical industry and market and finally qualitative data from expert interviews conducted in a number of major pharmaceutical firms.

4.3.2.1. Literature

Regarding its innovation activities and their systemic embeddedness, the pharmaceutical industry is rather well researched already. However, so far, the dynamics of change in relation to the extended healthcare market have not been of interest. Instead, the literature mainly evaluates the efficiency and growth potential of the industrial innovation activities from a static perspective. Additionally, those studies on the industry that focus on change at all concentrate very narrowly on the challenges and changes that the industry has experienced lately (and consequently also the discussion of rigidities to change). The discussion is one-sided: the literature examines the industrial adaptation processes with respect to bio-technology and chemical screenings only (see i.e. McKelvey and Orsenigo 2001).[37] The changes at the other end of the innovation spectrum, remain largely unconsidered by the literature; studies on the pharmaceutical industry take no notice of the emergence and growth of the health products market and fail to link health products to the industrial dynamics of innovation.

Nevertheless, the literature provides insights into the systemic and industrial interdependences and relations that shape the innovation processes of the pharmaceutical industry. Information on the key players in the innovation system and on the dynamics between them and the pharmaceutical firms can be deducted.[38] Bührlen and Kickbusch (2008) analyze the pharmaceutical industry from a systemic perspective, taking into consideration the network effects that determine the innovation activities. They differentiate between four system components in the pharmaceutical innovation system: demand and regulations, capital markets and competition, supply and industrial actors as well as science and training. The study examines the perspectives and needs of the those actors, evaluating in how far they differ and how those differences impact the efficiency of the innovation system. Nusser et al. (2007)

[37] Those technological and scientific developments revolutionized the R&D process of prescription drugs and made the development of individualized medication possible. The pharmaceutical industry — quite successfully — adapted its innovation processes to those new conditions (see Gaisser et al. 2005).

[38] The selected studies are among the most prominent ones on the pharmaceutical innovation process in Germany and the institutional influence on it. The amount of exploitable literature on the issue is limited as most studies and articles on the pharmaceutical innovation processes focus on the scientific aspects of pharmaceutical innovations and fail to address the regulatory frameworks.

discuss the attractiveness of Germany as a location for pharmaceutical innovations with respect to the institutional aspects and the market conditions in Germany.[39] Based on a systemic view on the pharmaceutical industry in Germany, the study develops a set of input and process-oriented indicators for the German location attractiveness for pharmaceutical innovation activities. Similarly, yet applying a narrower scope, Burr and Musil (2003) analyze the institutional frameworks in Germany and their role as supporting or restraining forces in the pharmaceutical innovation process.[40] Gaisser et al. (2005) take the same stance. They analyze the innovation potential of the German pharmaceutical industry in the systemic context and describe the industry and its dynamics of innovation in depth, mainly focusing on the institutional and regulatory frameworks in which the German pharmaceutical industry is embedded. Nusser and Tischendorf (2006) evaluate the pharmaceutical industry in a similar manner, yet more from the perspective of economics. They highlight the important role that institutions and the research infrastructure play for the performance of the pharmaceutical industry in Germany. Gassmann et al. (2008) examine the trends and drivers for growth of the leading pharmaceutical firms and their innovation pipelines, evaluating how pharmaceutical firms can deal with the ever increasing market pressure and the resulting need to continuously develop blockbusters. In their study Gassmann et al. also discuss the systemic aspects of the pharmaceutical innovation process, such as the high risk of R&D the risk of entry form competitors or the threat of substitute products.

Faeh (2008) provides an extensive evaluation of the marketing authorization process of prescription-only and non-prescription pharmaceuticals in a number of EU and non-EU countries. Thierolf (2008) discusses the role of R&D in the pharmaceutical industry, providing data on the industry-specific costs and the financing of innovation processes. Similarly, Sandner and Turowski (2011) as well as Santermans (2004) focus on the regulatory requirements of OTCs, arguing that they increasingly limit the innovation activities of pharmaceutical firms and consequently the dynamic growth of the OTC market. Jäckle (2011) provides a study of the distribution structures in which the pharmaceutical industry operates, analyzing the market structure and the regulatory frame conditions of the distribution structures for pharmaceuticals. The study focuses on the role of the pharmacists and their influence on the distribution structures in Germany.

Studies by Roland Berger Strategy Consultants (Kartte 2008; Roland Berger 2009), ICON ADDED VALUE (Icon Added Value 2011) and The Nielsen Company (Nielsen 2011) provide additional insights into the dynamics of the healthcare market, allowing to draw conclusions regarding the place and behavior of the pharmaceutical industry in it. The study by Icon Added Value (2011) provides insights into

[39] See also Reiss and Hinze (2010), who evaluate the pharmaceutical industry from an institutional-regulatory perspective too.

[40] See also Oberender and Rüter (1988) on this issue.

consumer behavior in Germany, focusing on the perception of pharmaceuticals and the pharmacy as the major distribution channel for health-related products.[41] It provides evidence that German consumers (still) prefer pharmaceuticals over non-pharmaceuticals and have considerably more trust in the pharmacy as the distribution channel for healthcare products than in the mass market. Interestingly, this is the case for pharmaceuticals and health products alike. The study by Nielsen applies a similar focus on the healthcare market, evaluating the significance of OTCs in today's life of consumers and drawing conclusions regarding the strategic orientation of OTC and health products innovations in the future. Similarly, the studies conducted by Roland Berger focus on the social changes underlying the emergence and growth of the extended healthcare market.

With respect to health products alone, only a small amount of literature on the categorization and regulation of health products is available and exploited for the analysis of resource dependences. Sandner (2006), Sandner et al. (2011) and Sandner and Turowski (2001) discuss the legal and regulatory aspects of health products, focusing on the regulation of health claims and marketing of health products. Similarly, Plantör (2006) focuses on the question of the distribution channel of health products, arguing in favor of the strong position of the pharmacy relative to the mass market for health products. Zulauf (2002) analyses the market of cosmeceuticals. Menrad (2000, 2001, 2003, 2005) approaches the market for Functional Foods from the perspective of technological systems of innovation, categorizing and evaluating the system along technologies, institutional infrastructure and economic competence.[42] He focuses on the innovation system that that has emerged between health and nutrition, identifying pharmaceutical firms as one player in the system. Interestingly, Menrad (2001) indirectly hints at inertia. He argues that pharmaceutical firms are attracted to Functional Foods because of 'the shorter development times and lower product development costs compared to pharmaceutical products' (184), yet that they

> 'often underestimate the specific characteristics of food markets and the needs of consumers in Europe, so that it can be expected that only single companies of this groups will move into the Functional Food market permanently.' (187)

4.3.2.2. Quantitative Data

The second supporting element to the analysis is quantitative data. Two sources of quantitative data are drawn from: raw data on the industry and the healthcare market that is provided to the author by German pharmaceutical associations and a small

[41] Computer-aided, nationally conducted telephone interviews among four random samples of 800 adults in Germany were conducted. The study was realized by the German Association of Producers of Pharmaceuticals (BAH) and Icon Added Value.

[42] Menrad refers to Carlsson's and Eliasson's concept of economic competence as buyer and supplier competence (Carlsson and Eliasson 1994).

number of openly available quantitative studies on the pharmaceutical innovation activities.

The data on the healthcare market comprises sales data from the pharmacy market and the mass market, denoted separately for Rx-products, OTCs and health products for the years 2008 to 2011/2012 (table 3). The data is employed for illustrating the market in terms of size and development. It allows to set the size of the market segments into relation to each other.

Of course the market data alone can — strictly speaking — not reflect the industrial behavior. As aggregate data on the revenues of the all pharmaceutical firms in the German market is unavailable, the market data can be used as an alternative. This is legitimate from a methodological standpoint, as the pharmaceutical industry must once again be considered a special case, as it holds a quasi-monopoly on the healthcare market: the Rx-market is fully controlled by the pharmaceutical industry, while significant activities of outsiders only take place in the market for health products and (to a very small degree) in the field of OTCs. If they do, it is mostly through acquisitions or cooperation with pharmaceutical firms.[43] The market data for OTCs and Rx-products can therefore (for both distribution channels) be treated as the aggregate sales volume of the pharmaceutical industry in Germany. The data on health products in pharmacies also reflect the sales of the pharmaceutical industry only, since the pharmaceutical industry dominates the health products market in this distribution channel almost entirely. The mass market data on health products also represents the sales activities of the pharmaceutical industry, as the data is only collected for pharmaceutical firms in the market. The numbers are therefore not representative of the entire market volume (in contrast to the other domains, where the sales volume of the pharmaceutical industry equals the market volume).

[43] Reckitt Benckiser or Proctor & Gamble are examples for corporations who have lately built up an OTC- and health products segment through strategic acquisitions. Similarly, in 2010 Nestlé started to invest into its Medical Nutrition segment by buying a number of small pharmaceutical firms (Nestlé 2011). Nevertheless, the innovation activities of such players represent only a tiny fraction of the healthcare market as a whole.

Pharmacy Market* 2008-2012	**Mass Market**** 2008-2012
Rx	-
Sales	-
Units	-
OTC	OTC
Sales	Sales
Units	Units
Health products	Health products
Sales	Sales
Units	Units

* Numbers are provided separately for online/ mail-order pharmacies and traditional pharmacies.

** Numbers are provided separately for supermarkets, drugstores, discounters and traditional foods retail.

Table 3: Overview of the quantitative market data used for the analysis (own illustration)

The market data described above is supplanted by data from the annual reviews and publications by German pharmaceutical associations, providing insights into the industry's innovation activities and the healthcare market (i.e. number of market authorizations granted, number of new products introduced to the market or the industrial R&D intensities).[44]

Wherever possible and needed the market data is supplanted by firm data from annual reports of major R&D based pharmaceutical firms. This is done as to underpin the market data by concrete examples from the industry, the focus lying on R&D intensities and product revenues. The companies whose data is used are selected according to the principles demonstrated above: only major, globally acting researching pharmaceutical firms, German or foreign, who are represented in the German market are considered.

4.3.2.3. Expert Interviews

Interviews with experts from pharmaceutical companies are the third data source employed for the analysis. While the literature and the quantitative data mainly provide evidence regarding resource dependences, the interviews are directed at unveiling routine rigidities in a number of pharmaceutical companies that are representative of the industry as a whole. Due to the iterative process of data analysis, however, the interviews contribute also to understanding resource dependence. The interviews are an important element of the empirical analysis of inertia in the pharmaceutical industry, as they provide primary data on routinized patterns of behavior and perception that direct the activities of the industry.

Interviews are the ideal tool to evaluate a phenomenon from an internal perspective (Piening 2011: 122). This is of particular importance for research on

[44] Openly available reviews and publications by the *Bundesverband der Arzneimittelhersteller (BAH)* and the *Verband der forschenden Pharmanternehmen (vfa)*.

routines, which are created and lived by individuals and are consequently not measurable from the outside. Different types of interviews exist, serving different purposes (see Miles and Huberman 1994). For this study, semi-structured expert interviews were selected, as they serve the research topic best. In contrast to other types of interviews, expert interviews focus on the organizational and institutional context in which the person interviews is acting, rather than on the individual and their personal views, opinions and social situations (see Meuser and Nagel 1991, 1997, 2010). Expert interviews are therefore not obliged to consider the larger social and personal context that impacts the interviewee's knowledge. Rather, the interview focuses on some 'clearly defined details of reality' (1991: 444), while other aspects of the expert (private and personal details in particular) may and must be ignored. At the same time, those slices of reality are covered in depth, so that thick information emerges from the interview, which can include information on habitual and implicit knowledge and routines. As Eisenhardt and Graebner (2007) point out interviewing experts is ideal for maximizing information on the topic in focus and limiting the bias the obtained data might have, arguing that

> '[a] key approach [for avoiding bias] is using numerous and highly knowledgable informants who view the focal phenomena from different perspectives. […] [i]t is unlikely that these informants will engage in convergent retrospective sense making and/or impression management' (28).

A discussion persists in the literature about who can be considered an expert, as there is the danger that any person who happens to know something about a topic of interest is considered an expert. Meuser and Nagel (1997) argue that the status of the expert is situative and relational, always dependent on the research interest. In general, an expert is a person, who is firstly responsible for the planning, controlling and implementation of problem solutions. Secondly, experts must have access to information about groups of persons and decision making processes that are of interest to the researcher; they must be a privileged part of the operating environment researched, in the sense that they have a clear advantage in knowledge, relative to others who could be interviewed (Meuser and Nagel 1997: 484; Liebold and Trinczek 2009: 34). This puts the expert in the position of not only being able to solve problems but also of knowing the causes for the problems and the organization-specific principles of detecting and solving them (Pfadenhauer 2009: 452); the expert has a strategic and operative overview. This allows the researcher to treat experts as representatives of their organization or institution who are able to describe, evaluate and communicate complex 'company knowledge'.

Expert interviews need some structure, as to account for the researcher's limited interest in the expert (anything beyond the factual knowledge of the expert is of no interest) and in order to guide the interview towards the topics to be investigated. Since only such a small part of the expert's reality is of interest to the researcher, fully unstructured interviews bear the danger of yielding only little concrete informa-

tion on the research topic (Meuser and Nagel 2010: 377). Also, having prepared general questions and an interview structure aiming at the research topic reflects that the researcher is prepared and has some sound knowledge on the topic. This prevents the expert from not taking the researcher seriously, which can otherwise easily happen and impact the course of discussion and depth of information negatively (Pfadenhauer 2009: 454). On the other hand, as Meuser and Nagel (1997: 464) point out, overly structured interviews with closed questions bear the danger that the expert communicates hard facts only, while it is the narrative parts that carry the most interesting and insightful information. The role of the researcher in an expert interview is not easy: the right balance must be kept between the 'critical distance' of an unprepared interviewer and the opposite phenomenon of 'going native' (Bock 1992: 92). Both extremes can lead damage the atmosphere during the interview, leading to reduced information flows.

The unit of analysis of the qualitative field study is the organization, the aim being to collect information about the routines guiding their dynamics of innovation. No standard rules regarding the sampling process and the sample size exist. The literature identifies a number of sampling strategies, among which are homogeneous and heterogeneous sampling (see Patton 2002; Miles and Huberman 1994). As the aim of this study is to draw a picture of the innovation routines of pharmaceutical firms in Germany, the selected cases must be comparable. Comparability is attained by selecting cases from the same setting and by observing comparable processes (Miles and Huberman 1994). Otherwise, the individual samples cannot be combined and evaluated towards a complete representation of reality. Selecting extreme cases makes no sense in the context of qualitative studies with a small number of cases, as they would make it impossible to obtain generalizability among cases and detect cross-case patterns of behavior and would not illustrate the observed situation realistically (Eisenhardt 1989: 537; Pettigrew 1990: 275). In contrast to quantitative sampling, where samples are selected randomly, '[q]ualitative inquiry typically focuses in depth on relatively small samples […], selected purposefully' (Patton 2002: 230). This is what Eisenhardt and Graebner (2007) call 'theoretical sampling', meaning that

> 'cases are selected because they are particularly suitable for illuminating and extending relationships and logic among constructs. […] just as laboratory experiments are not randomly sampled from a population of experiments, but rather, chosen for the likelihood that they will offer theoretical insight, so too are cases sampled for theoretical reasons, such as revelation of an unusual phenomenon, replication of findings from other cases, contrary replication, elimination of alternative explanations, and elaboration of the emergent theory' (27).

The selection of a sample is therefore 'purposeful' or 'theoretical', if 'information-rich cases' (Patton 2002: 230) are collected that provide a maximal contribution to the inquiry.

To ensure this comparability, the pharmaceutical firms studied are selected along the guidelines formulated above: all organizations examined are classical R&D based firms, operating in Germany and in the Consumer Healthcare segment. This ensures that the sample is representative of the industry. Interviews are conducted in nine pharmaceutical firms, among which are the biggest international and German pharmaceutical corporations.[45]

Regarding the sample size it was tried to obtain a number of pharmaceutical firms that is representative of the industry as a whole. Among the nine pharmaceutical firms who were willing to be researched are the largest firms in the industry: three companies are among the top six worldwide, two are the top two German pharmaceutical firms, ranging fifteenth and sixteenth worldwide. The remaining four companies are among the top ten German pharmaceutical firms[46]. This distribution of the cases makes the sample representative of the R&D-based pharmaceutical industry. As Miles and Huberman (1994) emphasize, the sample size must fit the purpose of the research; the perfect ratio between width and depth of the study that exists in theory can hardly be reached. The sample selected provides a sufficient range of comparable, yet different pharmaceutical firms as to obtain qualitative data. Additionally, as Eisenhardt argues

> '[…] while there is no ideal number of cases, a number between 4 and 10 cases usually works well. With fewer than 4 cases, it is often difficult to generate theory with much complexity, and its empirical grounding is likely to be unconvincing [...]. With more than 10 cases, it quickly becomes difficult to cope with the complexity and volume of the data'. (545)

Similarly, Yin (2014) emphasizes that only multiple case studies — similar to multiple experiments in a laboratory — allow the researcher to generalize the findings from the study;

> 'the mode of generalization is *analytic* generalization, in which a previously developed theory is used as a template with which to compare the empirical results of the case study.[2] If two or more cases are shown to support the same theory, replication may be claimed. The empirical results may be considered yet more potent if two or more cases support the same theory but do not support an equally plausible, *rival* theory'. (39)

Multiple case studies enable the researcher to push the analysis beyond 'the unique/extreme/critical case' (Baxter and Jack 2008: 550) and to arrive at looking at across-case similarities and differences more broadly. At the same time, of course, this requires the researcher to careful plan and track the time and resources invested in the study, as multiple case data collection and evaluation can be lengthy.

Additionally to the broader perspective and comparative insights that multiple case studies provide, they increase the chances of reaching sufficient construct valid-

[45] Due to the obligation to keep anonymity, the firm names are not mentioned here.

[46] Letters A to I are assigned to the firms, as to keep anonymity.

ity of the data, which is essential to obtaining reliable results. Conditions for contract validity to be present are the use of multiple sources of evidence in the study, as well as the creation of a chain of evidence rather than singular buckets of it that lack a clear connection (Yin 2014: 41). Clearly this can more easily be achieved in a multiple case study than if only one case is analyzed. After all, only multiple case studies can provide sufficient replication of data and observations to draw generalizable conclusions from it, ultimately leading to theory.

The selection of experts from pharmaceutical companies follows the same logic of comparability, as sufficient depth and comparability is not only to be assured with respect to the general unit of analysis but also regarding the interviewees. Therefore, persons with comparable areas of responsibility within the organizations were selected. Even more importantly, the employees selected all have comparable authorities and positions with the organizational hierarchy, classifying them all as experts on the same area of organizational activities (table 4). This ensures that they share comparable degrees of strategic knowledge concerning the dynamics of innovation of their organizations. All managers interviewed are decision makers in the CHC-departments (Consumer Healthcare departments) of the nine pharmaceutical firms and therefore directly occupied with the innovation activities and concerns regarding health products. At the same time, their expertise is not limited to CHC only, as their positions within the company give them a sufficient strategic and operational overview of the company's dynamics of innovation and the routine structure underlying them. They can abstract from the operational level onto the dimension of routines and cognition, which allows them to judge what drives and inhibits the organizational development.

In more than half of the organizations selected, two experts were interviewed. Even though the hierarchical position and strategic insights of both interviewees is comparable in all cases, the study of two perspectives allows a second (and probably in some respects differing) personal view, which is helpful as to enrich the data, to minimize bias and to maximize the validity of the results (Pfadenhauer 2009: 122). Not all pharmaceutical firms willing to participate in the study granted access to two experts. The communicated reasons varied, ranging from time constraints to an unwillingness to provide too much information.

Company	Interview	Position of Representative Interviewed
A	A [a]	Regional General Manager CHC
	A [b]	Regional Sales Director, CHC
B	B	Member of the Board, CHC Germany
C	C	Executive Director, CHC Germany
D	D [a]	Senior Director Business Development
	D [b]	Senior Director International Sales & Marketing, CHC
E	E [a]	Director Business Development, CHC
	E [b]	Associate Director, Corporate Development
F	F	Country Division Head, CHC Germany
G	G [a]	General Manager
	G [b]	Head of Marketing
H	H [a]	General Manager
	H [b]	Director, CHC
I	I [a]	Head Key Account Management, CHC Germany
	I [b]	Head of Marketing, CHC Germany

Table 4: Positions of the company representatives interviewed (own illustration)

As proposed by the literature (Pfadenhauer 2009: 455) the semi-structured interviews followed an openly handled guideline of questions (see appendix). Those guideline-questions used for the interviews are based on the theoretical framework on routine rigidity. This is legitimate for expert interviews, as long as the questions are posed and evaluated as openly as possible; the interviews are not to serve the mere testing of hypotheses but are supposed to approach the field fairly openly (Pfadenhauer 2009: 455). Yet, the researcher must have some theoretical concepts (vague hypotheses or assumptions deducted from the literature) in mind (Bock 1992: 94; Liebold and Trinczek 2009: 37). Expert interviews may neither be fully deductive (narrow questionnaires) nor fully inductive (i.e., unstructured, narrative biographical interviews); instead, ‘deduction and induction go hand in hand’ (Liebold and Trinczek 2009: 37). This ensures that enough data is gathered in a straight-forward, goal-oriented way, while at the same time it remains possible to modify the categories and theoretical concepts. Bock (1992: 91) emphasizes that the collection and analysis of qualitative data through expert interviews is an explorative process, where the researcher is constantly reflecting the gathered material back onto the theoretical prior knowledge and vice versa. As Eisenhardt (1989) points out, good qualitative

research must be guided by research questions and theoretical constructs, while it is also 'begun as close as possible to the ideal of no theory under consideration and no hypothesis to test' (536).

As outlined above, obtaining thick information on the organization and its behavior requires the openness of semi-structured interviews. The order of questions may be structured, yet the researcher must be able to change the structure and adapt it to the situation. Expert knowledge cannot be detached from the context in which the expert narrates it, which is why the researcher must allow the expert to take control of the conversation to some degree and to 'let them talk'. The questions must be adapted accordingly, while the researcher is responsive to eventual narrative sidetracks and unanticipated remarks of the interviewee. Keeping the balance between directing the conversation and allowing the interviewees to bring up their own areas of focus ensures the collection of sufficiently thick, variegated and at the same time comparable data (Bock 1992:94). Liebold and Trinczek (2009) call this an 'open and unbureaucratic handling of the interview-guideline' (35). This is particularly important when — as in the case of routine rigidity — the research aims at revealing habitual patterns of behavior that can perhaps not be directly communicated by the expert. Allowing interviewees to answer openly is therefore important, as pressure could inhibit them from disclosing this knowledge (Pfadenhauer 2009: 453)

Those considerations were integrated into the set up process of the interview-guideline. The questions were formulated according to the theoretical framework on organizational routines, yet they were loosely handled and adapted to the conversation. Subquestions to each main question were used as alternative questions and connection points in case the interviewee had to be redirected to the central topics.

4.3.3. Data Analysis

As mentioned above, the empirical study is structured along two phases that address the four specific research question successively: the analysis of resource rigidities (resource dependences and a potential lack of incumbent reinvestment incentives) and of organizational routines in major pharmaceutical firms (addressing the issue of routine rigidity). Data for the analysis is drawn from three sources: the existing literature on the pharmaceutical industry, quantitative market and industry data and qualitative primary data from expert interviews.

The empirical data collected is analyzed in this context. The process is organized in two major phases, following the general two-phase-structure of the research. First, an exploratory literature review is conducted, followed by the analysis of the interview data. The literature analysis includes the scanning of the literature of interest to the topic, described above. It also includes the analysis of the quantitative market and industry data on the pharmaceutical industry. A third phase brings the

results from the first two phases together, as to approach theory generation from the empirical results (figure 11).

The aim of the empirical study is neither to test static hypotheses, nor to generate theory in a fully inductive way. Rather, the goal is to add to theory by exploring the force of inertia in sectoral systems of innovation. This requires the analysis to act somewhere between induction and deduction as the guiding principle for the evaluation of data. Edmondson and McManus (2007) emphasize that establishing 'methodological fit' is an ongoing process, running through the entire research process and including the analysis; 'iterating between inductive theory development and deductive theory testing advances our understanding of organizational phenomena' (1173).

Locke et al. (2008) call this middle way of theory generation from empirical data 'abduction', claiming that abduction is the generation of ideas from the empirical material. This process of idea generation is neither closely linked to pre-existing hypotheses, nor is it completely open. Instead, it is oriented towards theoretical concepts, while at the same time being open for surprises. Locke et al. base this understanding of abduction on Charles Sanders Peirce (1976), who claims that, 'deduction proves that something *must* be; induction shows that something *actually is* operative; abduction merely suggests that something *may be*' (Locke et al. 2008: 907; emphasis as in the original).[47] Analyzing data abductively requires the researcher to turn doubt (the initial state that provokes the research question) into belief, which is the resolution of doubt. In this context, data analysis is rather a process of discovery validation, requiring the researcher to think critically about the relationships between theory and data and draw intelligent conclusions from it; 'abduction begins with an unmet expectation and works backward to invent a plausible world or a theory that would make the surprise meaningful' (Van Maanen et al. 2007: 1149). In other words, analyzing data abductively means to go backwards between theory and data to find evidence that relationships exist and expected constructs are in place. The process is neither a mere validation of the constructs that may be expected nor a fully data-driven, inductive analysis. For that purpose the researcher needs to jump back and forth between data and theory, as to constantly reflect theory onto practice and vice versa (Locke et al. 2008: 908). Eisenhardt (1989) points out that 'the central idea is that researches constantly compare theory and data — iterating toward a theory which closely fits the data' (541). As Langley puts it, abduction is for those researchers who

> 'are not in the business of hypothesis-testing (deduction), but who aim to reach beyond the detection of common surface patterns (induction) to develop plausible explanations for temporal dynamics' (419).

She states further that applying abduction to the analysis of qualitative data requires 'amplifying engagement with the phenomenon, permissively exploring possibilities

[47] The work of Peirce (1976) was not accessible, which is why the citation from Peirce's text is taken from Locke et al. (2008).

(where sensitizing concepts and theorizing strategies may assist), and selecting and shaping emerging ideas' (419).

It was mentioned above that the two analytical blocks — the exploratory literature analysis and the evaluation of the qualitative data — serve different purposes, as the literature analysis addresses mainly resource dependence, while the interviews aim at unveiling organizational routines. However, the phases are linked to each other, as resource and routine rigidities are casually interwoven. Also, since the analysis is designed as an iterative process, the analytical phases are corresponding to each other; the phases are 'iteratively connected', as described by Piening (2011: 138). As figure 11 below shows, despite the consecutive analysis of resource dependences and routine dependences, evidence can also flow backwards between the steps. This ensures that insights from the interviews that relate to the issue of resource dependences rather than to organizational routines can be added to the first part of the analysis.

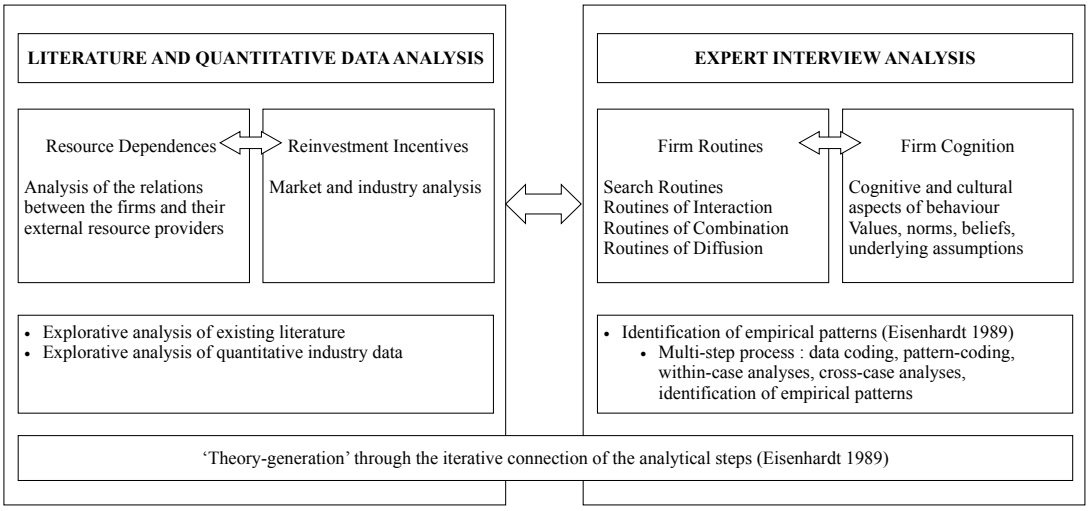

Figure 11: Conceptualization of the phases and methods of analysis (own illustration)

4.3.3.1. Phase I: Exploratory Literature and Qualitative Data Analysis

The aim of the exploratory literature analysis is to draw conclusions form the existing research on the pharmaceutical system of innovation and the industrial innovation patterns. As outlined above, the literature on the topic focuses not on the question of dynamics of innovation regarding health products or on the issue of change in the pharmaceutical industry. However, it provides evidence regarding resource rigidities from which information can be deducted and reflected onto the research topic. Both the pharmaceutical industry and its markets have been analyzed already. What the exploratory literature study contributes is an analysis of this research in relation to the extended healthcare market.

In accordance with Eisenhardt's concept of data analysis the literature is approached openly, without finely structured theoretical pre-conceptualizations (the literature to be analyzed has — of course — been selected in relation to the theoretical framework). It is scoured for explanations for the industrial behavior in relation to the extended healthcare market.

Subsequently, the quantitative data on the pharmaceutical market and the industry is integrated into the analysis. Again, the approach is — in the context of abduction as the theoretical concept driving the analysis — designed openly, while at the same time conducted iteratively and in close contact to the research questions and the already existing research results. This step in the analysis is supposed to underpin the evidence filtered from the literature and contribute to answering the research questions. As discussed earlier, introducing qualitative data into the analysis allows to look at the research problem from different perspective, to triangulate the analysis and ultimately to increase the validity of the research results.

4.3.3.2. Phase II: Interview Analysis

In the second phase of the study the data from the expert interviews is analyzed. Eisenhardt underlines that analyzing qualitative data is the most difficult and least conceptualized part of the qualitative research process. Meuser and Nagel (1991: 447) point out that the basis for the analysis of the expert interview must be a category-framework. At the same time, they underline the iterative character of the process, arguing that results from the interviews must be treated as research results and at the same time as the basis for an ongoing evaluation of the theory underlying the research (see also Eisenhardt 1989).

The data from the interviews is analyzed along Eisenhardt's concept of qualitative data analysis and in the spirit of the approach of adductive data analysis provided by Locke et al. (2008). In a first step, the interviews are transcribed and coded. In contrast to narrative interviews aiming at exploring context as well as context, expert interviews may be transcribed more liberally, meaning that the statements of the interviewee are transcribed, without noting down contextual aspects or other observations made (see Meuser and Nagel 1991, 1997, 2010). Also, filler words, pauses in the interviews as well as parts of the interview unrelated to the topic of research may be kept out of the transcripts (and consequently the coding). Of course, the transcripts include annotations and comments that the researcher may have made during the interview. Also, the semantic validity must be preserved while transcribing the data.

The aim of coding is to apply a first structure to the data, allowing to link it to the theoretical categories later. The aim is to create 'data descriptions', reworking the data and make it manageable without losing content or depth of information. Coding serves this purpose as it is a systematic way of describing data, reducing and struc-

turing it to a degree that can be worked with on a higher level, ultimately leading to conclusions and theory deducted from it;

> 'Description lays the basis for analysis, but analysis also lays the basis for further description. Through analysis, we can obtain a fresh view of our data. We can progress from initial description, through the process of breaking data down into bits, and seeing how these bits interconnect, to a new account based on our reconceptualization of the data. We break down the data in order to classify it, and the concepts we create or employ in classifying the data, and the connections we make between these concepts provide the basis of a fresh description.' (Dey, 1993: 31)

At the same time, coding the data allows — if correctly done — to really compare the data and to isolate the causal relations while ensuring maximal internal validity (see i.e. Van Maanen 1995: 134). As Yin (2014: 41) emphasizes, pattern matching is essential to establish internal validity of the study results, as it maximizes the chance that the interferences made by the researcher are correct: the more often a certain pattern is observable within (and across) cases, the more likely it is that the interferences made are valid.

In accordance with the adductive approach selected for this analysis, the coding process neither follows a theoretically pre-conceptualized catalogue of codes, nor is it created fully inductively and unrelated to the theoretical concepts. Instead, the process is guided by the research goals: the codes are not determined deductively in advance, but are created in an iterative process and in relation to the categories from the theoretical framework.

In a second coding process, 'within-case analyses' are run, comprising written summaries of the individual cases (Eisenhardt 1989: 540). During this process, pattern codes are created that serve to combine several single codes, contributing to the generation of categories that have explanatory value. Those analyses help to reduce the volume of data, become familiar with each case and obtain comparability among the cases. What starts to emerge at this stage is similar to 'second order themes', supporting the researcher in identifying 'whether the emerging themes suggest concepts that might help us describe and explain the phenomena we are observing' (Gioia et al. 2013: 20). Even though Gioia et al. follow a Grounded Theory approach, the logic of the process at this stage is the same: the initial codes are brought to a higher, more abstract level, allowing to better understand the data and compare the relationships and contracts — they may start to appear — at a higher level of aggregation. There is no standard format for within-case analyses, yet write-ups are among the most commonly used formats (Eisenhardt 1989: 540) and were also chosen for the nine case studies analyzed in this dissertation. The coded interview data is therefore compiled and structured in nine 'case stories', while it is made sure that no data and no nuances of the emerging explanatory patterns are lost. The process of writing-up the interview data is particularly useful and needed in the cases where two experts of one company were interviewed, as it helps combining the

views of both company representatives into a company case story (important differences between the interviewees' statements, however, are to be considered).

What follows is an analysis of cross-case patterns in the data. While the first order codes applied to the data in the first round of coding are not shown in the analysis, the pattern-codes represent the categories along which the case data is finally presented. The purpose of this analytical step is the examination of patterns to be found in numerous cases, which are indicators for larger concepts or regularities in the behavior. Differences between the cases also become visible. At the same time, however, the case-specific patterns that do not fit into larger cross-case patterns are kept, making sure that none of the granularity of the data is lost. As Eisenhardt puts it, 'one tactic is to select categories or dimensions, and then to look for within-group similarities coupled with intergroup differences' (540). The categories along which the cross-case patterns are analyzed are those that previously emerged out of the pattern-coding for each individual case study. Comparing the case studies unveils similarities and differences regarding the organizational routines of the nine pharmaceutical firms; '[t]he result of these forced comparisons can be new categories and concepts which the investigators did not anticipate' (541). The process helps identifying the larger routine patterns, which are needed to consolidate an aggregate picture of industrial routines. However, the differences between the routine structures of the pharmaceutical firms may not be ignored, which is why they are discussed as well. During this process, out of the cross-case patterns frames and concepts start to emerge that can be linked to the theoretical framework.[48]

4.3.3.3. Phase III: Theory Generation

The process of theory generation combines the empirical results from the first two phases of the analysis. The frames, themes and concepts that emerge from the analysis of resource and routine inertia are used for shaping hypotheses from the data. For that purpose, the emerging patterns and concepts are — following the iterative logic of the entire process — constantly compared with the data and theory and tested against it (see Edmondson and McManus 2007; Eisenhardt 1989; Eisenhardt and Graebner 2007; Mayring 2010), the aim being to obtain theory that fits the data. The fact that different data sources are triangulated in this study as well as the adductive approach of analyzing the data applied ensure maximal internal and external validity of the results, strengthening the value of the emergent theory. Relationships

[48] As Locke et al. (2008) imply, the framework to which the patterns are linked may not be treated as static, but may always be changed if the data indicates shortcomings of the theoretical pre-conceptualizations. This marks the very logic of iterative processes of qualitative data analysis. In the concrete case of the pharmaceutical industry, this means that if routines become apparent in the interview data that have not been considered by the theoretical framework that guides the study, those categories may be added. The opposite is also possible: if the theoretical framework considers aspects that are not found in the empirical data, the framework may be adapted accordingly.

between the emergent frames and the data and theory must be identified and tested, as only

> 'cases which confirm emergent relationships enhance confidence in the validity of the relationships. Cases which disconfirm the relationships often can provide an opportunity to refine and extend the theory.' (Eisenhardt 1989: 542)

The empirical patterns from the analysis are reflected onto the theoretical constructs and dimensions and vice versa. This interaction ensures not only a good understanding of the constructs and relationships in the data, but also 'why or why not [they] hold' (Eisenhardt 1989: 542). Ideally, the result is the result is the generation of internally valid and reliable hypotheses about why something is happening, which can be used to generate theory. Following Whetten (2009: 219), theory is explanation, it 'answers to "why" questions'. Further, he distinguished between paradigmatic theory and propositional theory that can be generated, putting the focus on propositional theory, as it 'reflects my general belief that fields of study should encourage modes of theorizing that can be widely used to generate new and improved explanations' (219).

The emergent relationships and contracts are ultimately compared and related back to the theories that produced the context of their analysis. As Eisenhardt (1989) points out, only if the theoretical context is re-set, showing in what respect the developed theory is similar to and differs from other theories, closure of the process of theory generation can be reached.

5. Empirical Findings

The methodology of the empirical study has been described above. This chapter presents the findings of the study and the results. The analysis focuses on inertia in the pharmaceutical industry, aiming at answering the overall research question:

> *In how far does inertia present in the pharmaceutical industry hinder the sectoral firms from extending their boundaries and adapt their innovation activities further to the extended healthcare market?*

Providing answers to the general research question and its subquestions is supposed to make a contribution to innovation research and — more precisely — to the understanding of the relation between the dynamics of innovation of the pharmaceutical industry and the expansion of innovation activities beyond its sphere of activity. At the same time, the analysis shall of course make a theoretical contribution towards the research on sectoral systems of innovation and the conceptualization of their ability to dynamically adapt and change. The iterative back and forth between the empirical findings on the pharmaceutical industry and the theory on sectoral systems of innovation and on inertia ensures a theory building process that serves the purpose of the research.

5.1. Resource Rigidities

In accordance with the theoretical framework, the analysis of resource rigidities is divided in two phases: the evaluation of resource dependences of the pharmaceutical industry as well as of the industry's market position and the corresponding incumbent reinvestment incentives.

5.1.1. Resource Dependences

The literature on the pharmaceutical industry emphasizes the central role of the regulatory bodies in the pharmaceutical innovation system, presenting the regulatory organs as the main resource provider for the industry. The innovation activities of the pharmaceutical industry are heavily impacted by the regulatory and institutional frame conditions that apply to pharmaceuticals. Complex regulations apply to the development, production and distribution of the products (Bührlen and Kickbusch 2008: 31; Burr and Musil 2003: 11; Nusser et al. 2007: 70). Certainly, this distinguishes the pharmaceutical sector from others, where governmental intervention through regulations on product quality, product safety, prices and distribution is less influential on the industrial innovation activities. As Reiss and Hinze (2010) argue,

> 'the innovation process in the pharmaceutical industry is different from other innovation processes, mainly due to the regulative influence of health authorities' (53).

Other resource providers, such as customer markets also impact the dynamics of innovation of the pharmaceutical industry and are therefore shortly discussed hereafter. However, as the regulatory regimes of the industry is crucial to the innovation activities, the analysis of resource dependences focuses mainly on this aspect of the system.[49]

5.1.1.1. Regulatory Frame Conditions

It is the institutional and regulatory sphere that provides, in the case of the pharmaceutical industry, the most powerful self-reinforcing effects determining the industrial dynamics of innovation: whether a pharmaceutical firm can develop a new product and introduce it to the market is first and foremost dependent on the regulatory situation, all other influences are secondary. The regulatory framework acts as the major external resource provider for the industrial innovation activities, externally determining the firm's strategic room for changes in innovation activities. It must therefore be evaluated, in how far the 'regulatory corset' of the pharmaceutical industry functions as a source of resource dependence in the case of health products. This chapter is to discuss the regulatory regimes for all fields of activity of the pharmaceutical industry: pharmaceuticals (including prescription-only medicines) and health products. This is necessary, as the regulations for all product types are interconnected. Also, the industrial innovation activities are dominated by pharmaceuticals. Potential resource dependences of this core segment of the industry can therefore have an impact on the behavior in relation to health products, too. This chapter is therefore dedicated to the regulatory frame conditions applying to the development of pharmaceuticals (both Rx products and OTCs) and non-pharmaceuticals, analyzing in how far they impact the dynamics of innovation of the pharmaceutical industry.

5.1.1.1.1. Pharmaceuticals

According to German drug law[50], pharmaceuticals are substances and preparations made from other substances with the purpose to be administered to humans or animals, as to

- (generally) impact their physical and mental condition and functions of the body, or

[49] As outlined above, the analysis covers pharmaceuticals and non-pharmaceuticals alike, as both product groups together represent the innovation activities of the pharmaceutical industry. The analysis discusses therefore the regulatory frame conditions for pharmaceuticals first, followed by a discussion of the regulations that apply to the development of health products.

[50] Arzneimittelgesetz, AMG

- (specifically) heal, alleviate, prevent or detect illnesses, ailments, physical injuries or chronic afflictions (§2 AMG).[51]

Further, the drug law names a negative list as to isolate the definition of pharmaceuticals further from other product categories. According to §2 AMG, pharmaceuticals may never be:

- foods,
- tobacco products,
- cosmetics or
- medicinal products.

German drug law considers pharmaceuticals a 'special good' that must be legally protected and whose development, production and distribution must be controlled (Sandner 2006: 9). The reasons for the regulation of the pharmaceutical market are, as Burr and Musil (2003: 12) outline, controversial: on the one hand, policy makers must make sure that the pharmaceutical firm is given the possibility to generate revenues that justify the innovation and its costs; at the same time, however, it must be ensured that pharmaceutical innovations are of the highest possible quality, reliability and efficacy. To make things more complicated, a third major concern of the policy maker is the limitation of the costs of the health care system. Of course, the higher the selling prices of pharmaceuticals, the higher the public health-costs are.

From the very beginning on, the innovation process of pharmaceuticals is therefore embedded in a complex network of regulatory guidelines. The process of development of a pharmaceutical can be divided into three major phases (figure 12): basic research, clinical trails and clinical development.

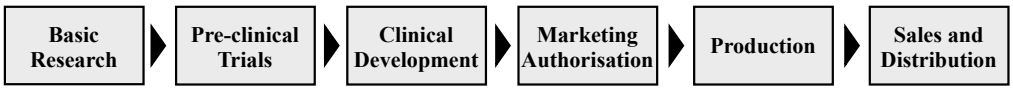

Figure 12: The major steps of the marketing authorization process of pharmaceuticals (own illustration)

Once those three stages are completed successfully, the product is granted marketing authorization by the national admission board, namely the Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM). By law, any new pharmaceutical product as well as any new active ingredient developed must undergo this process; no pharmaceutical may be marketed without such an authorization (§21 AMG). The complexity of the process is due to the high regulative requirements that the health authorities impose on the pharmaceutical firms.

Due to the high standards with respect to quality and safety, the marketing authorization process of pharmaceuticals is very long and expensive. The regulatory

[51] This is a comprising translation of the legal text; for the exact German text of §2 AMG as well as of all the legal texts mentioned see appendix.

organs and health authorities influence all aspects and stages of the pharmaceutical innovation process, the aim being to guarantee maximal efficacy of pharmaceuticals and maximal consumer-protection with respect to the consumption of pharmaceuticals. Health authorities are obliged to control safety and efficacy through a tight web of regulatory frameworks that monitor the entire R&D, production and distribution process of pharmaceuticals. At any step in the innovation and marketing process the quality and safety measures set by the state must be met. The process must be recorded and presented to the health authorities as to make sure that the quality standards are met.

What prolongs the process further is the duty of pharmaceutical firms to also document the therapeutical superiority of the product in development to already existing products from the same substance group or with a similar indication.[52] As table 5 shows, the probability of being granted marketing authorization for a new active ingredient and consequently for a new pharmaceutical is low until the late stages of the development process, while the time needed for research and development is long. According to Thierolf (2008: 127), in contrast to other industries, the ratio of development costs and revenues of a product is particularly large in the pharmaceutical industry. - Even in case the marketing authorization is finally granted, only one out of 10 products marketed yield revenues that cover the R&D costs, which can go up to $1 billion (Thierolf 2008: 127).

Phase	Time Period [years]	Probability of marketing authorization [%]
Basic research	2-5	≤1
Pre-clinical trials	1-3	1-10
Clinical trials, phase I	0.5-1	5-20
Clinical trials, phase II	1-2	15-40
Clinical trials, phase III	1-3	40-80
Marketing authorization process	0.3-0.5	75-90

Table 5: Development time and probability of success of the phases of the drug development (Thierolf 2008: 120)

So, in general, the marketing authorization process of a pharmaceutical is risky, lengthy and expensive; compared to the procedures undertaken for health products such as dietetic foods or food supplements, it is the most complex process in the market (Sandner et al. 2011: 254).

[52] Since 2004 pharmaceutical firms are required to submit their innovations to a test by a governmental agency, the Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG). The institute analyses whether the medicament is in fact superior or similar to existing alternatives, the aim being to reduce the number of 'redundant' product innovations (various products of one type and indication), as to diminish the cost of reimbursement that the statutory health system must carry (Deutscher Bundestag 2009).

Regulatory requirements also apply to the production of pharmaceuticals (Rx products and OTCs alike). The entire production process of pharmaceuticals must comply with GMP (Good Manufacturing Practice) standards, which regulate the production and quality management process of pharmaceuticals and pharmaceutical ingredients (Sandner et al.: 254). By applying the GMP standards the quality management and patient safety issues that are central to the development of pharmaceuticals are extended to the production process. The guidelines are extremely rigorous, which makes the production process of pharmaceuticals particularly lengthy and expensive.

In order to go further into detail on the regulatory frame conditions and their influence on the industrial dynamics of innovation, the discussion focuses on the two types of pharmaceuticals subsequently. Pharmaceuticals can either be prescription-only medicines or non-prescription medicines. Slightly different regulations apply to their development.

Prescription-only Medicines

Most pharmaceuticals are prescription-only pharmaceuticals (Rx-pharmaceuticals), which constitute the publicly financed first healthcare market (Kartte 2008: 3; Krimmel 2005: 188). Rx-medication cannot be distributed without the explicit order of a physician. Automatically, Rx-pharmaceuticals are always available in pharmacies only (§43 AMG). In Germany, this includes all classical products, such as antibiotics, strong painkillers or other sophisticated products. The reasoning behind the state-controlled distribution channel and the restricted access to powerful drugs (*Apotheken- und Rezeptpflicht*) is, again, consumer-protection and the prevention of drug-abuse. This is enhanced by the prohibition of advertisement and consumer promotion for Rx-pharmaceuticals anchored in German drug law (*Heilmittelwerbegesetz, HWG*). Rx-medication may not be advertised to patients (i.e., through TV spots), as to prevent negative reactions, such as an inappropriate consumption of medication. In contrast however, Rx-pharmaceuticals may be advertised among professional circles. This includes physicians, dentists, veterinarians and other persons who are authorized to trade with pharmaceuticals (§ 1; 2; 10 HWG).[53]

By limiting advertisement to professional circles and positioning the physician and the pharmacist as logistic intermediaries in the process of purchasing a Rx-pharmaceutical, the German legislator ensures a maximal degree of protection. The physician prescribes the pharmaceutical to an uninformed patient who is then collecting the product at a pharmacy. Both agents, the physician and the pharmacy provide consultancy and control. The costs for the pharmaceutical are mainly transferred to

[53] See appendix.

the insurance companies as in Germany, Rx-medication is mostly reimbursable through the statutory insurance system.[54]

This procedure represents a remarkable particularity of the Rx-market: firstly, the role of the patients is unusual as they are — unlike the classical consumer — only passively involved in the purchase decision. The physician is making a purchase decision on behalf of the patient, usually even without discussing it with them. The ultimate consumer of the medicament — the patient — is therefore not actively involved in the decision process. Instead, the patient's need for medication is translated into a demand that is transferred to the industry only indirectly through the physician; demanders and consumers are two separate economic entities. Similarly, the supply side — namely the pharmaceutical industry — is not communicating with the consumer either, as their access to the consumer (patient) is also blocked by the very same intermediaries. It is this 'demand management through physicians and patients' (Burr and Musil 2003: 14) that characterizes the market for Rx-medication.

This creates a market with two centers. On the one hand, there is the patient as the ultimate benefactor of Rx-innovations. The purpose of any Rx-innovation in the market is the treatment of their illnesses. However, due to the fact that the channels of direct communication between the patient and the innovating firms are blocked through regulatory barriers, the physician is established as a second centre of the market. Naturally, pharmaceutical firms therefore concentrate their innovation activities on the physician as the patient cannot be reached; product design, marketing and sales strategy address only the physician directly. In addition, the patient is not paying for the medication they receive, which contributes to the distance between supply and demand in the Rx-market. Figure 13 illustrates the process and the actors active in it.

[54] Except for those covered by private health plans, since January 1st 2004 patients insured through the statutory health system are obliged to pay a certain share of the selling price. The patient's contribution is 10% of the price, yet €5 at least and €10 at most (BMG 2004: 1). This arrangement is one of the various legal instruments that have been established to reduce the costs of the public health system.

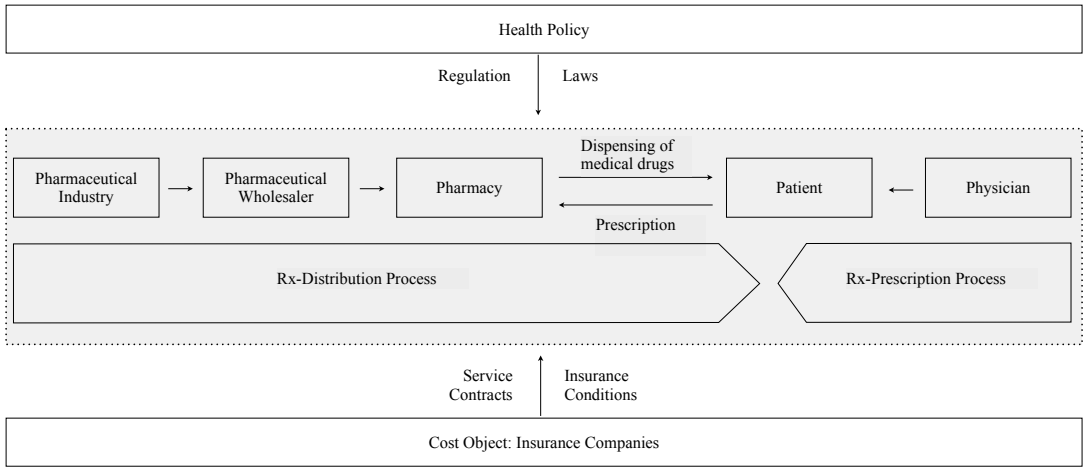

Figure 13: The distribution process of Rx-pharmaceuticals - players and processes (own illustration, adapted from Jäckle 2011: 39)

According to §48 of the German drug law any new active ingredient developed (and consequently any new pharmaceutical containing a new ingredient) is automatically classified as a Rx-medicament (*automatische Verschreibungspflicht*). The reasoning behind it is, once again, one of patient-protection: potential harmful side-effects of the new drug might be unknown of, which requires health authorities to control distribution, as to be able to react in case problems occur. Interestingly, once the pharmaceutical firm has obtained the marketing authorization for its innovation, it is protected by a clear legal situation: as soon as the product is licensed, the responsibility with respect to the claims and potential side-effects of the product lies with the state authorities (Sandner et al. 2011: 256).

Additionally, any Rx-innovation is — once it has obtained marketing authorization — protected by a patent. This means that for 20 to 25 years from the patent application, the innovating pharmaceutical firm has the right to produce and sell the new drug exclusively (Burr and Musil 2003: 11). The patent-protection is necessary for the pharmaceutical firm in order to make a return on investment sufficing to compensate the extraordinarily high development costs. What contributes to this protectionist effect of patents is the relative freedom with respect to pricing that the innovator enjoys. While the innovating firm has the exclusive marketing rights to its product it may set the selling price. State-intervention with respect to pricing starts only after the patent has expired and generics enter the market whose prices are regulatorily controlled. This again is a noteworthy characteristic of the market for prescription-only (patent-protected) innovations. What other market exists where innovators can for 20 years sell their products at any price they wish and under legal protection from competition? Of course all this must be seen against the enormous R&D effort that the innovating firm invests in advance and the high regulatory barriers to market entry. Finally, however, a new Rx-pharmaceutical enjoys the benefits of being the only one of its kind in the market, which gives it a monopolistic position.

Rx-pharmaceuticals are, however, not the only pharmaceuticals. Non-prescription pharmaceuticals (over-the-counter medicines, OTCs) are the second category of pharmaceuticals and it is here where some consumer-orientation enters the industry's innovation activities. However, their regulatory regime is closely tied to that of Rx-products, which is why they must be analyzed in light of the Rx-regulations.

Non-prescription Medicines (OTCs)

OTCs are pharmaceuticals, yet their distribution is usually not bound to doctoral advice.[55] Non-prescription drugs are distributed without prescription so that patients can purchase them independently of a doctor in order to treat themselves. At the same time they are exempted from the reimbursement through the statutory health insurance, which means that the consumers bear the costs themselves.[56]

The OTC-market is traditionally referred to as the market for self medication (figure 14). The traditional definition of self medication is limited to OTCs and consequently to pharmaceuticals; self medication is the responsible and autonomous treatment of minor illnesses and physical ailments by the consumers themselves (Beitz et al. 2004: 1043; Santermans 2004: 1). This may include well-being and prevention.

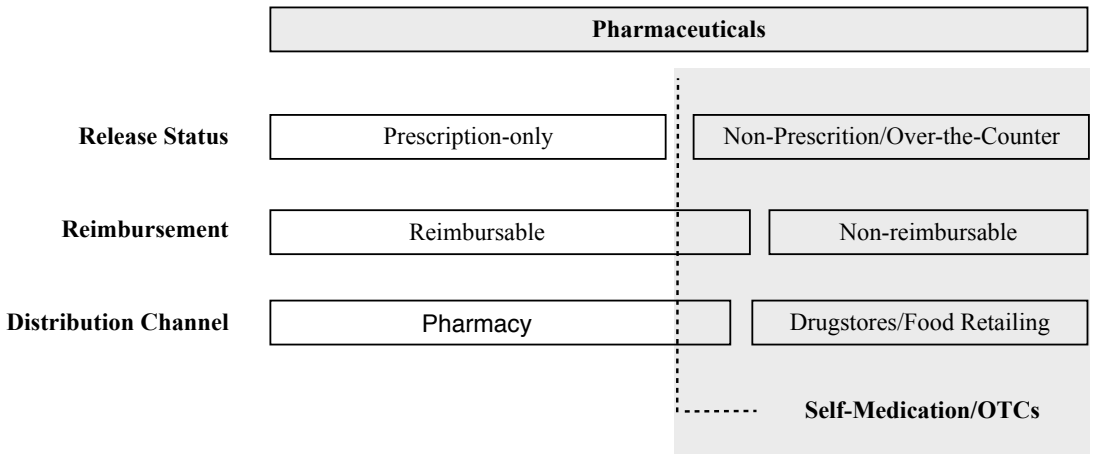

Figure 14: The traditional conceptualization of self medication (adapted from Santermans 2004: 2; Dambacher and Schöffski 2008: 282) The size of the boxes is not representative of the size or potential of the market segments listed.

A key characteristic of the regulatory regime for OTCs is that they are pharmaceuticals on the one hand, yet sold without prescription and not reimbursed by health insurance companies. OTC-innovations are — unlike new Rx-products — not pro-

[55] Some OTCs are to be prescribed by the physician (OTX), yet they represent a minority of about 4% of non-prescription medicines (BAH 2011:3).

[56] According to an exception provision, OTCs must be reimbursed by the health insurance company for young adults under 18, suffering from disorders of physiological development, as well as for children under the age of 12. Also, the consumer is to be reimbursed if the OTC purchased is classified by the legislator (Gemeinsamer Bundesausschuss) as a 'standard' for the therapy in question (§34 Sozialgesetzbuch V).

tected by patents but enter open competition once their marketing authorization is granted.

It is important to note that in order to be classified as non-prescription drugs, OTCs may not contain *new* substances and active ingredients, the reason being that new substances fall under the *automatische Verschreibungspflicht* discussed above. Instead, OTCs may only contain substances of *well-established use*. Those are substances that have been marketed for a long time, having shown no harmful side-effects or other risks of consumption (§48 AMG). Products containing those substances are therefore considered 'safe enough' to be distributed more freely than Rx-medication. It can happen that a pharmaceutical substance is — at a low concentration — considered a substance of well-established use and therefore marketed as an OTC, while it is classified a Rx-pharmaceutical at higher concentrations (§48 AMG). For instance, the painkiller Ibuprofen can (independently of the producer) be purchased without prescription up to a dosage of 400 mg per pill, while any dosage going beyond it, such as 600 mg, is usually classified as a Rx-pharmaceutical.

This is an important characteristic of OTCs and their market, as it blocks classical pharmaceutical research as the source of OTC-innovations. In other words, if a pharmaceutical firm came up with a new substance suitable for the OTC-market, it would not be able to market it as such, due to the fact that it would automatically be classified as a Rx-product. So, if not through fundamental pharmaceutical research, what other options has a pharmaceutical firm to develop OTC-innovations?

1. Most OTCs are born out of *Rx-to-OTC switches (OTC-switch)*. An OTC-switch is an administrative process by which a Rx-drug is granted OTC status. The switch of a Rx-product can have two reasons: either it is actively initiated by a pharmaceutical firm as to prolong the life-cycle of a Rx-product once the patent expires or it is the result of a politically motivated transition of entire classes of drugs to OTC status (Cranz 1999: 573). The latter is a commonly used health policy tool to reduce healthcare costs (once a pharmaceutical is stripped of its Rx-status the consumer bears the cost). If a Rx-product is switched it may be marketed as an OTC without undergoing further regulatory procedures, as long as no changes of any sort are made.
2. In case new OTCs are to be developed independently of switches, pharmaceutical firms may only re-combine already existing substances of well-established use to a new product. Due to the high regulatory requirements, the marketing authorization process takes 2-3 years for those products (AESGP 2011: 208).
3. A third option of OTC-innovations within the regulatory realm is the extension of already existing product lines through the development of new product attributes. Yet, even in that case all steps of the authorization process must be passed trough as to obtain marketing authorization.

At the same time, however, OTCs are subject to largely the same regulatory controls as Rx-medicines. From a regulatory perspective, no substantial difference is

made between OTCs and Rx-products: the requirements with respect to safety, efficacy and quality are the same and in order to obtain a marketing authorization from the BfArM for an OTC, the same documents and certificates must be submitted than for Rx-pharmaceuticals. Also, the requirements regarding the production of OTCs are the same as for Rx-products (Sandner et al.: 254). In other words, pharmaceutical firms must undergo almost the same process of product development to obtain a marketing authorization for an OTC-innovation than for Rx-products. Yet, one major difference remains: no new substances may be employed.

German drug law differentiates between two kinds of OTCs: pharmacy-only OTCs (*apothekenpflichtige Arzneimittel*), which may only be sold through pharmacies and OTCs that can be freely marketed through other channels as well, such as drugstores or supermarkets (*freiverkäufliche Arzneimittel*). This represents a further gradation of consumer-protection regarding the access to pharmaceuticals. Pharmacy-only OTCs may only be sold under observation of the pharmacist; self-service is prohibited, which means that the product must be physically distributed by the pharmacist. This is to ensure expert advice regarding the intake and the possible side-effects or reciprocations of the OTC. Bayer's Aspirin™ is among the most prominent examples of freely marketed OTCs in the German market: it is a pharmaceutical that can be purchased without prescription, yet in pharmacies only.

In contrast, freely marketed OTCs may be distributed via self-service in pharmacies, drug stores or supermarkets. - The responsibility for consumption lies entirely with the consumer. Generally, those OTCs are among the least powerful medicaments with the least severe indications and a minimum amount of harmful side effects. German drug law (§44 AMG) requires them to carry indications other than the healing of acute illnesses and chronic ailments. In other words, they are required to be pharmaceuticals not serving their classical purpose as defined in §48, AMG. It is here where a certain grey area is entered and the notion of wellness, prevention and health-management in the larger sense enters the product claims.

The points of sale of freely marketed OTCs must provide some general knowledge about the sale of pharmaceuticals, in order to qualify for the distribution of OTCs (*Sachkundenachweis*). According to German drug law (§50 AMG) any retailer must employ a specially trained person as to ensure a responsible-minded storage and sale of pharmaceuticals. Retailers with more than one subsidiary must employ such a qualified person in every branch.

Freely marketed OTCs may also be sold in pharmacies and in fact more than half of them are (BAH 2010, 2011). While self-service is prohibited for pharmacy-only OTCs, freely marketed OTCs may — if sold in pharmacies — be openly accessible to the consumer (§ 17 Verordnung über den Betrieb von Apotheken). Usually, they fill the shelves that are not directly behind the counter and therefore beyond the physical control of the pharmacist.

In terms of advertisement, the legal situation is the same for both kinds of OTCs: in contrast to Rx-medication, OTCs may be advertised to the general public via any kind of media. However, form and content of the advertisement are still highly regulated (in contrast to advertisement for commodities). One requirement is the inclusion of a mandatory note of warning:

> "For risks and undesired effects, please read the patient information leaflet and ask your doctor or pharmacist." (§ 4, section 3 HWG)[57]

Any advertisement must include the name of the product and the producer, information regarding the product's active ingredients and composition, as well as of the indications, and potential harmful side effects of the product (§2 AMG; §4 HWG). Additionally, the advertisement for OTCs may not be deceptive in the sense of false mechanisms of action and healing. This is true for any kind of advertisement, yet is particularly strictly enforced in the case of pharmaceuticals. For instance, the advertisement may not connote certitude with respect to the success of the therapy or may not imply that the duration of the therapy is proportional to the probability of success. Also, OTC-advertisement must not be designed for the sake of competition but rather for consumer information only. Comparative advertisement is prohibited; only the results of studies and official test may be used to advertise the products independently from competing products. Phrases like 'clinical test have shown that...' or 'long-term studies have proven that...' are therefore usually to be found in OTC-advertisement (Weidner 2012: 17).

Discussion

The analysis is at this point looking for systemic conditions hindering the pharmaceutical industry from adapting its current OTC-innovation activities to the changing market conditions, bringing OTCs closer to the consumer. After all, the traditional market for self medication looks like the ideal starting point for an expansion of the industrial innovation activities towards health products. This is — in theory — right, as OTCs are in deed a consumer- and brand-driven products, whose market functions independently of physicians and prescriptions, targeting less serious indications than the traditional healthcare market. Also, their development is easier and quicker than that of Rx-products, as no lengthy R&D process for the identification of a new substance is required.

At the same time, the innovation activities of the pharmaceutical industry have not increased significantly during the last years: the number of OTC-marketing authorizations granted in 2012 did not even exceed the level of 2006 (table 6). This indicates that the pharmaceutical industry does not exploit their OTCs as a platform for adaptation of the innovation activities towards health products.

[57] This is a comprising translation of the legal text; for the exact German text see appendix.

There must be a reason for this. Does the regulatory corset in which the industry is embedded allow no such exploitation of the OTC-segment? As it has been shown above, regulations are the major force impacting OTC innovation activities: the development of new pharmaceuticals is to a very high degree dependent on the regulatory frame conditions to which the industry is subject. What does this imply with respect to the dynamics of innovation of the OTC-segment?

	Marketing Authorizations Granted						
	2006	**2007**	**2008**	**2009**	**2010**	**2011**	**2012**
Rx-medicines	2.367	1.987	2.027	2.494	2.749	2.528	2.428
Self Medication (OTC)	226	166	84	99	159	168	182
Total	**2.593**	**2.153**	**2.111**	**2.593**	**2.908**	**2.696**	**2.610**

Table 6: New marketing authorizations for pharmaceuticals in Germany, 2006-2012 (BAH 2005, 2006, 2007, 2008, 2009, 2010, 2011, 2012; own illustration) [Veterinary drugs excluded]

First and foremost, it must be underlined that the *automatische Verschreibungspflicht* for any new active ingredient allows for no fundamental OTC-innovations in the sense of new substances developed for the self medication market. Instead, OTC-innovations are necessarily by-products of Rx-innovation activities of the pharmaceutical industry, as they are in every case switched Rx-products: either they are recombinations of switched Rx-ingredients (substances of well-established use) or they are Rx-products that have been switched to OTC-status without any 'innovative change'.

This has important implications for the opportunities of the pharmaceutical industry in the health products market: it can be argued that the limited degree of novelty that OTCs can possess makes it impossible for the pharmaceutical industry to exploit its core strength, namely the fundamental pharmaceutical research, for the sake of the OTC-market. This naturally reduces the possibilities of an evolutionary growth at the boundaries of the industry's innovation activities.

However, this does not mean that the pharmaceutical industry has no other options than OTCs for an extension of its innovation activities to the health products market and one could argue at this point that the industry can easily adapt to the regulatory difficulties by focusing on health products instead of OTCs. As we will discuss below, this is already happening to some degree. Yet, it is certainly important to note that the regulatory barriers to fundamental OTC-innovations hinder the industry from transferring its *core* business — namely pharmaceuticals — to another stage and market. This means in turn that pharmaceutical firms have huge disadvantages when trying to compete directly with the innovators in the food and cosmetics industries who are free from those constraints with respect to their traditional field of innovation.

Secondly, by applying a uniform set of regulatory tools with respect to drug safety and quality to Rx-pharmaceuticals and OTCs alike, German drug law fails to mirror the diverging needs of the two product segments and markets (Sandner et al. 2011: 254). The complexity of the marketing authorization process that OTCs must pass through makes OTC-innovations lengthy and expensive, relative to their already limited degree of novelty. Additionally the same regulations regarding production apply to OTCs than to Rx-medicines, increasing the production expense of OTCs.

At the same time, OTCs cannot yield the same return on investment as Rx-products: neither is their purchase reimbursed by health insurance companies, nor do they enjoy the freedom with respect to the pricing and the almost guaranteed sales through patent protection that Rx-innovations benefit from. Pharmaceutical firms must cover the high R&D costs for their OTC-innovations in a less regulated consumer market where — as the state protection of prices enjoyed by Rx-products is absent — margins are significantly lower than in the Rx-market. After all, it must be kept in mind that the costs of innovation of all OTCs are — due to the regulatory conditions — comparable. This produces different market realities for OTC-innovations: in contrast to the Rx-market that is decoupled from the real consumer-demand for pharmaceuticals, allowing the producing firm free price-setting under the protection of patents, OTC-innovations must be priced according to competition and demand (after all the consumers make the purchase decision themselves). Naturally, this results in significantly lower selling prices for OTCs than for Rx-medicines. In terms of units sold the OTC-market is bigger than the Rx-market, yet revenues show that the Rx-market is by far more profitable (table 7). Selling prices for OTCs are significantly lower than for Rx-products (table 8). Bayer provides a good example: Aspirin™, the company's strongest OTC and one of the world's strongest OTC-brands (marketed in more than 80 countries), generated revenues of only €440 million 2011, while Bayer's strongest Rx-product, Betaferon™, generates almost three times that amount (Bayer 2011). The one Rx-product alone is thereby responsible for far more than 10% of Bayer's overall healthcare revenues (tables 9 and 10).

	Market Size (€m)	Proportion	Market Size (units m)	Proportion
Rx-medicines	33.530,0	84,53 %	692,0	46,80 %
Self Medication (OTC), pharmacy	5.610,0	14,14 %	679,0	45,92 %
Freely Marketed	528,5	1,33 %	107,8	7,29 %
Pharmacy (pharmacy-exclusive)	288,5	0,73 %	36,8	2,49 %
Drugstores	138,0	0,35 %	39,1	2,64 %
Supermarkets	55,3	0,14 %	20,4	1,38 %
Online-pharmacies	32,2	0,08 %	3,8	0,25 %
Discounters	8,6	0,02 %	4,9	0,33 %
Traditional food retailers (Sales Area <800 m2)	5,9	0,01 %	2,8	0,19 %
Total Market Size	39.668,5	100,00 %	1.478,8	100,00 %

Table 7: The market for pharmaceuticals in Germany (2011) in terms of sales at consumer prices and channels of distribution (BAH 2011, IMS data; own illustration)

	∅ **Consumer Price per Package** (€)		
	2010	**2011**	**2012**
Rx-medicines	48,32	48,45	49,28
Pharmacy-only OTC*	7,83	7,86	8
Freely marketed OTC	3,17	3,16	3,19

Table 8: Average consumer prices for pharmaceuticals (BAH 2010, 2011, 2012; own illustration)

* Online pharmacies and mail-order businesses are included; OTCs on prescription (OTXs) are excluded from the calculation

Rx	**2010** (€m)	**2011** (€m)	**OTC**	**2010** (€m)	**2011** (€m)
Betaferon™	1.206	1.117	Aspirin™	418	440
Kogenate™	1.004	1.075	Aleve™	273	285
YAZ™	1.111	1.070	Bepanthen™	212	235
Nexavar™	705	725	Canesten™	210	224
Adalat™	664	640	One a Day™	178	174

Table 9: Top 5 Rx and OTC products at Bayer in terms of revenue (Bayer 2011; own illustration)

	2010	**2011**	**± Δ on previous year (%)**
Pharma	9.954	9.949	-0,1
Consumer Healthcare	6.959	7.220	+3,8
Consumer Care	3.371	3.534	+4,8

Table 10: Bayer: revenues by business section for 2010 and 2011 (Bayer 2011; own illustration)

As table 8 shows, selling prices for OTCs are even significantly lower outside the pharmacy, the reason being the open pricing pressure in retail, partly generated by the dominance of a few big retail chains. In that sense, Aspirin™ is still well off, as it is sold in pharmacies. The selling price of freely marketed OTCs in contrast to their pharmacy-only counterparts is even lower, reducing the margins further. Table 7

shows the large ratio of units of freely marketed OTCs sold and the revenue generated from it, producing the low margin. Certainly, this makes innovation activities regarding freely marketed OTCs economically even less attractive then pharmacy-only OTCs. The market size of both OTC-segments reflects this; pharmacy-only OTCs represent 91% of the entire market for self medication in 2011 (figure 15). One may assume that this contributes to the fact that more than half of the freely marketed OTCs is exclusively sold through pharmacies, even though their legal status allows also the distribution through other channels. This portion contributes for 5% of the entire market for self medication; only 4% of the OTC-revenues generated by the pharmaceutical industry in Germany is generated outside the pharmacy (figure 15).

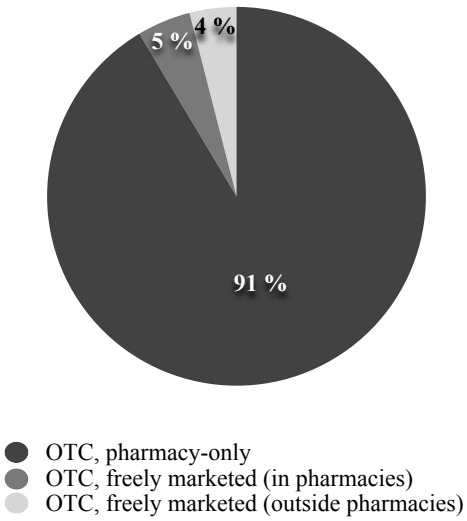

Figure 15: The market for self medication (sales) in terms of distribution channels (IMS data; own illustration)

The tensions between the regulatory conditions and the market realities of OTCs must be seen as a second major force of dependence, creating rigidity to change. It indicates that an expansion of the OTC-innovation activities to the field of health products would — ceteris paribus — be economically unattractive, if not to say destructive for the pharmaceutical innovator, the reason being the imbalance between the institutionally required costs of innovation and the lack of protection in the market. In order to put OTCs into competition with health products, innovators must be able to develop and produce them cheaper than today and distribute them beyond the pharmacy. It is understandable that, as long as the regulatory requirements for pharmaceuticals keep ignoring the different realities of OTCs and Rx-medication, dependences remain, holding self medication in its status quo.

Another regulatory disadvantage of self medication that strengthens the position of the pharmacy and decreases the attractiveness of OTC-innovations further is surely the the *Sachkundenachweis* that selling points for freely marketed OTCs must provide. Health products are non-pharmaceuticals and can therefore be sold through

any selling point (drugstores, supermarkets, retail stores, discounters , etc.). The fact that this freedom is limited for freely marketed OTCs is certainly a regulatory disadvantage. Again, potential dynamics of innovation of the self medication are paralyzed: how could a pharmaceutical firm possibly transform its OTCs into more of a health product if those products could then not access the mass market but would be limited to a relatively small part of it? Table 11 illustrates this paradox: the number of selling points for pharmaceuticals in the mass market equals just the number of pharmacies in Germany. This indicates that the pharmaceutical industry reaches only a fraction of the total amount of selling points of the German mass market with a total of about 15.000 drugstores and 55.000 supermarkets (including discounters and heath shops).

	Number of selling points
Pharmacies	21.481
Drugstores	12.950
Supermarkets	8.635
Health shops[1]	1.448
Total	**44.514**

Table 11: Points of sale for pharmaceuticals in Germany in 2010 (BAH 2010; own illustration)

1 *Reformhaus*

Certainly the speed at which OTC-innovations can be realized contributes to the dilemma of self medication, too. As it has been outline above, the health products market is trend-based; health products are fast-moving consumer goods with relatively short life-cycles and high rotation. OTCs are designed for consumer markets, yet require development times of up to three years, even if only minor product attributes are changed in order to extend a product line. They must consequently serve two masters at a time: research and regulation on the one hand and the consumer at the other. This leads automatically to a speed of innovation that cannot keep pace with that of health products, who are not required to complete the same lengthy regulatory procedures. Logic suggests that these are disadvantageous conditions for OTCs to face competition from the health products market.

Another regulatory frame condition to be discussed here is the restricted freedom of advertisement regarding pharmaceuticals. Pharmaceutical firms may actively market and promote their OTCs, yet with considerable restrictions, ranging from product design and packaging to regulations regarding health claims and promotion campaigns (i.e., no free samples). This is another facet of the regulatory regime on which the industry is embedded and reduces the possibilities of expanding the OTC segment of the industry to the health products market further. After all, the consumer-oriented extended healthcare market is driven by marketing and advertisement. - Products that may be advertised restrictedly only have little chances to success.

The preceding discussion has shown how the regulatory framework conditions in which the German OTC-industry (as a subpart of the pharmaceutical industry) is embedded hold the dynamics of innovation for self medication products in its current status quo. The main aspect of the regulatory 'dilemma' in which the market for self medication finds itself is the contradiction between the Rx-orientation of the OTC-regulations on the one hand and the OTC-market conditions. It explains why, even though OTCs are positioned 'closer' to the consumer than Rx-medicines, the OTC-market is not growing in size (even 'conservative' OTC-innovations cannot be called rewarding) and — more importantly for this analysis — can hardly induce a strategic reorientation towards health products. The regulatory 'corset' guiding the innovation can be considered a major source of resource dependence regarding the OTC business of the pharmaceutical industry. Obeying to the rules of innovation provides the 'increasing benefits' (Sydow et al. 2009: 694) that characterize resource rigidity (see Gilbert 2005); put differently, a strategic reorientation away from OTCs as simply the by-products of Rx-products would put an end to the benefits that OTC-innovations generate. Evidence suggests that the regulatory frame conditions lying beyond the control of the firm render it (independently of the firm's ambitions) impossible for the pharmaceutical industry to expand the innovation activities of the traditional second healthcare market to the field of self care. This is an important insight as it means that the core business of the pharmaceutical industry — pharmaceuticals — cannot directly be extended to the new market; the regulatory conditions inherent to the sectoral system of innovation disrupt the evolutionary process of adaptation that one would expect and makes change in this respect impossible.[58]

However, there is a second aspect to the analysis of the framework conditions as a source of resource dependence. It has been shown earlier that the pharmaceutical industry has already responded to the growth of the self care market by launching a (small) range of health products. Also this segment seems unable to respond to the pressures of the new healthcare markets, which seeks explanation.

5.1.1.1.2. Non Pharmaceuticals - Health Products

Pharmaceutical firms have started to include health products into their portfolios in the 1990s when the expansion of the healthcare market to non-pharmaceuticals picked up pace (Plantör 2006: 7). Until that point the product category between pharmaceuticals and commodities (foods and cosmetics) was non existent.

There is no clear definition of health products, as they are not clearly legally defined; in general, it is used as an umbrella term for various product groups. According to broad definitions, they are products of self medication (OTCs), food supplements, dietetic foods, medicinal products, special cosmetics and Functional Foods

[58] This, however, shall not imply that within the prevalent market, OTCs are unable to play an important role in the future whatsoever. As the issue of prevention will remain important and even become more important, OTCs will surely retain their right to exist (see Sigrist 2007), independently from their ability to transform and grow into the market for self care

(Plantör 2006: 7). This represents the entire range of self care products between Rx-pharmaceuticals and ordinary foods and cosmetics.

Other definitions are narrower, counting OTCs as health products if they carry 'light' claims only, positioning them closer to health-related indications than to 'hard' illness-related ones. An example for such a differentiation would be a medicinal tea (i.e., an amber infusion) versus an anti-inflammatory OTC (Sandner 2006: 16). While formally both products are pharmaceuticals, the strength of their indications and health claims differs, positioning the tea much closer to non-pharmaceuticals. This might justify the inclusion of some freely marketed and pharmacy-exclusive OTCs in the definition of health products.

From an even narrower perspective, health products contain only those non-pharmaceuticals that are competing directly with classical OTCs, in the sense that they are substitutes. This 'substitution principle' assumes that any food or cosmetic with health claims or product attributes similar to those of OTCs is a health product, as it could (from a consumer perspective) replace OTCs. IMS Health and the German Association of the Producers of Pharmaceuticals (BAH) follow this view by defining health products as food supplements and dietetic foods, medicinal products and — to some degree — special cosmetics. This includes both distribution channels accessible for those products: pharmacies (non-pharmaceuticals as pharmacy-exclusive parapharmaceuticals) and the mass market. What those products have in common is their pharmaceutical-like or 'parapharmaceutical' appearance, which positions them rather close to pharmaceuticals.

This excludes Functional Foods, as they are not characterized by parapharmaceutical attributes and are therefore closer to foods than to pharmaceuticals. According to IMS Health they can therefore not compete as directly with pharmaceuticals than the other product categories.

In fact the boundaries between classical health products, as defined by IMS Health and the BAH and Functional Foods are thin and somewhat artificial. In general, dietary supplements, medicinal products and dietetics have a therapeutic purpose, even though they are not pharmaceuticals. Functional Foods and cosmeceuticals are mainly foods/cosmetics, with a therapeutic upgrade. However, often only 'soft' attributes differentiate ordinary Functional Foods or cosmeceuticals from the classical health products. For instance, a cholesterol-lowering spread is closer to a health product than a vitamin-enriched yoghurt with a general health claim, yet both are Functional Foods.

Of course, the understanding of health products differs between the industry players. The view of health products as quasi-drugs or parapharmaceuticals (non pharmaceuticals with attributes of pharmaceuticals) reflects the standpoint of the pharmaceutical industry. In contrast, from the perspective of the foods industry, health products are mostly Functional Foods and — to some degree — food supplements. Figure 16 illustrates this situation: the pharmaceutical industry and the foods

and cosmetics industry approach health products from different angles, which produces diverging innovations in that field.

Consequently, the definition of health products and of the corresponding market must include Functional Foods and cosmeceuticals, at least partially. Even though they are farthest away from pharmaceuticals, in terms of purpose and design they represent the transportation of health-issues beyond the boundaries of the classical market for pharmaceuticals. While the centre of the health products market is certainly to lie with the classical OTC-substitutes as defined by the BAH and IMS Health, Functional Foods and special cosmetics may not be ignored (figure 16). The market of health products, including parts of the Functional Foods can therefore be referred to as the 'extended OTC-market'.

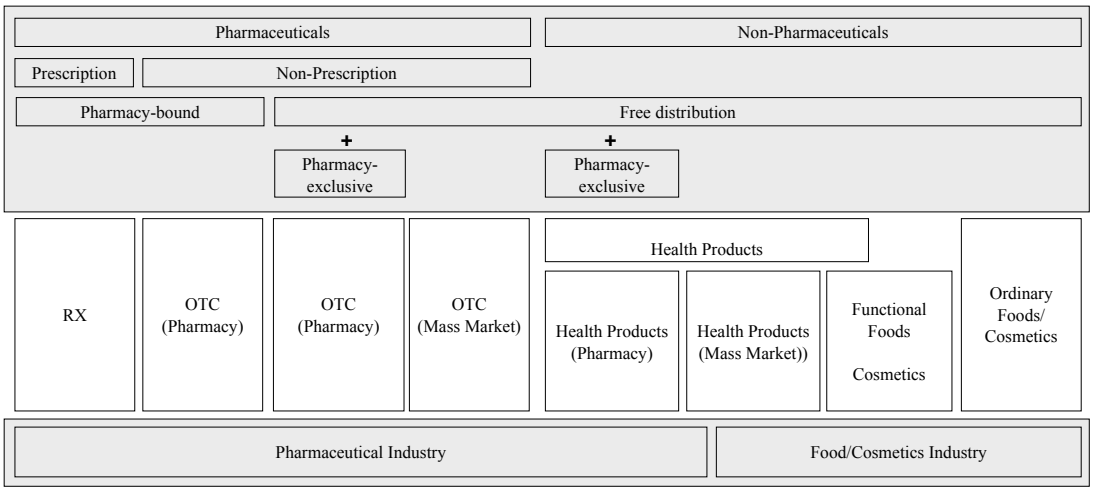

Figure 16: The second healthcare market in context (own illustration) [The size of the boxes is not representative of the size or potential of the market segments listed].

Like the previous passages on OTCs, the following passages of this chapter present the regulatory regimes of the different types of health products, followed by the discussion of the resource dependences that might flow from them with respect to health products innovations.

Food Supplements

Foods supplements represent the biggest and probably most important type of health products. According to European and German law, food supplements are foods

1. assigned to supplement the general nutrition.

They may be

2. a concentrate of nutrients or other substances that — alone or combined with each other — have a physiological or nutritional effect.
3. They are marketed in dosed quantities, especially in the form of capsules, lozenges, tablets, pills, effervescent tablets or a similar administration form. Al-

> ternatively, they can be marketed in the form of liquids or powders suited for accurate dosage of small quantities of consumption (ampules, bottles with portioning device, powder sachets) (§1 NemV, Nahrungsergänzungsmittelverordnung).[59]

In terms of ingredients, various vitamins, minerals and mineral substances may be used in the manufacture of food supplements.[60] The guidelines concerning the administration form of food supplements are crucial, as they bestow food supplements with parapharmaceutical outer product characteristics (*Arzneimitteltypische Darreichungsform*); even though they are foods, their administration form gives them a pharmaceutical-like appearance.

The major difference between pharmaceuticals and foods in terms of the innovation process is the regulatory environment. While the barriers to marketing authorization of pharmaceuticals are extraordinarily high, foods in general require no marketing authorization or other regulatory permission for market introduction (Sandner 2006: 21). Instead, a new product must 'only' be registered with the *European Food Safety Authority* (*EFSA*) on the European level and the *Bundesamt für Verbraucherschutz und Lebensmittelsicherheit* (*BVL*) on the German level. The BVL is not obliged to inspect the product registered.

The only exception are *Novel Foods*. These are foods or ingredients of foods (*zulassungspflichtige Zusatzstoffe*) that were not in the market before 1997. Often, those are foreign or highly modified *designer foods*, for instance foods with changed molecular structures (i.e., fat substitutes), foods from certain microorganisms and algae, or foods that are produced using novel techniques whose effects on the product and the human organism is not yet entirely known (Artikel 1, *Novel-Food Verordnung*). Novel Foods need to go through an authorization process and may only be marketed if the EFSA considers them harmless to the human health. Once the novel food is authorized it may be marketed or (if it is a novel ingredient only) incorporated into another product for the health products market. This resembles the process of marketing authorization of a pharmaceutical with the BfArM, as it is concerned with product safety and consumer protection. The authorization process for foods is, however, considerably less lengthy and expensive than for pharmaceuticals, as it includes no or only very small studies on the novel food. Also, once the EFSA has passed studies on foods, new products can be constructed from different foods and ingredients, based on those studies. This would be unthinkable for OTCs, where any recombination of substances of well-established use required extensive clinical studies to be made in order to attain a marketing authorization for the product.

To be marketed as health products, foods need *health claims*. The European Health Claims Directive (European Parliament 2006b) provides the legal guidelines

[59] The European Directive 2002/46/EC of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements was incorporated into German law in 2004 as the Nahrungsergänzungsmittelverordnung (NemV). For the exact German text see appendix.

[60] For a full list of those ingredients see the annexes to the directive 2002/46/EC (European Parliament 2002).

for the statements that the innovator may make with respect to the health-benefit of the food product. Basically, the directive differentiates between three claims that foods can make (European Parliament 2006b):

1. *Nutrition claim*, being

> 'any claim which states, suggests or implies that a food has particular beneficial nutritional properties' due to the energy (calorific value) or the nutrients or other substances it does or does not provide or contain in reduced or increased amounts (European Parliament 2006b: Art. 2)

2. *Health claim*, being

> 'any claim that states, suggests or implies that a relationship exists between a food category, a food or one of its constituents and health' (European Parliament 2006b: Art. 2)

3. *Reduction of disease risk claim*, being

> 'any health claim that states, suggests or implies that the consumption of a food category, a food or one of its constituents significantly reduces a risk factor in the development of a human disease.' (European Parliament 2006b: Art. 2)

Within the legal boundaries, health claims and reduction of disease risk claims are of the biggest interest for innovators of health products (Sandner 2006:25), as they bestow the food product with the parapharmaceutical image that characterizes health products. Since 1 January 2012 a white list and a negative list are available, listing all sorts of claims that may or may not be made. Their variety is of course restricted by those lists; according to European legislation,

> 'nutrition and health claims may be used in the labeling, presentation and advertising. […] [They] shall not:
>
> (1) be false, ambiguous or misleading;
>
> (2) give rise to doubt about the safety and/or the nutritional adequacy of other foods;
>
> (3) encourage or condone excess consumption of a food;
>
> (4) state, suggest or imply that a balanced and varied diet cannot provide appropriate quantities of nutrients in general. […]
>
> (5) refer to changes in bodily functions which could give rise to or exploit fear in the consumer, either textually or through pictorial, graphic or symbolic representations.' (European Parliament 2006b: Art. 3)

Interestingly, the obligations to produce proof of the validity of the health claims differs among the three types. While nutrition claims and health claims can be justified rather easily (often no or only simple studies are required), reduction of disease risk claims require much sounder scientific studies. They are still not comparable to pharmaceutical studies, yet significantly more complex than the studies for the other types of health claims.

Despite their parapharmaceutical characteristics, food supplements are, however, foods in the first place. Any similarity with pharmaceuticals must be avoided (European Parliament 2002: Art. 2; Sandner 2006: 30). According article 2 of the European regulation on food law and safety (European Parliament 2002), a food can be

> 'any substance or product, whether processed, partially processed or unprocessed, intended to be, or reasonably expected to be ingested by humans. […] [It] includes drink, chewing gum and any substance, including water, intentionally incorporated into the food during its manufacture, preparation or treatment.'

This is of course a very broad definition that could also apply to pharmaceuticals. In order to differentiate health products from pharmaceuticals, article 2 of the same European regulation 178/2002 states at the same time clearly that food must not include pharmaceuticals. Nevertheless, as Sandner (2006: 30) claims, it can easily occur that a product could be classified as food and pharmaceutical simultaneously. For instance, a marketing authorization for vitamin C (1000 mg) as an OTC exists in Germany, while it is authorized as a food supplement at the same time. According to European legislation,

> '[i]n cases of doubt, where, taking into account all its characteristics, a product may fall within the definition of a "medicinal product" and within the definition of a product covered by other Community legislation the provisions of this Directive shall apply.' (European Parliament 2002: Art. 2)

In other words, whenever the situation is unclear, a product is considered a pharmaceutical rather than a health product.

Dietetic Foods

The second type of foods among health products are dietetic foods. Like food supplements they are modified foods. However, in contrast to the former, dietetic foods are designed for special nutrition for

1. sick people;
2. people who are in a 'special physiological condition';
3. healthy infants and babies (§1, section (2), Diätverordnung)

The regulatory effort for marketing a new dietetic food is slightly larger than for Functional Foods (Sandner 2006: 33), which positions them closer to pharmaceuticals. This is mainly due to two facts: the German *Diätverordnung* (*DiätV*) requires the target groups (patients) for dietetic foods to be clearly identifiable, by common symptoms or sicknesses (i.e. diabetics or patients with inflammatory bowel diseases) (Sandner 2006: 32). Health claims may therefore not just address general well-being, as food supplements often do, but must be disease-related. This relatedness must of course be scientifically proven. At the same time the target group must provably have

the medical need for a special nutrition, such as an increased consumption of nutrients or the need for a special combination of nutrients. This bestows dietetic foods with properties similar to the pharmaceutical indication.

Consumers in a 'special physiological condition' represent a special case, as they are not necessarily sick. For instance, pregnant women or performance sportsmen are considered to be in such a condition. Dietetic foods can therefore be designed for healthy people who just need a special diet to compensate for the conditions they are in. However, the consumers must be in the special physiological condition at the time they consume the dietetic food; a dietetic food may not carry a preventive claim, such as 'as a preventive therapy before a pregnancy' (Sandner 2006: 34).

This automatically produces higher regulatory barriers to market entry. Despite them, however, dietetic foods enjoy two advantages in contrast to food supplements: firstly, the range of ingredients allowed to use for manufacture is larger (vitamins, mineral substances, amino acids, other acids, carnitines, taurine, nucleotides)[61] and secondly, their disease-related health claims represent an advantage over the general health claims of Functional Foods, as they allow to name concrete diseases. In general, foods must not make advertising claims as targeted as this, as to avoid delusion concerning their therapeutic effects.[62] The exclusion of dietetic foods from that give innovators more freedom regarding marketing and advertisement.[63]

Functional Foods

The third group of foods to be mentioned is Functional Foods. Those products are certainly farthest away form pharmaceuticals, in terms of product design and composition. Yet, they represent a segment of the health products market and the major field of activity of the foods industry, therefore being worth a closer look.

Hasler (2002) states that

> '[f]unctional foods can be considered to be those whole, fortified, enriched or enhanced foods that provide health benefits beyond the provision of essential nutrients (e.g., vitamins and minerals), when they are consumed at efficacious levels as part of a varied diet on a regular basis.' (Hasler 2002: 3772)

Just like food supplements and dietetic foods, Functional Foods are products combining nutrition and health. Functional Foods differ from food supplements and dietary

[61] For a full list of allowed ingredients see appendix 2 of the Diätverordnung. Appendices 3-23 regulate the exact dosages and combinations of the ingredients.

[62] For details on the prohibition of disease-related advertisements for foods in general and the exclusion of dietetic foods from it, see §12, Lebensmittel-, Bedarfsgegenstände- und Futtermittelgesetzbuch (LFGB): Verbot der krankheitsbezogenen Werbung.

[63] This freedom is limited as disease-related claims may not be made for all indications of dietetic foods (see §3, DiätV). The restrictions apply for the majority of the major fields of indication. Yet at the same time, all dietetic foods are required to carry a compulsory food labeling, including information about the nutritional content and purpose. When disease-related health claims cannot be made, innovators often use those labels to make claims indirectly (Sandner 2006).

foods in terms of the administration form. While food supplements and dietetic foods are (and must be) presented in a parapharmaceutical fashion (small, parceled dosages; disease related health claims, etc.), Functional Foods are very close to regular foods and free with respect to their administration form. Functional Foods can and shall be consumed like commodities and have healthy 'side-effects' only, rather than a health-benefiting purpose and self-conception (Plantör 2006: 14). Put differently, they are mainly foods, yet with a health upgrade. In contrast, dietetics and food supplements are mainly health products, with a food being the vehicle only. Consequently, the competition of Functional Foods are mostly other foods, rather than pharmaceuticals. This differentiates Functional Foods from the other groups of foods as health products:

> 'whatever definition is chosen, "Functional Food" appears as a quite a unique concept that deserves a category of its own, a category different from nutraceutical, f(ph)armafood, medifood, designer food or vitafood, and is also a concept that belongs to nutrition and not to pharmacology. Functional Foods are and must be foods, not drugs. Moreover, their role regarding disease will, in most cases, be in 'reducing the risk' rather than 'preventing' it. (Roberfroid 2002: 134)

While dietetic foods and food supplements represent the immediate borderline between drugs and health products, Functional Foods can be seen as their counterpart at the border between health products and foods/commodities.

Except for novel foods, which must be officially licensed before being marketed or added to products, Functional Foods per se need no formal marketing admission. The requirements for a Functional Food to be marketed are the same as for ordinary foods, concerning composition, safety, labeling and promotion. Core regulations concern the nutritional added value of Functional Foods which may not be deceptive (§11 LFGB, Lebensmittel, Bedarfsgegenstände- und Futtermittelgesetzbuch) and the advertisement, which may not be illness-related (§12 LFGB). If illness-related claims are made, they must be proven and scientifically tested (yet at another level of detail than pharmaceuticals). Additionally, the European directive on health claims (European Parliament 2006b) discussed above is also valid for Functional Foods. Similarly, the number of vitamins and mineral substances Functional Foods may contain as to bestow them with an added nutritional value is regulated.[64]

No restrictions are made with respect to what foods Functional Foods can be, with the exception that they may be regular foods only (Plantör 2006: 14). Popular Functional Foods in Germany are prebiotic and probiotic products, *ACE-drinks* (fruit juice with high concentrations of vitamins A, C and E) and products with omega-3 fatty acids (Plantör 2006: 14). Unilever's Becel™ is a prominent example of the latter category. The margarine is particularly rich in omega-3 and omega-6 fatty acids. According to its health claim, Becel™ can thereby contribute to holding down the

64 The European directive 1925/2006 (European Parliament 2006a) includes a list of allowed additives and their amount.

cholesterol level, preventing vasoconstriction and cardiovascular diseases. Recently, Unilever launched Becel pro aktiv™, which makes an even more daring promise as it claims to be actively reducing a high cholesterol level, rather than just preventing it from rising. The high concentration of plant sterols in the margarine is said to be responsible for this effect. The product is heavily criticized by consumer protectors and food analysts for its health claims that are clearly at the borderline to those of Functional Foods or even pharmaceuticals. This underlines once more how thin the borderline between the different categories of health products is.

Medicinal Devices

Medicinal devices represent another category of health products that has enjoyed ongoing success over the last decades. According to the Medizinproduktegesetz (§3, section 1), medicinal products are medically effective products with mechanisms of action that are mainly physical. They are designed for the use in and on the human body (see also Sandner 2006: 45). Medicinal products are different from other health products in the sense that they may not only be medicinal preparations, but also instruments, technical devices and appliances or even special software that support or carry out the product's medicinal purposes. This produces a very broad spectrum of what medicinal devices can be, ranging from bandages, materials for surgeries, (active) implants, electro-medicinal devices and dental devices up to diagnostic agents and testing devices (i.e., pregnancy or diabetes tests); it is therefore not the medicinal effect but rather the intended purpose of the product that defines a medicinal product (Sandner 2006: 45).

Often, the regulatory distinction between medicinal devices and pharmaceuticals is — as it is the case with all health products — difficult. For instance, lactic acid bacteria may be marketed as medicinal devices if their purpose is to change the pH-value at the location where they are applied. In contrast, they are classified as a pharmaceutical if they have an impact on the immune system as a whole (Sandner 2006: 45). Even distinguishing between a functional food and a medicinal device can be difficult. An example for a product on the borderline between the two product categories are certain capsules for weight reduction that multiply their volume once swallowed (as to soak up gastric acid, thereby reducing a feeling of hunger). Their mode of operation is clearly physical, which makes the product a medical device. At the same time it is a capsule, administered orally. This positions it close to being a parapharmaceutical and therefore a food supplement (Plantör 2006: 9). Other common medical devices in the German market are certain seawater nasal sprays, artificial tears, contact lenses, defoaming agents for the gastrointestinal tract or even dialysis machines (Plantör 2006: 9; Sandner 2006: 48).

For certifying for a medicinal product for market introduction, the producer needs to provide clinical data on the degree of risk of the product (§19, section 1, Medizinproduktegesetz). The product is then classified along four risk classes: class

1 for very low risk, class 2a and 2b for medium risk and class 3 for high risk (Sandner 2006: 45).

The certification of a medicinal product is similar to the marketing authorization of a pharmaceutical, yet it is easier and much quicker to obtain (the certification for class 1 products, for instance, can be done by the producers themselves). In contrast to pharmaceuticals, the channel of distribution is not regulated; the producer of a medicinal product can therefore freely chose whether to place the product in the pharmacy or in the mass market (Sandner 2006: 47). In terms of advertisement and marketing the situation is similar to that of foods: health claims can be made and used for advertisement purposes.

Overall, medicinal devices offer the same advantages as the other types of health products presented above. They can be an attractive way to introduce new products to the market without undergoing the long and expensive marketing authorization process of pharmaceuticals. Also, the more liberal situation regarding health claims and advertisement add to their attractiveness. What they also share with the other health products, however, is the lower degree of legal security, due to the lacking marketing authorization or patent.

Cosmetics

The last category of health products is cosmetics. Cosmetics are substances or compounding that are applied to the outside of the human body or to the oral cavity, with the purpose to clean, protect, maintain, perfume, change appearance or change the scent of it (§2, section 5, Lebensmittel-, Bedarfsgegenstände- und Futtermittelgesetzbuch). They can either have a decorative or nurturing function (Plantör 2006: 10).

What is central to the position of cosmetics among the health products is the nurturing and protecting function they can have. In this context, cosmetics can carry claims regarding prevention of diseases, just as long as it is prevention in the sense of protection (Sandner 2006: 50). Otherwise, if its purpose were prevention through pharmacology or even to heal, it would be classified as a pharmaceutical.

Like all other health products, cosmetics/cosmeceuticals require no registration with health authorities. Producers of cosmetics are obliged to test safety, efficacy and risk of the product, yet no official validation of the data through health authorities takes place. Negative lists name substances that may not go into cosmetics, as well as the maximal amount of others (Sandner 2006: 51). All substances that are not named in the lists are allowed to go into a cosmetic. This includes some substances that are (at higher dosages) pharmaceuticals or pharmaceutical ingredients (Sandner 2006: 52). Therefore, the regulatory distinction between cosmetics and pharmaceuticals is — again — difficult and very much dependent on the context in which the health claim of the cosmeceutical is justified by the producing firm.

Discussion

What can be concluded from the discussion of the regulatory environment for health products? What does it contribute to the understanding of resource dependences of the pharmaceutical industry? In the case of pharmaceuticals the situation was clear: regulatory frame conditions render an extension of OTC-innovations closer to health products unreasonable, if not possible.

The opposite is apparently true for health products: from a regulatory perspective, obstacles to innovations that are beyond the industry's control are absent. This might sound simplistic and only too obvious, yet it is relevant for the understanding of the situation. It shows that in contrast to pharmaceuticals, health products can be developed and marketed relatively easily. Perhaps most importantly, the major regulatory barrier to innovations in the OTC-market, the *automatische Verschreibungspflicht*, applies not to health products. Consequently, the range of development possibilities is much larger than with pharmaceuticals, yet at the charge of 'hard' claims and indications as possible with pharmaceuticals.

Despite the limitations that the Health Claims Directive imposes on the nutrition and health claims made on foods, the regulatory freedom of health products regarding the auditability of studies for product claims is still large, compared to pharmaceuticals. The lack of creative leeway for innovations characterizing the market for pharmaceuticals cannot be identified in the field of health products. Disease-related statements may be made and the toxicological and pharmacological research to underpin the claim is small-dimensioned relative to pharmaceuticals.

Products can be developed much cheaper and quicker than OTCs and can be advertised and marketed freely. No long and expensive marketing authorization process must be undertaken for introducing a new Health Product to the market. Instead, only a registration with the responsible authorities is needed. This is crucial as it cuts costs drastically and shortens the development time of a Health Product to six months on average, as compared to 3-10 years for OTCs. After all, being a market of fast moving consumer goods with short product life-cycles and fierce competition, speed of innovation is a success factor in the health products market (Sandner 2006: 21).

Also, relative to pharmaceuticals, production of health products is cheap and quick and the choice of distribution channel is not legally restricted. All health products may be sold in pharmacies, drugstores, supermarkets or traditional retail. Finally, advertisement is less regulated as well: health products may be openly advertised, including disease-related claims that may be made.

This creates a situation of high regulatory attractiveness of health products innovations, relative to pharmaceuticals. Those regulatory dependences that were identified for OTCs are clearly absent in the case of health products.

Yet, when estimating the attractiveness of the regulatory environment for health products innovations, the market structure must also be considered. Just like in the case of OTCs, the pharmacy market differs significantly from the mass market in terms of feasible selling prices and ultimately the innovator's margins. The average price level of pharmacy-exclusive health products and pharmacy-only OTCs is comparable, making pharmacy-only health products — in light of their cheap development — financially relatively attractive (table 12). [65] In contrast, selling prices in the mass market are drastically lower (table 12), while the production and development costs for health products remain the same, independently of the distribution channel chosen for them. As the data shows, compared to OTCs, the discrepancy between the two distribution channels is even larger for health products. Additionally, the opportunity for sufficient margins is reduced further by the high advertising and promotion intensity that health products require.

	∅ Consumer Price per Package (€)		
	2010	**2011**	**2012**
Pharmacy-only OTCs*	7,83	7,86	8
Pharmacy-exclusive health products*	8,09	8,53	8,81
Freely marketed OTCs	3,17	3,16	3,19
Freely marketed health products	1,61	1,64	1,68

Table 12: Consumer selling prices per package for OTCs and health products 2010-2012 (IMS Data; own illustration)

* Online pharmacies and mail-order businesses included

The discrepancy of the margins (resulting from the lack of 'regulatory protection' of health products) turns the mass market for health products into a much less attractive field. Health products lack the regulatory protection mechanisms that pharmaceuticals enjoy: neither patent nor marketing authorizations and the possession of exclusive studies safeguard the products form imitation and fierce competition. This applies to both distribution channels, as pharmacy-exclusive health products enjoy no additional protection from competition or advertisement pressure. The regulatory inferiority of health products to pharmaceuticals allows no selling prices at the same level as for OTCs in the mass market. This explains (at least partly) the innovatory focus of the pharmaceutical industry on the pharmacy as their exclusive distribution channel for health products. The growth of the pharmacy-market of health products over the last three years underlines this (figures 17a and 17b).

[65] In fact, most pharmacy-only OTCs reach higher prices than pharmacy-exclusive health products, due to the regulatory superiority of pharmaceuticals over non-pharmaceuticals. However, generic OTCs (i.e., ASS Ratiopharm™, IbuHexal™, etc.) represent a large quantity of OTC sales in terms of units, which brings down the average selling price of OTCs in the statistics.

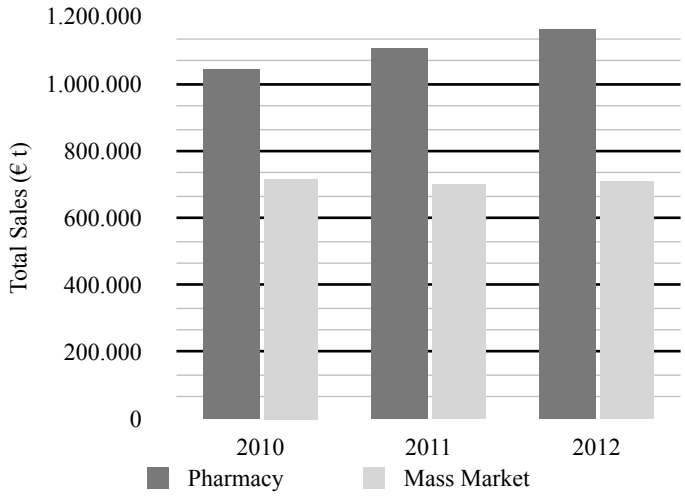

Figure 17a: The development of the health products market in terms of total sales per year (BAH 2010, 2011, 2012)

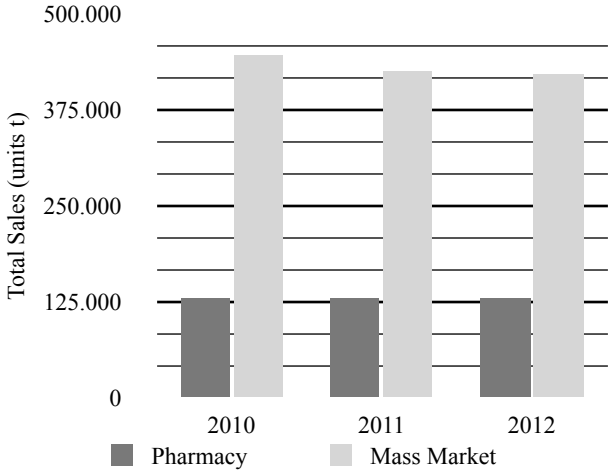

Figure 17b: The development of the health products market in terms of units sold per year (BAH 2010, 2011, 2012)

This produces a mixed, yet overall positive picture regarding the regulatory barriers to an expansion of innovation activities to the extended OTC-market. The pharmacy is clearly the more attractive channel of distribution for health products, providing positive feedback through the price structure. One could argue that this should serve as a motive for the industry to increase its efforts in this market segment and develop pharmacy-exclusive health products.

The different economic and financial dynamics of health products in the mass market certainly explain partly the behavior of the pharmaceutical firms and its focus on the pharmacy. However, even though those mechanisms are absent in the mass market, the importance of this segment may not be underrated. Beyond the pharmacy, parapharmaceuticals alone represent a market volume that cannot be ignored, as the Functional Foods and cosmetics segment of the market do. The significantly lower selling prices for health products realizable in the mass market should be offset

by the larger overall size of the mass market, relative to the pharmacy market. After all, the market segment enjoys increasing interest on the part of the foods and cosmetics industry. Logic alone implies that health products would not have found their way into the mass market if the segment was economically unattractive. Some pharmaceutical firms already innovate in the field: for instance, Merz Pharma operates a mass market segment with prominent products, such as Tetesept™ and Merz Spezial™. If the economics of the market are disadvantageous, what is then motivating those companies? And more importantly for this analysis: if those companies can exploit the regulatory niches of health products and be active in the extended OTC-market beyond the pharmacy, why is that not becoming an industrial movement?

In the light of the overall regulatory 'attractiveness' of health products and the lack of direct dependences flowing from regulation, it remains surprising that the pharmaceutical industry is not more consistent in its efforts to adapt its innovation activities to the extended OTC-market. Simply put: the industry could in principle expand its innovation activities to the health products market without coming across insurmountable barriers to innovation. Even though market realities might drag the industry continuously back to the pharmacy and the development of pharmacy-exclusive health products only, it remains surprising why the industry is neither innovating intensively in the pharmacy market for health products nor expanding to the mass market (from a regulatory standpoint a dual-channel distribution would also be feasible without additional efforts).

5.1.1.2. Customer Preferences

A second source of resource dependence is the customer markets and demand imposing 'performance requirements' (Gilbert 2005: 742) in the larger sense on the pharmaceutical industry.

German consumers are highly loyal to the pharmacy (ICON Added Value 2011: 36). Behind this stands a close emotional relation between consumers and the pharmacies, characterized by a high degree of trust with respect to the pharmacy as an institution and the pharmacist as a trustworthy expert on health questions.[66] What is particularly interesting is that German consumers perceive pharmacists as significantly less mercenary than other selling points for pharmaceuticals and health products (retail chains, drugstores, discounters). At the same time, however, consumers attest pharmacies to be less modern than their competition in the healthcare market. The emotions are strongest with respect to three values consumers associate with pharmacies: subject-specific competence, reliability, friendliness and a resulting feeling of safety. 24% of German consumers of healthcare products would even cov-

[66] The measure for overall trust consists of three sub-indicators: brand likeability, brand loyalty and brand trust. All measures are well above the average for commercial enterprises in Germany.

er additional insurance for getting more pharmaceuticals reimbursed (Nielsen OTC Survey 2010:14).[67]

Accordingly, 71% claim that they prefer buying pharmaceuticals (OTCs) in pharmacies over purchasing them in supermarkets or drugstores (ICON Added Value 2011: 38). They explicitly state that they do not like the idea of a deregulation of the pharmaceutical market and the increased sale of pharmaceuticals through retail. Among all possible chains of distribution of healthcare products of any sort German consumers prefer the pharmacy.

The study also finds that German consumers trust OTCs less than Rx-pharmaceuticals. OTCs are perceived as less potent and innovative than Rx-medicines, yet their overall potency and quality is never doubted. At the same time they tend to be seen as dispensable and overall as too expensive. However, the degree of trust in OTCs is still significantly high (ICON Added Value 2011: 75).

What does this imply, regarding the situation of the pharmaceutical industry? The relation between the pharmacy and the industrial actors has grown over time and the regulatory frameworks (at least with respect to pharmaceuticals) never gave much freedom of choice to the industry. The high loyalty of consumers with respect to the pharmacy is certainly a result of this development.

This explains the dominance of the pharmacy as the major distribution channel for pharmaceuticals further, beyond the focus on the pharmacy created through regulations. It underlines the argument that crystallized out of the above discussion: the attractiveness of the pharmaceutical that emerges out of the regulatory regime in which it is embedded is increased by the dependence on the customer markets who demand pharmaceuticals to a higher degree than health products. Also, the important role of the pharmacy as a resource provider, that was discussed above, is reflected in the customer market: consumers prefer the pharmacy over other channels of distribution for healthcare products (Sigrist 2006: 185). Wellness products, however, are mainly purchased via the drugstores (57% of consumers), followed by pharmacies (33%) (Sigrist 2006: 184).

Of course, this keeps down the incentive for the pharmaceutical industry to depart from the distribution channel and from the product image that the pharmacy bestows health products with. Among consumers who believe in the pharmacy, a health product that is sold through pharmacies has certainly a higher value than the same product sold in the mass market. The parapharmaceutical attributes of health products are therefore likely to be boosted even more by the innovating firm, as to create a pharmacy-image. As Jäckle (2011: 87) outlines, producers of pharmaceuticals typically try to benefit from the positive image of the pharmacy and from the lower price-competition in the channel. Pharmacy-exclusiveness is therefore attract-

[67] Survey by letter of 6,000 German households (only those members of the households who do the shopping were surveyed). The study was realized by the market research institute The Nielsen Company and the German Association of Producers of Pharmaceuticals (BAH).

ive for the freely marketed OTCs and the health products. Additionally, the situation increases the relative attractiveness of OTCs and of pharmaceuticals in general, which reinforces the dependence of the pharmaceutical industry.

The discussion has shown that strong rigidities are present that clearly aggravate a strategic shift of the pharmaceutical industry towards the extended OTC-market. On the regulatory level, health products are at an advantage regarding the formal 'ease' of innovation; OTCs are embedded in regulatory structures that allow no substantial changes, neither the move out of the pharmacy, nor a shift towards more consumer-oriented products. However, it turned out that the tight regulatory corset of OTCs brings about substantial economic advantages for the innovator. This means that the core business of the pharmaceutical industry — pharmaceuticals — as well as the sub-segment of OTCs is protected by its own regulations, producing strong dependences. Due to the regulatory realities and their effect on the market, it makes good economic sense for the pharmaceutical firms to stick to their traditional portfolio. The traditional market (OTCs) adjoining the new health products market cannot be expanded naturally, while at the same time its regulatory regime provides some advantages that the health products market cannot offer. Because of those dependences pharmaceutical firms keep focusing on OTCs instead of health products and on the pharmacy instead of the mass market. This is reinforced by the consumer behavior as a second source of resource dependence. The consumers' fidelity towards the pharmacy and their belief in the pharmaceutical as being superior to health products rigidifies the dependence of the pharmaceutical industry on their traditional innovation activities.

What remains, however, is the question why the pharmaceutical industry in Germany is — despite the dependences — not investing in the health products market as a second pillar of their business. This would allow the industry to exploit the health products market, independently of the advantages that OTCs have relatively to it. Firms could exploit the regulatory advantages of health products independently of the pharmaceuticals business.

This relates directly to the second part of the analysis of resource rigidities, addressing the reinvestment incentives for the established firms in the industry that flow out of their market position and the corresponding resource allocations.

5.1.2. Incumbent Reinvestment Incentives

The second aspect of resource rigidity relates to the market position of the pharmaceutical industry. According to theory, the stronger an industry is in one segment and the more internal resources are allocated there, the less likely it is to move to another one that would require changes in the resource allocation or would threaten the strong market position in the core field of activity. As the analysis shows, the strength of the pharmaceutical industry lies with pharmaceuticals, Rx-

products in particular. Resources are allocated accordingly, functioning as sources of rigidity regarding the adaptation of the innovation activities towards health products.

5.1.2.1. The Dominance of Rx-products

The traditional innovation trajectory of the pharmaceutical industry has always been dominated by pharmaceuticals, Rx-pharmaceuticals in particular. In terms of sales, pharmaceuticals represent 95% of the health market, while only 5% are non-pharmaceuticals (figure 18). Out of the 95% market share of pharmaceuticals, 84% are held by Rx-products alone.

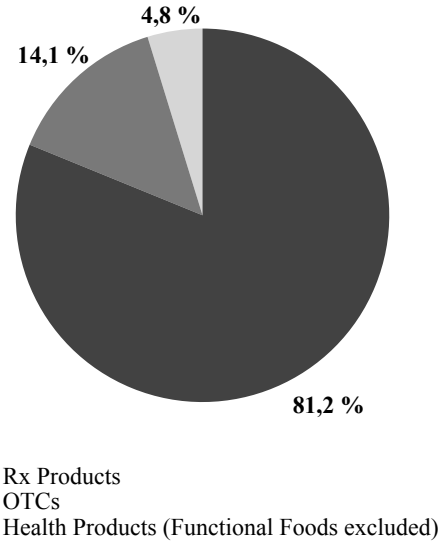

Figure 18: The health market 2011/2012 (MAT/8/2012) in terms of sales in the pharmacy and the mass market (IMS data; own illustration)[68]

The composition of the marketing authorizations granted in Germany also illustrates this dominance of Rx-innovations: the number of authorizations granted for Rx-medicines has constantly been more than tenfold the number of OTC-authorizations over the last years, representing over 90% of the entirety of marketing authorizations issued (table 13).[69] A look at the number of products in the market (table 14) confirms this: while the absolute number of pharmaceuticals marketed has grown steadily over the last years, the dominance of Rx-pharmaceuticals has also remained stable.[70]

[68] In reality, the proportion of health products developed by the pharmaceutical industry is even smaller than illustrated here (approximately 3%), as the pharmaceutical industry limits its activities almost entirely to the pharmacy.

[69] Table 13 is also displayed as table 6 and is reproduced here.

On average, only 11% of the authorizations granted account for pharmaceuticals with new substances or active ingredients. The remaining authorizations are issued for new combination preparations (BAH 2011, BAH 2010; BAH 2009; BAH 2008; BAH 2007; BAH 2006; BAH 2005).

[70] The table only displays the number of different products, not always counting all line extensions of product families. The difference in the number of products in subsequent years is therefore not always congruent with the number of marketing authorizations issued during that time period, as displayed in table 13.

	Marketing Authorizations Granted						
	2006	**2007**	**2008**	**2009**	**2010**	**2011**	**2012**
Rx-medicines	2.367	1.987	2.027	2.494	2.749	2.528	2.428
Self Medication (OTC)	226	166	84	99	159	168	182
Total	**2.593**	**2.153**	**2.111**	**2.593**	**2.908**	**2.696**	**2.610**

Table 13: Marketing authorizations granted in Germany, pharmaceuticals, 2006-2012 (BAH 2005, 2006, 2007, 2008, 2009, 2010, 2011, 2012; own illustration) [Veterinary drugs excluded]

	Rx	**Pharmacy-only OTCs**	**Freely marketed OTCs**	**Registered OTCs**	**Total**
2011	45.597	7.580	611	2.397	56.185
	81,2 %	13,5 %	1,1 %	4,3 %	100,0 %
2010	43.069	7.413	610	2.326	53.418
	80,6 %	13,9 %	1,1 %	4,4 %	100,0 %
2009	40.326	7.264	594	2.373	50.557
	79,8 %	14,4 %	1,2 %	4,7 %	100,0 %
2008	37.827	7.175	586	2.258	47.846
	79,1 %	15,0 %	1,2 %	4,7 %	100,0 %
2007	35.802	7.103	573	2.210	45.688
	78,4 %	15,5 %	1,3 %	4,8 %	100,0 %
2006	33.814	6.928	567	2.114	43.423
	77,9 %	16,0 %	1,3 %	4,9 %	100,0 %
2005	31.466	6.731	538	2.069	40.804
	77,1 %	16,5 %	1,3 %	5,1 %	100,0 %

Table 14: Number of authorized pharmaceuticals (Rx-products and OTCs) in Germany (BAH 2005, BAH 2006; BAH 2007; BAH 2008; BAH 2009; BAH 2010; BAH 2011; own illustration)

The focus on pharmaceuticals in general and Rx-medicines in particular has always characterized the traditional innovation trajectory and has recently even increased, due to the growing importance of molecular biology and biopharmaceuticals (see i.e. McKelvey and Orsenigo 2001). Financial data from the industry underlines this. Among leading German and foreign pharmaceutical firms, the revenues from prescription-only pharmaceuticals make up about three quarters of the overall

turnover (table 15, lines 2 and 3). [71][72] What must be added to this is the share of revenues from Consumer Care, which includes OTCs (lines 5 and 6). This underpins what the market data above already indicates: Rx-medicines dominate the innovation activities of the pharmaceutical industry, while OTCs play a minor role only. The data also shows that the third product group, non-pharmaceuticals (line 8 or 5)[73], is highly underrepresented in the pharmaceutical industry.

		Bayer	Boehringer Ingelheim	Merz	Pfizer	Novartis	Glaxo SmithKline
1	**Total Revenues ***	36.500,0	13.171,0	780,4	52.276,2	45.407,6	33.936,9
2	Pharma (Rx)	9.949,0	10.096,0	558,8	44.772,6	26.754,8	27.499,4
3	% of total	27,26 %	76,65 %	71,60 %	85,65 %	58,92 %	81,03 %
4	Consumer Healthcare **	7.220,0	3.069,0	67,1	7.250,8	3.590,5	6.437,4
5	Consumer Care †	534,0	1.396,0	-	4.027,9	2.579,5	6.437,4
6	% of total	1,46 %	10,60 %	-	7,71 %	5,68 %	18,97 %
7	OTCs	N/A	N/A	-	2.370,2	N/A	2.453,0
8	Health products	N/A	N/A	67,1	1.657,6	N/A	3.997,8
9	% of total	19,78 %	23,30 %	8,60 %	13,87 %	7,91 %	18,97 %

All amounts are rounded. This might produce slight imprecisions.

* All amounts of 2011, stated in million €; ** Sometimes differing from the segment Consumer Care, as Consumer Healthcare can include other segments, such as animal health, hygiene products, etc.; † Including OTCs and health products

Table 15: Selected financial data from leading pharmaceutical firms (computations based on data from Bayer 2011; Böhringer Ingelheim 2011; GSK 2011; Merz 2011; Novartis 2011; Pfizer 2011; own illustration)

What is interesting to this analysis are signs for a particular allocation of resources of the pharmaceutical industry that has — over time — developed along with the exclusive focus on pharmaceuticals. Certainly, the innovation strategy has coined the resource distribution of the pharmaceutical industry. The innovation system in which the industry is embedded is coined by pharmaceuticals, precisely Rx-products. The particularities of this innovation system determine the resource allocations of the pharmaceutical firms. What does the concentration on pharmaceuticals imply for the resource compositions of the pharmaceutical industry?

[71] The selection of pharmaceutical corporations listed in this table is to represent a cross-selection of research-intensive, globally acting pharmaceutical firms who innovate in pharmaceuticals as well as (to a limited degree) in health products. In terms of size, Pfizer (US) is the world's number one, followed by Novartis (CH). Glaxo SmithKline (UK) is ranked seventh (vfa 2012: 15). Those three corporations are to represent the top of the international pharmaceutical industry. Bayer and Böhringer Ingelheim were added to the list as they are the biggest two German pharmaceutical firms, ranging at place 15 and 16 internationally (2012, in terms of the size of their pharmaceutical business). Merz, in contrast, is much smaller but represents another powerful and R&D intensive German pharmaceutical corporation.

[72] Bayer and Novartis are exceptional cases. Bayer is more diversified than the other pharmaceutical corporations, as it runs a segment on CropScience and one on MaterialScience as well. Yet, pharma (Rx) and Consumer Healthcare (including OTCs) together constitute about 50% of the total revenues. In the case of Novartis, pharma (Rx) excludes generic pharmaceuticals (produced by Sandoz, 16% of total revenues) and the ophthalmologic segment (Alcon, 17% of total revenues). Pharma (Rx) and Consumer Healthcare stand therefore for the innovative pharmaceutical activities alone.

[73] Not all corporate annual reports split the declaration of revenues from consumer care by segment, which is the reason for the incomplete data in lines 5-8 of the table.

5.1.2.2. R&D Intensity

The self-understanding of pharmaceuticals is the result of the regulatory environment in which they are developed. Pharmaceuticals are first and foremost designed for *healing illnesses*. They are employed in a reactive way, as a response to the diagnosis of physical or mental problems. Their consumption pattern is therefore different from that of any other product or commodity: it is supposed to last as shortly as possible. In other words, the (juridically enforced) 'sense of mission' of pharmaceuticals, namely healing, implies that their consumption is never a question of needs or preferences (as it is the case with ordinary commodities, such as foods), but rather one of necessity. The shorter the duration of the therapy, the better it is (Sigrist 2006: 47). Of course the degree of this varies among the categories. OTCs entail more voluntariness and enjoyment of consumption that Rx-products, as they are marketed without prescription, carrying less serious indications and addressing more wellness-related aspects of the human health than Rx-medication. Nevertheless, they share their basic attributes with Rx-medication.

As the analysis of the regulatory frameworks has shown, this seriousness of the purpose of pharmaceuticals is reflected by the high regulatory standards with respect to quality, safety and distribution. Research and development on the basis of sophisticated technological facilities are therefore the main drivers of pharmaceutical innovations, always under a strict controlling regulatory regime. Only slight differences are made between Rx-pharmaceuticals and OTCs in this respect; pharmaceuticals are necessarily a response to the existence and spread of illnesses and a function of the technological and scientific capabilities, rather than of market needs, as it is the case with commodities. As the analysis has shown, this results in extremely high development costs for pharmaceuticals.

Accordingly, the competences of pharmaceutical firms are concentrated on research and development, including the development of molecules and new pharmaceutical substances, as well as clinical testing. This requires the firms to hold up a high level of concentrated expert knowledge on the matter and, more importantly, to invest significant amounts of time and money in their innovation activities. Research is the crucial ingredient to innovations in this field.

Table 16 illustrates this: on average, R&D-based pharmaceutical companies operate at R&D intensities of 13%, compared to an average of 4% among all other R&D-intensive industries; worldwide the pharmaceutical industry spends €92,1 billion on R&D. The data from major pharmaceutical firms in Germany underlines this (table 17): together with the focus on pharmaceuticals comes a concentration of resources in terms of R&D spending in that domain. The overall research intensity

(line 9) lies on average at about 15%, which is already quite high.[74] Yet, looking at pharma (Rx) only, most of the corporations listed spend more than three quarters of their R&D budget on Rx-pharmaceuticals (line 6). In the case of Böhringer Ingelheim for instance, almost one quarter of the revenues from pharmaceuticals was spent on R&D in the segment in 2011 (line 10).

R&D staff (% of total)	
Pharmaceutical industry in Germany	20
Other R&D-based industries (average) in Germany	9
R&D Intensity (%)	
Pharmaceutical industry in Germany	13
Other R&D-based industries (average) in Germany	4
Total R&D spending, pharmaceutical industry	
Leading Industrial Countries: Europe (incl. Germany), Japan, USA (€bn)	92,1
Germany (€bn)	7,4

Table 16: Industry data on R&D intensity in terms of staff spending (vfa 2012; own illustration)

		Bayer	Boehringer Ingelheim	Merz	Pfizer	Novartis	Glaxo SmithKline
1	**Total Revenues ***	36.500,0	13.171,0	780,4	52.276,2	45.407,6	33.936,9
2	Pharma (Rx)	9.949,0	10.096,0	558,8	44.772,6	26.754,8	27.499,4
3	Consumer Healthcare **	7.220,0	3.069,0	67,1	7.250,8	3.590,5	6.437,4
4	**Total R&D Expense ***	2.932,0	2.516,0	133,4	7.054,7	7.163,2	4.967,8
5	Pharma (Rx)	1.556,0	2.372,0	129,1	6.703,4	5.318,7	4.658,0
6	% of total	53,07 %	94,28 %	96,78 %	95,02 %	74,25 %	93,76 %
7	Consumer Healthcare **	392,9	144,0	4,3	361,3	226,4	189,6
8	% of total	13,40 %	5,72 %	3,22 %	5,12 %	3,16 %	3,82 %
9	R&D intensity	8,03 %	19,10 %	17,09 %	13,50 %	15,78 %	14,64 %
10	Pharma (Rx)	15,64 %	23,49 %	23,10 %	14,97 %	19,88 %	16,94 %
11	Consumer Healthcare	5,44 %	4,69 %	6,41 %	4,98 %	6,31 %	2,95 %

Table 17: Selected 2011 financial data from leading pharmaceutical firms (computations based on data from Bayer 2011; Böhringer Ingelheim 2011; GSK 2011; Merz 2011; Novartis 2011; Pfizer 2011; own illustration)

* All amounts are rounded, which might produce slight imprecisions; all amounts stated in €m. ** Sometimes differing from the segment Consumer Care, as Consumer Healthcare can include other segments, such as animal health, hygiene products, etc. † Including OTCs and health products

The focus on R&D and the resource-concentration in this field is of course understandable, regarding the needs of pharmaceuticals and their dominance in the pharmaceutical industry. The success and innovative dynamism of pharmaceutical firms in their traditional field of activity is fundamentally dependent on this core competence. That is not surprising, as pharmaceutical innovations cannot be induced by anything else but the combination of a scientific and a regulatory opportunity; the

[74] Once again, Bayer is an exception. This is due to the low R&D-intensity of CropScience and MaterialScience, which reduces the average corporate R&D-intensity. Yet, 53% of the total R&D expenses went into pharma (Rx) and 13,5% into Consumer Healthcare in 2011 (lines 12 and 14), which shows the high resource concentration in those fields more clearly than the average numbers.

R&D competence enables the firms to meet the regulatory requirements of drug development.

5.1.2.3. Marketing and Advertising

Another aspect of the resource composition of the pharmaceutical industry that flows out of its innovative focus on pharmaceuticals is the relatively low marketing and advertising intensity at which it operates (table 18).

	Bayer	Pfizer	Glaxo SmithKline
Total Revenues *	36.500,0	52.276,2	33.936,9
Advertising and Promotion (A&P) Expense**	2.078,00	3.023,80	1.127,64
A&P Intensity	5,69 %	5,78 %	3,32 %

Table 18: The 2011 A&P Intensities of leading pharmaceutical firms (computations based on data from Bayer 2011; Böhringer Ingelheim 2011; GSK 2011; Merz 2011; Novartis 2011; Pfizer 2011; own illustration)

* All amounts are rounded, which might produce slight imprecisions; all amounts stated in €m.
** The costs for the field force are excluded

As table 18 illustrates exemplarily for three of the largest pharmaceutical firms, their Advertising and Promotion (A&P) intensities lie far below their R&D intensities, which indicates the clear prioritization of R&D over marketing. The A&P efforts made by the companies include the marketing to professionals, to which advertising of Rx-products is limited. Data on the aggregate level of advertising and promotion expenses for non-professionals (table 19) indicates further that pharmaceutical firms invest only a fraction of their A&P expenses on advertisement for non-professionals, which equals the marketing for OTCs and health products.[75]

	Expenses (€m)	**Proportion**
Total*	**601,0**	**100,0 %**
Television Advertising	364,0	60,6 %
Consumer Periodicals	200,0	33,3 %
Online Campaigns	17,0	2,8 %
Radio Advertising	12,0	2,0 %
Newspaper Advertising	8,0	1,3 %

Table 19: Aggregate expenses of the pharmaceutical industry in Germany on advertising to non-professionals in 2011 (BAH 2011: 10)

* At least €20 million of the entire go on the compulsory statements required by law (BAH 2011)

[75] This shall not imply that marketing and advertising is not known to the pharmaceutical industry whatsoever. After all, most pharmaceutical firms develop and produce OTCs and (few) health products, despite the dominance of Rx-medicines and the corresponding high intensity and sophistication of pharmaceutical R&D. The consumer care segments of pharmaceutical firms are necessarily used to employing more marketing-focused tools for innovation, such as line extensions and the diversification of product indications. Accordingly, the R&D intensity for those development processes is lower than for Rx-innovations, as some steps in the clinical studies can be waived. Competences with respect to advertising and promotion are also more developed for non-prescription medicines, as this is required in the OTC-market. Moreover, those health products that the pharmaceutical industry already markets are successfully advertised, proving the presence of some competences in this domain.

Again, this weighting is only logical, given the regulatory restrictions that pharmaceutical firms must bow to and the dominance of Rx-products. The innovation process for Rx-products includes no direct links between the innovating firms and the patients (consumers), the reason being the advertisement and promotion ban for Rx-pharmaceuticals (except for information given to expert groups, like physicians and pharmacists). The communication between the innovating firm and the market is confined to the link between the pharmaceutical firms and the physicians and is filtered by various interest groups (Medical and Pharmaceutical Associations) operating as controlling entities in between the pharmaceutical industry and the service providers (Bührlen and Kickbusch 2008: 30). Sales activities and advertising campaigns are therefore limited to this channel and to very formalized campaigns among physicians and hospitals only, which makes the process of communication and sales activities more complex than in most other sectors.

The situation is different in the OTC market as conventional consumer advertisement is allowed to some degree. The innovating firms can openly advertise and promote OTCs through conventional consumer advertisement tools, thereby maintaining the kind of direct link to the consumers that is absent in the Rx market. Yet, the dominance of pharmacy-only and pharmacy-exclusive OTCs in the market positions the pharmacists as the major target of advertisement and promotion incentives. Just like physicians for Rx-products, pharmacists are the major demanders for pharmacy-only and pharmacy-exclusive OTCs. The innovating firms must — independently of the consumers' demand — first of all make sure that their products are listed by pharmacists. Therefore, despite the direct consumer advertisement allowed in the OTC market, the advertisement among professionals plays a central role.

The central role that the service providers play in both markets and the fact that over 90% of the industrial innovation activities take place in those markets explains the overall low A&P intensity and the even lower investment in advertising to non-professionals. The market realities position the field force at the centre of sales activities and make conventional consumer advertising resources unnecessary for success in the market. This underlines the assumption that A&P resources are developed to a very limited degree only.

5.1.2.4. The Established Distribution Channels

The Sales Force

As a consequence of the limited consumer advertisement for pharmaceuticals, the field force plays an even more important role for the marketing activities of the pharmaceutical industry. Pharmaceutical firms maintain large sales teams, informing about and selling pharmaceuticals to physicians and pharmacists (Jäckle 2011: 84). This is reinforced by symposia hosted by pharmaceutical corporations and advertisement campaigns to health professionals. The field forces replace consumer mar-

keting in the market for pharmaceuticals. In other words, almost all of the industry's pharmaceuticals (and consequently over 90% of its products in total) are marketed via salesmen: Rx-medicines are promoted via the physician and OTCs via the pharmacists (as OTCs are not prescribed but distributed to the consumer by the pharmacy).

The market structure explains why this is necessary: more than 150.000 independent physicians and about 21.300 pharmacies operate in Germany, only very few of them integrated into larger cooperation (ABDA 2013: 40; Kopetsch 2010: 50; Sigrist 2006: 133). Marketing must target them all individually, requiring huge teams of field workers, making personal contact with each physician and pharmacist.

Of course this sales strategy bounds enormous amounts of human and financial resources. Between 1994 and 2000 alone, the number of filed workers doubled almost (Sigrist 2006: 133). On average, German pharmaceutical firms spend 25-30% of their revenues on their salesforce (Nusser and Tischendorf 2006: 55), representing one of the biggest segments of their cost of sales. Moreover, an average of 30% of the field workers are university graduates, German law requiring pharmaceutical sales people to possess specialized pharmaceutical and medicinal knowledge in order to ensure a high-quality of the sales process (Nusser and Tischendorf 2006: 55; §75 AMG). To ensure this, pharmaceutical firms often hire academics as salesmen. Clearly this increases costs further.

The Role of the Physician and the Pharmacy

Another thought is closely related: what characterizes the traditional distribution channels of pharmaceuticals is that the final purchase of the product is made through the pharmacy. As point of sale for pharmaceuticals in Germany, the pharmacy enjoys a monopolistic position: about 1% of the market for pharmaceuticals is outside the pharmacy. Additionally, Rx-products are prescribed by the physician, who acts as another intermediary in the distribution process; this means that more than three quarters of the pharmaceuticals are distributed through the physician and the pharmacist before they reach the patient (see table 7).

Jäckle (2011) emphasizes repeatedly throughout his analysis the strong position of the physician and the pharmacy among German patients and consumers, arguing that their position is — because of product safety issues alone — unlikely to change in the near future.[76] Also, as it was outlined earlier, the margins attainable in the pharmacy market are considerably higher than in the mass market, which certainly contributes to the strong position of the pharmacy as it provides no incentive

[76] Clearly, no changes will occur regarding the position of the physician in the distribution structures for Rx-products, as the safety regulations for prescription drugs require the prescription of those medicines to the patient. Also, consumer safety guidelines are unlikely to change with respect to the physical distribution of Rx-medicines via the pharmacist, as it is the pharmacist who ensures the correct administration of the medicine and takes care of potential issues of pharmacology and problematic interactions of medicines.

for the pharmaceutical firms to change distribution channels towards the (low margin) mass market.

5.1.2.5. Discussion

Necessarily, health product innovations stem from another background than pharmaceuticals. As the analysis above made clear, pharmaceutical research alone is insufficient for developing health products; the pharmaceutical industry would have to change its resource allocations in order to account for that. In contrast to pharmaceuticals, the consumption of health products is proactive; their central purpose is not healing, but *prevention* of minor illnesses and the *maintenance* of the general well-being. While the consumers of pharmaceuticals are rather passive patients, consumers of health products are proactive consumers, voluntarily consuming the products; the consumption is to last as long as possible.

Health product innovations are a function of demand for 'healthiness' and well-being rather than a reaction to scientific breakthroughs that allow the development of new therapies. Consumer needs must therefore be created and maintained, pushing marketing and advertising at the centre of product development (table 20). Also, the lack of competitive protection of the products through patents or marketing authorizations leads to reduced possibilities of differentiation among the products as compared to the pharmaceuticals market. Differentiation between health products is therefore managed mainly through branding, rather than through the scientific/pharmacological characteristics (Sigrist 2006).

First Health Market	Second Health Market
Rx-medication for ill persons • Healing	**Products for healthy persons** • Prevention and well-being • Wellness • Fitness • Life-style
Mechanisms • Reactive • Aim to recover from an illness	**Mechanisms** • Proactive • Aim to stay healthy/fit
• Only invalids are 'consumers' of those products, nobody wants to become a consumer	• People become consumers of the products voluntarily
• Ideal duration of consumption: the shorter the better	• Ideal duration of consumption: the longer the better • In the extreme case the consumption of products (i.e. Functional Foods) is even desirable/enjoyable
Market Drivers • Research • Technology and diagnostics • Serious diseases of civilization	**Market Drivers** • Marketing and branding • Holistic perception of health • Desire to be always young / immortal • Successful prevention

Table 20 Mechanisms and market drivers of the first and the second health market (own illustration, adapted from Sigrist 2006: 47)

Also, the looser regulatory regime of health products (ranging up to the extreme case of Functional Foods) requires significantly smaller R&D efforts than for pharmaceuticals, being replaced by marketing and branding. Despite slight regulatory variations among them, 'classical' health products (dietetics, food supplements) may be advertised relatively openly. In the case of Functional Foods, regulations are even almost fully absent. Health products require marketing and branding competences to a much higher degree than pharmaceuticals (Rx-products in particular).

While in the pharmaceuticals market each and every physician/pharmacist must be visited by salesmen, the mass market for health products in Germany is dominated by just a few powerful retail chains. No big sales force is needed to reach them. Also, in the mass market distributors and service providers are usually not independent entities, as in the Rx-and OTC-market. The sales activities for Rx-pharmaceuticals and OTCs (pharmacy-bound and pharmacy-exclusive) take place between the salesforce and the service providers (physicians, pharmacists), while the majority of the products is physically distributed via wholesalers. In the mass market those two channels are combined, as the wholesalers and retailers are at the same time the products' distributors ('service providers').

The analysis suggests that the market position of the pharmaceutical industry and the resource allocations that come with it hold the industry in a trajectory very distant from the changes taking place in the second healthcare market. The dominance of pharmaceuticals in the innovation portfolio of the industry (Rx in particular) and the resulting orientation of the industrial resources represent rigidities when it comes to change. In that context, the strong position of the physician and the pharmacist in the industrial distribution structures solidify the market position of the industry.

Of course, the resource allocations and the market position of the industry alone are insufficient to create rigidities if the status quo is not supported by success. - The pharmaceutical industry in Germany enjoys ongoing success in its core market. Worldwide, the market for pharmaceuticals grew from $365 billion in 2005 to $956 billion in 2011 (vfa 2012: 13), which also affected the German market and the pharmaceutical firms in it. The development of the pharmaceutical industry in Germany alone reflects this: aggregate revenues rose by more than 25% between 2005 and 2011, while the per capita spending on pharmaceuticals in Germany is one of the highest worldwide (vfa 2012: 19).[77] The industry can rest upon high barriers to market entry (which result out of the extremely high standards for and the R&D intensity of pharmaceutical innovations), a quasi-monopoly on pharmaceuticals and consequently only little turbulence, a loyal installed customer base and ongoing financial

[77] This growth, however, is reduced by increasing price pressure onto the industry, particularly through *Rabattverträge.* The net revenues of the pharmaceutical industry in Germany has therefore been growing at a lower rate (vfa 2012: 19).

success. This is clearly contributing to the industry's resource rigidity and the inertia flowing from it.

This situation implies that a strategic 'investment in discontinuous change' (Gilbert 2005: 742), as the organizational inertia literature requests it is unlikely to come about. The industry's success and the stability of its market give the sectoral firms no incentive to strategically reorient towards the extended healthcare market; the gap between the traditional market of the pharmaceutical industry and the health products market is — in light of the industry's market position — rather wide.

Figures 19a and 19b illustrate the situation in which the pharmaceutical industry finds itself in and the resource rigidities discussed in this chapter, holding the pharmaceutical in its rigid path of development. As discussed in above in detail, the enormous regulatory influence on the industrial innovation activities produces resource dependences. Those keep the industry off from exploiting its core business to deviate from its traditional innovation trajectory and innovate in the health products market.

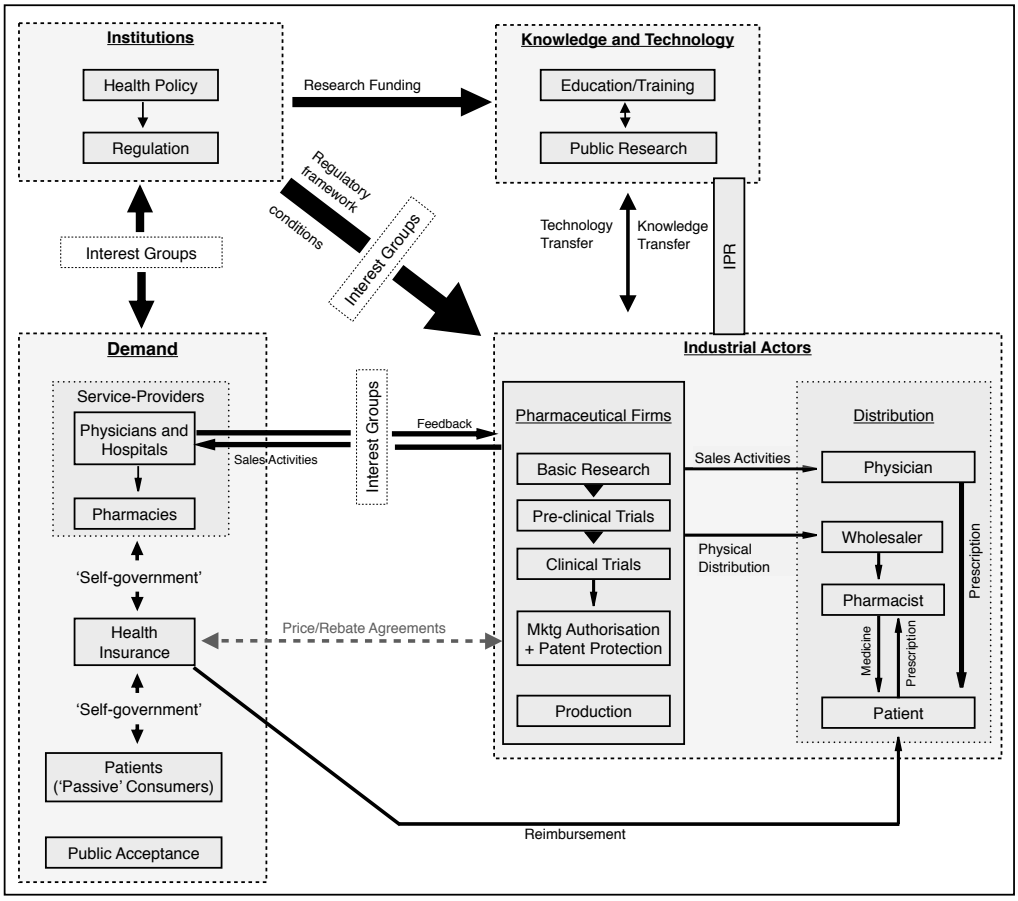

Figure 19a: Conceptualization of the pharmaceutical innovation system (Rx) (own illustration, adapted from Bührlen and Kickbusch: 30)

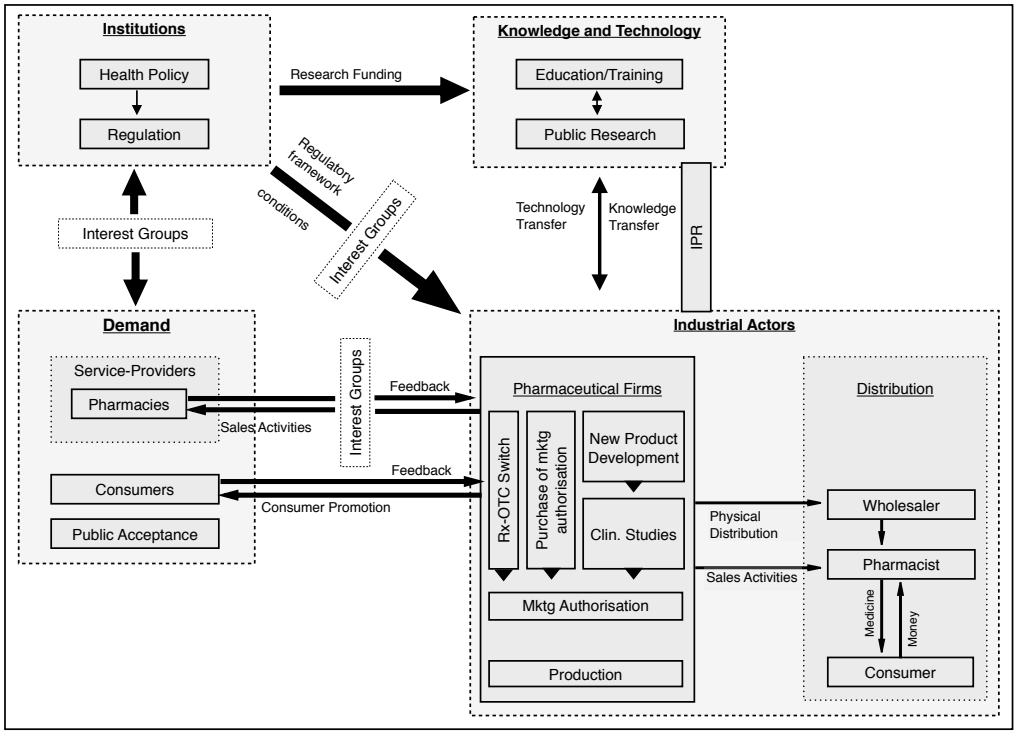

Figure 19b: Conceptualization of the pharmaceutical innovation system (OTC) (own illustration, adapted from Bührlen and Kickbusch: 30)

From the perceptive of reinvestment incentives, the structural and strategic focus on R&D-intensive Rx-pharmaceuticals qualifies the industry not to develop health products, as those require very different development resources. Recombining the existing resources would be insufficient to face the challenges from the health products market: the complex and highly regulated processes of product development and distribution have influenced the resource allocation of the industry accordingly, having left no space for building up additional resources required for successfully innovating in the health products market. At the same time the success the industry enjoys in its core business produces no incentives to acquire completely new resources.

Secondly (and even more importantly), the market position of the pharmaceutical industry represents a rigidity regarding the mass market for health products. The pharmacy market provides protection, as it allows pharmaceutical firms to employ the habitual methods of advertising and promotion to place health products in the market, leaving the final customer contact mostly to the pharmacist. The pharmaceutical industry operates the Rx-segment - more than 90% of their overall business — without any direct ties to the final consumer of the product, neither via education nor through consumer advertisement. Instead, the innovation process takes place between the industrial actors and the physicians, taking the role of the demanders (figure 19a). The OTC market functions similarly, reflecting the regulatory relatedness to the Rx-market (figure 19b): while limited promotion and feedback links to the consumer are in place, the point of contact for the industry is still (for most

OTCs) the pharmacy. Even though the final consumer actively demands an OTC, the industrial actors market their OTCs to the pharmacy in the first place. Like for Rx-products also the physical distribution is managed by the pharmacist as intermediary. Again, in the light of the industry's successful performance this produces no substantial reinvestment incentives.

Additionally, the considerably margins in the pharmacy increase the attractiveness of the distribution channel and the adherence of the industry to it. This indicates why the pharmaceutical industry enjoys some success in the consumer care segment, at least in the pharmacy. The mass market, however, provides no such protection and would require the innovating firms to drastically upgrade their marketing resources. This is another cause for the hesitant involvement of the pharmaceutical industry in it, as the expansion of innovation activities beyond the pharmacy would bear the risk of cannibalizing the existing structures. Rigidities could only be broken at very high costs for the pharmaceutical industry.

It therefore seems hard for the industry to compensate the dominance of the dynamics of innovation dictated by the Rx-segment, as prescription-only innovations still dominate the industry by far. It is after all precisely the advantage of health products over pharmaceuticals that they require no lengthy and expensive development processes and can therefore be placed in the market relatively easily. Their major cost, however, is intensive consumer marketing. In light of the above discussion it must be assumed that the pharmaceutical industry is unable to exploit those major advantages of health products easily, due to the concentration of its resources in R&D and the absence of substantial advertising and promotion resources. While this status-quo is beneficial for the traditional core business of the industry, it turns into a rigidity in the health products market. At most, health products are developed for the pharmacy only. This allows to fall back onto most of the existing resources, as pharmacy-exclusive health products can be distributed and advertised within the known structures.

However, two questions remain at this point. First, why is the pharmaceutical industry not at least exploiting the attractiveness of pharmacy-exclusive health products? After all, the analysis so far revealed that innovations can be placed in this market segment rather easily. Secondly, the more general question merges, why the resource rigidities identified are not removed. The inertia identified so far is rather 'technical' in nature and could in theory be overcome: neither prevent the regulations on pharmaceutical innovations the firms from getting involved in health products separately from their core business, nor should the industry in principle be considered unable to build up lacking marketing and advertisement resources as well as new channels of distribution. Is it really only the success the industry enjoys that keeps it pharmaceutical firms doing this?

The analysis therefore merits a closer look at the industrial dynamics. As the discussion of organizational inertia already indicated, resource dependences alone

constitute only a part of firm rigidity, since firm routines and the underlying organizational cognition also impact the organizational flexibility to change. The following discussion is therefore dedicated to the analysis of routine rigidities, following the theoretical framework for the study. The aim is to add another layer to the analysis, exploring in how far organizational routines and cognition constitute — in addition to the resource rigidities identified earlier — sectoral dynamics that hamper industrial processes of adaption and change. The empirical results are unveil at what points routine rigidities complement, reinforce or contradict resource rigidities and how the types of rigidities are connected.

5.2. Routine Rigidities

As specified in the theoretical framework, this part of the empirical study focuses on the identification of routine patterns and patterns of managerial cognition that appear out of the cross-case analysis of the interview material. The patterns are to provide evidence for potential sources of routine rigidities with respect to inertia flowing from firm routines as well as cognitive determinants of firm behavior. The categories for coding and analyzing the data are also provided by the empirical framework. The empirical material was analyzed along four routine categories: search routines, routines of interaction, routines of combination and finally routines of diffusion. For the identification of patterns of firm cognition, the data was filtered for norms, beliefs and shared values among the interviewees that impact their behavior concerning the health products market.

Table 21 provides an overview of the findings from the case studies. It summarizes the empirical patterns that became obvious in the interviews. Detailed evidence from the interviews concerning the patterns is presented hereafter. It is highlighted how valid and relevant the patterns are in terms of the number of interviews in which they appeared. The impact of the patterns identified on the behavior of the firms and their rigidity regarding health products innovations is discussed in detail in the subsequent chapter.

1. SEARCH ROUTINES
1a. Systematic observation of the changes in the second healthcare market is conducted
By internal tools: market research
By external tools:
Information collection via industrial networks and associations
Information collection via consulting and PR firms, scouts
1b. Knowledge inflow is promoted through HR (Human Resources)
FMCG employees are hired for positions that require non-pharma knowledge
2. ROUTINES OF INTERACTION
2a. Systematic coordination efforts to increase the communication between pharma and CHC are made
Via the promotion of interdepartmental synergies
By fostering of interrelations of the departments
2b. CHC enjoys (partial) autonomy of decision
CHC organized along independent structures, no structural dependence from Rx
No structural separation between OTCs and health products
2c. The hierarchical relation between Rx and CHC is balanced
CHC & Rx equally represented
CHC in present on the executive level
Hierarchical dominance of Rx over CHC
2d. Profitability as the decisive criterion for innovation decisions
High margin is crucial
Preservation of high margin through distribution channel
Preservation of high margin through product status
2e. Favoritism of the pharmaceutical over the non-pharmaceutical
Maximum product exclusivity desired for new products
Attained through the distribution channel: pharmacy
Attained through product status: pharmaceutical
The product status is crucial when planning innovations
Product status irrelevant
Product status relevant
Health products developed function as strategic bridges
2f. Consideration for the market power of the pharmacist
Loyalty to the pharmacy market to maintain the pharmacy as the major source of revenue
3. ROUTINES OF COMBINATION
3a. Interdisciplinary coupling of org. knowledge as to facilitate CHC innovations
Exploitation of synergies between CHC and Rx
Exploitation of interrelations of the CHC and Rx departments
3b. Combination of internal and external knowledge for fostering CHC innovations
Recognition of the importance of consumer-pull and market-push stimuli for CHC innovations
3c. Lack of exploratory learning regarding CHC innovations
Health products as preparation for potential market deregulation
4. ROUTINES OF DIFFUSION
4a. Knowledge is formally diffused within the organization and among departments
Newsletters, centralized collection of innovative ideas

5. FIRM COGNITION
5a. The firms feel the duty to conserve its values
Obligation to adhere to highest scientific standards for all products
Accepting the moral responsibility and ethics coming along with the production of pharmaceuticals
5b. Ambition to maintain image/reputation
Commitment to the pharmaceutical and the pharmacy as the basis of industrial reputation
5c. Retention of the exclusive distribution channel pharmacy
Pharmacists as competent sales agents
Pharmacies as premium outlets
5d. Commitment to core competences
Focus on traditional innovation trajectory/Indifference towards health products and the mass market
5e. Perception of the competition and of the market development
Protection through barriers to market entry
Competence building hardly possible for outsiders
Credibility is only enjoyed by established players
No threat from deregulation to the pharmaceutical industry

Table 21: Routine patterns from the case studies

5.2.1. Firm Routines

5.2.1.1. Search Routines

Search routines impact the ability of an organization to look for and react to changes in their environment. Ideally, they ensure constant scanning process of the environment, providing the organization with knowledge on threats and opportunities. Two major patterns could be identified from the interview data. Firstly, a systematic observation of the changes in the second healthcare market is conducted in the all firms analyzed. Secondly, knowledge inflow concerning the CHC (Consumer Health Care) market is promoted in many of them through recruitment decisions (table 22[78]).

1. SEARCH ROUTINES	
ROUTINE PATTERNS	**EVIDENCE**
1a. Systematic observation of the changes in the second healthcare market is conducted	**A** [a, b]; **B**; **C**; **D** [a, b]; **E** [a]; **F**; **G** [a, b]; **H** [b]; **I** [a, b]
By internal tools: market research	**A** [a, b]; **B**; **C**; **D** [a, b]; **E** [a]; **F**; **G** [a, b]; **I** [a, b]
By external tools:	**C**; **D** [a]; **E** [a]; **G** [a];
Information collection via industrial networks and associations	**A** [a, b]; **B**; **G** [b]; **I** [b]
Information collection via consulting and PR firms, scouts	
1b. Knowledge inflow is promoted through HR	**A** [a, b]; **F**; **G** [a]; **I** [a, b]
FMCG employees are hired for positions that require non-pharma knowledge	

Table 22 : Search routines — patterns from the case studies

[78] The column on evidence lists the interviews in which the respective pattern becomes apparent. Selected passages from those interviews are presented in the discussion of the patterns.

Pattern 1a: Systematic observation of the changes in the second healthcare market is conducted

A first pattern observable in all pharmaceutical firms is the screening of the extended healthcare market. The firms are actively examining the development of the market, independently of the degree of their individual involvement in it; none of the firms is completely unaware of the market and its development.

'[…] wir schauen uns in der Tat über unsere Marktforschung die Grenzmärkte an, weil wir wissen wollen, was passiert da, was sind die Alternativprodukte, die sich Konsumenten im Vergleich zu unserem Portfolio anschauen und als Ersatz kaufen.' (Int. I[b])[79]

Three concrete tools of market observation are apparent: observation through internally conducted market research[80], through the membership in industrial networks and associations[81], and through the commissioning of consulting and PR firms and scouts[82]. The majority of the pharmaceutical firms rely on internal market research as their major instrument for scanning the second healthcare market and its development. Databases are the main tool for market monitoring processes (usually, the companies obtain market data from IMS Health).

'Wir hören sehr stark auf unsere eigenen Ideen und die interne Marktforschung, halten aber auch guten Kontakt zu Partnern nach Außen, um möglichst alle neuen Strömungen und Themen im Markt schnell aufzunehmen.' (Int. G[a])[83]

'PR-Agenturen sind weltweit damit beauftragt, alles zu scannen, was für uns interessant sein könnte und was wir eventuell weiterverfolgen möchten.' (Int. A[a])[84]

Company F provides an example for routinized search processes, institutionalized to perfection: an internal 'Marketing Excellence Program' coordinates a centralized search process by systematically segmenting consumer groups and markets.[85] The collection process is conducted by an international organ of the company, who then distributes the market insights to the marketing and development departments of the national subsidiaries.

Also, some companies use their salesforce to transport market insights into the firm, thereby keeping track of the changes and developments in the market.[86]

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[79] 'As a matter of fact, we observe the borderline markets through our market research tools since we want to know what is happening in the market. We want to know what alternative products to ours are available that consumers take notice of and that they eventually buy as substitutes for our products.' (Int. I[b])

[80] Interviews A [a, b]; B; C; D [a, b]; E [a]; F; G [a, b]; I [a, b].

[81] Interviews C; D [a]; E [a]; G [a]; H [b].

[82] Interviews A [a, b]; B; G [b]; I [b].

[83] 'We carefully listen to our internal market research and take our internally generated ideas very seriously. Yet, we are also in close contact to external partners, in order to be always aware of new tendencies and themes in the market.' (Int. G[a])

[84] 'Worldwide, PR-agencies are commissioned to scan everything that could be of interest to us and worth following up.' (Int. A[a])

[85] Interview F.

[86] Interviews A [a]; D [b]; E [a]; F; I [a].

'[…] das größte Scanning-tool ist der Außendienst; alle Außendienstmitarbeiter haben den erklärten Auftrag, über Markt- und Wettbewerbsveränderungen zu berichten und die Augen und Ohren offen zu halten.' (Int. A[a])[87]

The exchange of information through membership in pharmaceutical associations represents another search processes ensuring the inflow of external knowledge into the organization.[88] The collaboration of firms in various committees set up by the pharmaceutical associations is used as a platform for knowledge exchange and product development.

'Wir überlegen auch auf Verbandsebene intensiv, wie wir das Thema Selbstmedikation in Zukunft wieder stärker forcieren können.' (Int. H[b])[89]

The third channel through which search routines are exercised is PR-agencies, external scouts and consulting firms, assigned to systematically scan the extended healthcare market.[90] Company I for instance cooperates intensively with those PR-agencies and consulting firms who also work for FMCG (Fast Moving Consumer Goods) companies competing with company I in the health products market.[91] The strategic aim of company I's management is to use the cooperation to develop in the same direction as the FMCG companies in the health products market.

Pattern 1b: Knowledge inflow is promoted through Human Resources

A second general cross-case pattern of search routines concerns the selection of employees in the CHC-departments. The majority of the decision makers that were interviewed have no pharmaceuticals background but gained experience in consumer goods industry before switching to the pharmaceutical industry.[92] Among other interviewees, who have made their career in the pharmaceutical industry, business economists outnumber natural scientists.[93] This is remarkable, as in terms of human resources the Rx-segment of the pharmaceutical industry is usually dominated by natural scientists. The departure from that principle in the CHC-segments underlines that efforts are made to tap into new sources of knowledge useful for innovations in the extended healthcare market.

In order to acquire further external knowledge about the changes in the second healthcare market, staff with expertise from the fast moving consumer goods industry are preferably hired. The companies are aware that consumer goods industry (mainly foods companies) is the main source of competition in the extended healthcare market. They are also aware of the advantages that FMCG-companies have, due

[87] 'Our biggest scanning tool is our salesforce; all sales people are to be attentive and report to us about changes in the market and in the competitive landscape.' (Int. A[a])

[88] Interviews C; D [a]; E [a]; G [a]; H [b].

[89] 'Within the pharmaceutical associations, we actively think about ways of revitalizing the issue of self medication in the near future.' (Int. H[b])

[90] Interviews A [a, b]; B; G [b]; I [b].

[91] Interview I [b].

[92] Interviews A [a, b]; F; G [a]; I [a, b].

[93] Interviews H [a, b]; E [a].

to their knowledge of the structures of the mass market and the organizational requirements for successful innovations in it. The firms therefore attempt to gain such knowledge through human resources.

> *'In meinem Marketingteam sind 75% der Mitarbeiter FMCG-Leute, wir denken nicht in Pharmastrukturen. Wir sind ja daran interessiert, die smarten Ideen für die Umsetzung eines Claims zu finden.' (Int. I[b])*[94]

Summary, Similarities and Differences

The data draws a relatively homogeneous picture regarding the presence and intensity of search routines in the pharmaceutical firms. Routinized behavior concerning the systemic observation of the health products market can be observed in all pharmaceutical companies. All companies employ at least one of the three tools of observation identified, many of them even operate routines making use of multiple of them (table 23). This indicates that all firms are equally informed about the market developments.

However, only four companies systematically expand their scanning tools to human resources, hiring employees from the FCMG sector in order to obtain insights into the market. This differentiates the four companies (A, F, G and I) from the remaining five.

PATTERN	SIMILARITIES	DIFFERENCES
1a. Systematic observation of the changes in the second healthcare market is conducted	Systematic scanning processes of the health products market take place in all firms	The number of scanning tools employed varies across cases
1b. Knowledge inflow is promoted through HR		Firms A, F, G and I hire FMCG employees in order to obtain additional insights into the health products market

Table 23: Search routines — cross-case similarities and differences

5.2.1.2. Routines of Interaction

Routines of interaction are responsible for the processes of communication and coordination across the departments of the firm, contributing to the exchange of knowledge. They are crucial of the organizational dynamics of innovation as the systematic exchange of information and knowledge within the company supports the diffusion of knowledge and consequently the generation of knowledge. This includes routines of decision making, who impact the way in which knowledge and ideas can be recombined initiating innovative problem solving processes. Six cross-case patterns of routines of interaction crystallized out of the interview data (table 24).

[94] '75% of staff in my marketing team is former FMCG-employees. We do not think in pharmaceutical terms; after all, our aim is to find the smartest ideas to operationalize and market a health claim.' (Int. I[b])

2. ROUTINES OF INTERACTION	
2a. Systematic coordination efforts to increase the communication between pharma and CHC are made	**A** [a, b]; **B**; **D** [a]; **E** [a]; **F**; **G** [a]; **I** [a, b]
Via the promotion of interdepartmental synergies	**A** [a, b]; **D** [a]; **F**; **G** [a]; **I** [b]
By fostering of interrelations of the departments	**B**; **D** [b]; **E** [a]; **F**; **I** [a, b]
2b. CHC enjoys (partial) autonomy of decision	**A** [a, b]; **B**; **C**; **D** [a, b]; **E** [a, b]; **F**; **G** [b]; **I** [b]
CHC organized along independent structures, no structural dependence from Rx	**A** [a]; **B**; **D** [a]; **E** [a]; **F**; **G** [b]; **I** [b]
No structural separation between OTCs and health products	**A** [a]; **B**; **C**; **D** [a]; **E** [a]; **F**; **G** [b]; **I** [b]
2c. The hierarchical relation between Rx and CHC is balanced	**A** [a,b]; **B**; **C**; **D** [b]; **E** [a, b]; **F**; **G** [b]; **I** [a, b]
CHC & Rx equally represented	**A** [a, b]; **B**; **D** [b]; **F**; **G** [b]; **I** [a, b]
CHC in present on the executive level	**A** [a]; **B**; **C**; **F**; **I** [b]
Hierarchical dominance of Rx over CHC	**D** [a, b]; **E** [a, b]
2d. Profitability as the decisive criterion for innovation decisions	**A** [a, b]; **B**; **C**; **D** [a,b]; **E** [a]; **F**; **G** [a, b]; **H** [a, b]; **I** [a]
High margin is crucial	**A** [a, b]; **B**; **C**; **D** [b]; **E** [a]; **F**; **G** [a, b]; **H** [a, b]; **I** [a]
Preservation of high margin through distribution channel	**A** [a]; **B**; **C**; **D** [a, b] **G** [a, b]; **H** [a, b]; **I** [a]
Preservation of high margin through product status	**B**; **C**; **D** [b]; **E** [a] **G** [b]; **I** [a]
2e. Favoritism of the pharmaceutical over the non-pharmaceutical	**A** [a, b]; **B**; **C**; **D** [a, b]; **E** [a, b]; **F**; **G** [a, b]; **H** [a, b]; **I** [a, b]
Maximum product exclusivity desired for new products	**A** [a, b]; **C**; **D** [a, b]; **E** [a]; **F**; **G** [a, b]; **H** [a, b]; **I** [a, b]
Attained through the distribution channel: pharmacy	**A** [b]; **C**; **D** [a] **F**; **H** [a, b]; **I** [a, b]
Attained through product status: pharmaceutical	**A** [a]; **C**; **D** [a, b]; **F**; **G** [a, b]; **H** [a,b]; **I** [b]
The product status is crucial when planning innovations	
Product status irrelevant	**A** [a, b]; **G** [a]
Product status relevant	**B**; **C**; **D** [a, b]; **E** [a, b]; **G** [b]; **H** [a, b]; **I** [a, b]
Health products developed function as strategic bridges	**E** [a, b]; **G** [a, b]; **H** [a, b]; **I** [b]
2f. Consideration for the market power of the pharmacist	
Loyalty to the pharmacy market to maintain the pharmacy as the major source of revenue	**A** [a, b]; **B**; **C**; **D** [b]; **E** [a, b]; **F**; **G** [b]; **H** [a, b]; **I** [a, b]

Table 24: Routines of interaction — patterns from the case studies

Pattern 2a: Systematic coordination efforts to increase the communication between pharma and CHC are made

Many firms systematically exploit synergies between the CHC and the Rx-sections.[95] This is noteworthy, as otherwise the structures and processes are separated,

[95] Interviews A [a, b]; D [a]; F; G [a]; I [b].

functioning independently from each other.[96] It is pointed out in the interviews that continuous attempts are made to coordinate the synergetic exchange between the departments. Interestingly, this is done in order to increase efficiency by sharing administrative resources, such as back office facilities, human resource management structures or IT. At the same time it establishes institutionalized channels of communication.

'[Wir nutzen] Synergien überall dort, wo es Sinn macht. Natürlich gibt es ein Dach über den einzelnen Segmenten, was die Beteiligten auch zwingen soll, sich auszutauschen und Bescheid zu wissen.' (Int. D[b])[97]

More importantly however, coordination routines regarding formal interrelations and channels of communication between the different departments within and beyond the CHC-segments of the firms are observable.[98] The coordination efforts undertaken to install and maintain those channels of communication are a reaction to identified weaknesses in this domain. It is pointed out that the relation between the R&D or regulatory departments and the marketing department hampers the innovation activities. Traditionally, R&D and marketing are completely separated, the reason being that R&D controls the development process of pharmaceuticals, while marketing plays only a minor role.[99] The interviewees state that the reversal of this distribution of roles is difficult. While the regulatory authorities assess the value of innovation projects according to their scientific feasibility, marketeers apply clearly different standards. Consequently, the routinized cooperation patterns between the two departments bear tensions, in particular with respect to the development of health products, who require even more marketing than traditional pharmaceuticals.

'Bei Pharma ist es vielleicht dringender erforderlich, dass Medizin und Marketing strikt getrennt sind, beispielsweise aus Compliancegründen und natürlich, um die wissenschaftliche Validität des Produkts nicht zu gefährden. Dass ist bei OTCs und besonders bei Gesundheitsmitteln natürlich ganz anders, da müssen wir umdenken.' (Int. F)[100]

'Die Kommunikation funktioniert gar nicht, das muss man so klar sagen. […] Unsere F&E ist ausschließlich pharma-orientiert: Die wissen, wie man einen Stoff baut und nachbaut und eventuell noch verbessert und wie man daraus eine Tablette macht. Aber die sind überhaupt nicht marktorientiert. Und ich glaube, dass das einer der Haupt-

[96] See pattern 2c.

[97] '[We make use of] synergies wherever it is possible and useful. However, all segments operate of course under a single roof, which forces actors to exchange knowledge and to keep informed about what is happening in the organization.' (Int. D[b])

[98] Interviews B; D [b]; E [a]; F; I [a, b].

[99] As discussed above, marketing in the classical sense is of little to no importance for the development and merchandising of pharmaceuticals (Rx products in particular). The dominant drivers of pharmaceutical innovations are R&D and the marketing authorization process.

[100] 'Perhaps, the separation between marketing and the medical apartment is more important for pharma, for instance, for reasons of compliance and of course in order to not threaten the scientific validity of the product. Of course the situation is different for OTCs and even more so for health products. Here we must change our thinking.' (Int. F)

punkte ist, warum die Pharmaindustrie im Bereich der Gesundheitsmittel kein Treiber ist.' (Int. E[a])[101]

The deficits with respect to the interdisciplinary communication have been recognized as a barrier to efficient CHC innovation processes. Coordination efforts are therefore made in order to institutionalize communication structures that allow efficient cooperation between R&D and marketing. This includes platforms for interdisciplinary exchange and business units within the CHC department. They act as coordinating organs that synchronize the interdependent activities of the various departments involved in the innovation process.

'[…] Wir versuchen schon aktiv, die Kommunikation [zwischen Marketing und R&D - AN] zu verbessern. Sie sehen das daran, dass es seit 4 Jahren unseren Bereich [Brand Business Support - AN] gibt, vorher hat sich niemand mit der aktiven Suche nach OTCs und Food Supplements für Innovationen beschäftigt. Es gibt da klar die Bestrebung, mehr marktorientiert auf Produkte zu schauen, zusammenzuarbeiten, uns Produkte zu suchen, die nicht Arzneimittel sind.' (Int. E[a])[102]

'[…] Wir haben vor vier oder fünf Jahren eine eigene strategic business unit ins Leben gerufen, darin sitzen Vertreter von Regulatorik, Marketing, Medizin an einem Tisch, um genau diese Zusammenarbeit zu prüfen und zu verbessern. Das ist nicht dasselbe wie Marketing, es ist eine eigene SBU [Strategic Business Unit - A/N]. Dabei geht es, wie der Name sagt, um strategy, business und unity. Das ist sehr wertvoll.' (Int. F)[103]

Pattern 2b: CHC enjoys (partial) autonomy of decision

Routines of interaction can also be observed with respect to decision making processes. Despite the exploitation of synergies between CHC and the rest of the organization[104], most of the pharmaceutical firms organize their CHC business independently from the Rx business. Innovation processes are conducted independently of the Rx-section of the firm; the CHC departments direct their activities largely themselves, enjoying a stand-alone status within the larger organization.[105] This independence of CHC from the remaining organization is due to separated organizational structures that they have available. The CHC departments usually operate their own marketing and R&D departments and distribute their products through an individual sales force. Again, those routines arise naturally from the diverging needs of

[101] 'The communication is not working at all, I must say. […] Our R&D department is fully pharma-oriented: all they know is how to design and recreate an ingredient, perhaps even how to improve it and integrate it into a tablet. Yet, nothing they do is market-oriented. I believe that this is a main reason why the pharmaceutical industry is no driver for health products.'

[102] '[…] We are already trying actively to enhance the communication [between the marketing and R&D department - AN]. The fact that our department [Brand Business Support - AN] has existed for four years already visualizes this. Before, nobody was concerned with searching for ideas for future OTC and Food Supplement innovations. Strong attempts are made to look at products from a more market-oriented perspective, to cooperate and to watch specifically out for ideas for new non-pharmaceuticals.'

[103] '[…] Four or five years ago we set up a strategic business unit in which representatives of the regulatory and the medicinal department and marketing come together to improve cooperation. This does not equal the work of the marketing department, it is organized as an independent SBU. It is concerned with what its name suggests: strategy, business and unity. That is very valuable.'

[104] See patterns 2a. and 3a.

[105] See interviews A [a]; B; D [a]; E [a]; F; G [b]; I [b].

Rx- and CHC-innovations. An infrastructure shared by Rx and CHC could not be efficiently used by both segments.

As a result of this structural division, the CHC departments enjoy significant freedom of action with respect to their decision making processes. Considering the significant difference in size between the Rx and CHC businesses of the firms, the structural independence is remarkable. It indicates that the firms are — despite the tiny size of CHC in contrast to Rx — willing to strengthen the position of CHC. The interviews yield that this impacts the decision making routines positively, as it enables decision makers to really live the different dynamics of innovation of CHC products.

> *'Wir sind nicht pharma-dominiert, den Eindruck hatte ich in 15 Jahren nicht. Wir sind natürlich verbunden, unsere Geschäftsführung wird aber von denen überhaupt nicht gebremst. Im Gegenteil: wir profitieren von deren Forschung. Gleichzeitig mischen sie sich in die operativen Dinge nicht ein, weder in die Werbung, noch in die Personalpolitik bzgl. der FMCG Leute.' (Int. I[b])*[106]

> *'Die Geschäfte sind komplett getrennt. Wir arbeiten mit Parallelstrukturen: Pharma- und CHC-Geschäftsführer arbeiten mit ihren Abteilungen unabhängig voneinander. Trotzdem laufen Prozesse Hand in Hand wo immer möglich, logische Synergien in den Bereichen Backoffice, HR, Finanzbuchhaltung, IT werden genutzt. Die operative und strategische Zweiteilung zieht sich bis zum CEO hinauf, er ist die einzige Person, die alle Segmente der Firma in sich vereint; der president pharma berichtet genauso an den CEO wie der president CHC.' (Int. A[a])*[107]

However, the innovation processes are not operated independently from the larger organization in all respects. Decision making is not entirely up to the CHC departments of the pharmaceutical firms. Bonds and structural dependencies to the Rx-department are present with respect to regulatory and medicinal questions. Regulatory and scientific questions, which are crucial for CHC innovations, remain under the control of the central authorities in the large majority of the firms.[108]

> *'Bei Fragen des Marketings und F&E hat CHC bereits einen stand-alone Status. Es gibt noch enge Verzahnungen in den Bereichen Regulatorik, Medizin, Enabling Functions. Unsere strategische Perspektive ist aber der Ausbau des CHC-Geschäfts und diese Umstrukturierung dahin wird auch in Zukunft aufmerksam von uns weiter betrieben' (Int. B)*[109]

This also impacts the decision routines with respect to CHC innovations. As already highlighted above, it is stressed that the different understanding of innova-

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[106] 'We are not pharma-dominated, I have never had this impression for the last 15 years. Of course, we are connected, yet this does not affect our management at all; in contrast, we profit from their research. At the same time they do not intervene in our operative business, neither in marketing and advertising, nor in our human resources policies regarding FMCG hires.' (Int. I[b])

[107] 'The businesses are completely separated. We work in parallel structures: the executives in pharma and CHC manage their departments independently from each other. Yet at the same time, processes are synchronized whenever possible, logical synergies in areas such as back office, HR, accounting or IT are used together. This operative and strategic separation is maintained through the hierarchy up to the CEO. He is the only person combining all segments; the president pharma reports to the CEO just like the president CHC does.' (Int. A[a])

[108] Interviews A [a, b]; B; D [a]; E [a]; F; G [a]; I [a, b].

[109] 'Regarding marketing and R&D questions CHC has obtained stand-alone status already. There are still interconnections in the areas regulatory, medical affairs and enabling functions. But our strategy is to expand the CHC business and the corresponding restructuring is attentively pushed forward by us.' (Int. B)

tions of the central regulatory organs of the firms and the CHC departments produce tensions that hamper the CHC innovation processes. The limited freedom of action of the CHC departments regarding regulatory and medicinal questions underlines this. The freedom of decision of CHC allows the segment to develop their individual decision routines regarding the implementation of innovation projects. The structural separation between CHC and Rx, which is the basis for the divergent decision routines, thereby reflects the diverging requirements for successful innovation activities of both segments.

What is clearly missing, however, is a further structural differentiation between pharmaceuticals and health products within the CHC divisions.[110] Usually, CHC-brands of pharmaceutical firms comprise OTCs as well as health products (i.e., certain products are sold at two different dosages, where the higher one is marketed as a pharmaceutical, while the lower dosage is classified as health product). Viewing the significantly different product development processes of OTCs and health products, a structural separation on this level would be appropriate. However, decision processes ignore the different product statuses of OTCs and health products. Instead, all pharmaceutical firms pool both product categories within the same structures: usually, the product manager for each individual CHC brand is responsible for all products it comprises.

> *'Grundsätzlich sind die Gesundheitsmittel den OTCs hierarchisch untergeordnet und komplett in deren Strukturen verankert; dabei sind die Gesundheitsmittel sicherlich der kleine Bruder der OTCs. Auch innerhalb der Firma und der Unternehmensleitung sind sie nicht einzeln aufgestellt.[…] Beispielsweise wurde bei einem unsere Produkte als Ergänzung zum OTC das Produkt irgendwann in einer Darreichungsform auch als Nahrungsergänzungsmittel in den Markt gebracht. Entwickelt und vertrieben werden aber beide Produktkategorien von ein und derselben Person, dem OTC-Produktmanager. Da unterscheiden wir zwischen den einzelnen Marken, nicht zwischen den Verkehrsfähigkeiten. Annähernd einen stand-alone Status hat nur unser größtes Gesundheitsmittel, da lohnt sich das.' (Int. E [b])*[111]

Pattern 2c: Hierarchy

The hierarchical relations between the organizational segments also impact the decision making routines of the pharmaceutical firms. In the majority of the firms the relation between the Rx-segment and CHC is described as one of two equals, where the CHC segment is equally represented in the decision making organs of the firm.[112] This is the case, even though CHC and Rx differ significantly in terms of the amount of revenues they generate. The interviewees indicate that naturally, the concerns of

[110] Interviews A [a]; B; C; D [a]; E [a]; F; G [b]; I [b].

[111] 'In general, health products are subordinate to OTCs in hierarchical terms and rooted in their structures completely. This certainly makes health products the little brother of OTCs. For instance, a food supplement was once developed from one of our OTCs and launched in addition to the OTC. However, both product categories were developed and marketed by the same single person, the OTC project manager. We do not differentiate between the different product categories but between our brands. Only our biggest health product comes close to enjoying a stand-alone status, in this one case it is worth it.' (Int. E [b])

[112] Interviews A [a,b]; B; D [b]; F; G [b]; I [a, b].

the Rx-segment outweigh those of the CHC segment in decision making processes, simply because of the strategic importance of the Rx-business for the whole organization, resulting from the difference in size. Nevertheless, it is repeatedly stated that this does not affect the relative weight of CHC-innovations adversely. Decisions about the allocation of resources for future innovations are made democratically, based on the equal evaluation of CHC and Rx innovation projects.[113]

> *'[…] jeder [Rx und CHC - AN] versucht eigenständig, seine Ziele zu erreichen, ohne allzu große gegenseitige Beeinflussung. Beide haben dieselbe Stimme, auch wenn Pharma wegen des Größenunterschieds natürlich die größere Bedeutung hat. - Trotzdem: schließlich sind wir der Teil, der wächst. Das stärkt die strategische Position von CHC im Unternehmen, wir werden ernstgenommen.' (Int. A [a])*[114]

The democratic decision making processes anchored in the decision routines observable in the majority of the pharmaceutical firms is also reflected in the executive structures: the CHC business is represented in the majority of the executive boards.[115] This illustrates that CHC is actively included in the strategic decision making process at the executive level of the organization.

> *'Im Executive Board ist Health Care vertreten, das schließt natürlich OTCs und Gesundheitsmittel gleichermaßen ein. Die OTC-Sparte ist an sich strategisch wichtig für uns und auch als solches erkannt.' (Int. F)*[116]

Company B is particularly good example for the role CHC plays in the decision making processes. As a reaction to an increasing importance of the segment over the last years, the company's executive board was expanded by a representative of CHC:

> *'Wir haben uns jüngst umstrukturiert, es gibt neuerdings im Vorstand einen eigenen Bereich, der sich nur mit Tiergesundheit und CHC beschäftigt. Früher war CHC ein Teilbereich von Pharma und damit natürlich immer der kleinere Partner. Die Alleinstellung des Bereichs allein sendet schon eine Botschaft.' (Int. B)*[117]

In two company cases only was it pointed out that the hierarchical dominance of the Rx segment is not counterbalanced by democratic decision making routines and that instead the CHC segment is clearly at disadvantage.[118] It is emphasized in those cases that strategic decisions about innovations are usually made in favor of Rx-pharmaceuticals, while the CHC-portfolio is put at a disadvantage.

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[113] This aspect of decision making is concerned with the strategic question of whether or not to invest in a CHC innovation. It is independent of the decisions of the CHC department regarding the practical realization of the innovation projects, once they are approved (patterns 2d., 2e., 2f.).

[114] '[…] everybody [Rx and CHC - AN] tries on their own to reach their goals, without too much of mutual interference. Both have the same say, even though pharma is — due to its size — obviously more important. However, we are the segment that grows. This strengthens the strategic position of CHC within the company; we are taken seriously.' (Int. A [a])

[115] Interviews A [a]; B; C; F; I [b].

[116] 'The Health Care segment is represented in the executive board, this includes OTC and CHC alike, of course. The OTC segment per se is important for us and one is aware of that.' (Int.F)

[117] 'We did some restructuring recently, CHC and animal health are now represented in the board. In the past, CHC was a subpart of pharma and this always made it pharma's inferior partner, of course. Now, the stand-alone status of the department sends a signal on its own.' (Int. B)

[118] Interviews D [a, b]; E [a, b].

'Natürlich beeinflusst die Struktur die Kommunikation über Innovationsvorhaben und beeinflusst auch das Gewicht, das OTCs und Gesundheitsmittel haben. Unser Vorstand Produktion ist Apotheker, viele andere Vorstände auch. Durch die Historie sind wir von der ganzen Struktur her natürlich stark Rx-geprägt, das beeinflusst auch die strategischen Entscheidungen. […] OTC und GM sind ganz klar der kleine Bruder von Rx, wobei Gesundheitsmittel unter OTC laufen und keine eigenen Strukturen haben: alle Schritte von der Entwicklung bis zur Vermarktung laufen in denselben Strukturen ab.' (Int. E [a])[119]

Pattern 2d: Profitability as the decisive criterion for innovation decisions

The empirical data indicates that in addition to the structural conditions, impacting the decision making routines regarding CHC innovations, profitability of product innovations is a major decisive criterion for innovation decisions.[120]

'Ich halte die wirtschaftlichen Möglichkeiten für den ausschlaggebenden, vielleicht sogar den einzigen Grund für die unterentwickelte Innovationskraft der Pharmaindustrie im Bereich der Gesundheitsmittel.' (Int. C)[121]

The interviews point out that the quality a new product is determined by its margin. This maxim is deeply anchored in the decision routines of all pharmaceutical firms examined.[122] Of course this reflects perfect entrepreneurial thinking and sounds barely worth mentioning. However, in this case it effects the dynamics of innovation regarding health products, as their margin lies considerably below that of pharmaceuticals. Two patterns become apparent in the data: decision making processes aim at preserving high margins through the selection of the distribution channel and through the product status.

Firstly, the interviews highlight that the complex process of deciding about Health Product innovations is mainly reduced to the question of their margins and profitability. The pharmaceutical firms are used to very high margins attained in the Rx-market, which the health products mass-market can hardly yield. In order to obtain the highest possible margins, most of the firms limit their activities regarding health products to the pharmacy market, making use of the fact that the average selling prices for health products in pharmacies are higher than in the mass market.[123]

'Entscheidend für die Wahl der Apotheke als Vertriebskanal ist natürlich die Marge. Sie werden im Vergleich zur Apotheke im Mass Market nie Geld verdienen, selbst bei riesigen Absatzmengen, Umsatz und Profit sind in der Apotheke massive höher, nicht zuletzt, weil es da natürlich auch keine Händlermacht gibt, die über Kooperationen

[119] 'Of course the structure impacts the communication regarding planned innovations as well as the weight that OTCs and health products have internally. Our CPO is a pharmacist by training, many of his colleagues are pharmacists as well. Due to our company history our entire structure is coined by Rx and this impacts the strategic decisions made. […] OTCs and health products are clearly Rx's little brothers, while health products are subordinate to OTC, having no independent structures. All steps — from development to marketing — take place in the same shared structures.' (Int. E [a])

[120] Interviews A [a, b]; B; C; D [a,b]; E [a]; F; G [a, b]; H [a, b]; I [a].

[121] 'In my opinion the economic opportunities are decisive, perhaps they are the only reason for the underdeveloped innovative capacity of the pharmaceutical industry with regard to health products.' (Int. C)

[122] Interviews A [a, b]; B; C; D [b]; E [a]; F; G [a, b]; H [a, b]; I [a].

[123] Interviews A [a]; B; C; D [a, b] G [a, b]; H [a, b]; I [a].

und Listungen Preise durchsetzt (siehe Rossmann oder dm), die nicht für eine anständige Marge reichen.' (Int H [b])[124]

'Der deutsche Apothekenmarkt ist im Grunde ein Paradies für uns. Das Apothekengeschäft ist viel preisattraktiver, margenstärker, nicht bedroht durch Handelsmarken (bis auf einige wenige punktuelle Ausnahmen).' (Int. B)[125]

'Pharmaunternehmen sind sehr verwöhnt durch ihre Margen und es fällt ihnen schwer in einen Markt zu gehen, der zwar Umsatz verspricht, aber auch niedrigere Margen. […] Die Marge ist ein Hauptgrund, warum Pharmaunternehmen den Gesundheitsmittelmarkt und besonders dessen Teil außerhalb der Apotheke nicht anfassen.' (Int. E[a])[126]

Those decision routines result in a deliberate refusal of the mass market as the (second) distribution channel for health products. Instead, the established distribution channel is exclusively used for health products.

However, a second aspect of significant influence on the pharmacy-focus is the principle to avoid involvement in the market mechanisms of the mass market. The mechanisms of the mass market differ enormously from those in the pharmacy market, leading to the erosion of selling prices and margins relative to the pharmacy. The data indicates that the firms are and feel foreign to the pharmaceutical firms. Learning how to act in them is no option for the firms; it appears as a cross-company pattern of decision making not to leave the known terrain of the pharmacy at the risk of 'drowning' in the unknown market structures. Interestingly, the fact that the pharmaceutical industry does not yet have the competences required for mastering the mass market seems to serve as an argument to not build them up. The result are decision routines that leave no space for a strategic reorientation towards the mass market.

'Das Thema ist, dass im Mass Market ein hoher Wettbewerbsdruck herrscht. […] Ich bewege mich dann also zum einen in einer Rabatt- und Kommissionsstruktur, die nicht dazu geneigt ist, mir als Hersteller am Ende Geld zu bringen und zum anderen habe ich dann die Diskussion mit dem angestammten Publikum, also dem Apotheker, der fragt, warum gehen Sie in den Mass Market, wollen Sie uns eigentlich ärgern? […] Aus der Sicht, so lange die rechtliche Situation so ist, dass wir nicht gezwungen sind, über den Markt nachzudenken, sollten wir die Entscheidung, in den Markt zu gehen, sehr mit Bedacht fällen.' (Int. I[a])[127]

[124] 'Of course the margin is what drives our decision for the pharmacy as the distribution channel for our products. Compared to the pharmacy you will never earn money in the mass market. Even if massive volumes are sold, revenues and profits are always much higher in the pharmacy. This is not least because the wholesalers have less power in the pharmacy market. So it cannot happen that wholesalers enforce cooperation or price agreements (like Rossmann or dm) that make decent margins impossible.' (Int H [b])

[125] 'In general, the German pharmacy market is paradise for us. The pharmacy business is much more attractive in terms of prices and margins and is not put under pressure by merchandise marks (apart from some exceptions).' (Int. B)

[126] 'Pharmaceutical companies are very much spoiled by their margins and they have had trouble entering a market that holds out revenues yet much lower margins. The margin is another main reason why pharmaceutical companies avoid the health products market in general and its mass market segment in particular.' (Int. E[a])

[127] 'The problem is the high competitive pressure in the mass market. […] This puts me in structures driven by rebate and commission agreements that are unsuited for earning money in them as a manufacturer. At the same time entering the market would raise discussions with my established customers, the pharmacists. They would ask why are you entering the mass market, do you want to upset us? […] In that context, we should be very cautious with deciding about entering that market, as long as the legal environment persists and does not force us to do so.' (Int. I[a])

'Wenn wir uns in den Löwenkäfig der Handelsketten steigen, müssen wir uns vorher klar gemacht haben, dass wir da zerfleischt werden. […] Wir schätzen uns klar nicht stark genug dafür ein, weil wir auch von der Vertriebsseite dafür nicht ausgestattet sind und alle Strukturen neu aufbauen müssten - Sie brauchen key account management und alle Strukturen sind ganz anders, auch wenn das Produkt im Grunde dasselbe ist, das auch in der Apotheke verkauft wird.' (Int. E[a])[128]

'[Im Mass Market herrscht - AN] wesentlich weniger Differenzierungspotential für die Produkte, wesentlich stärkerer Preiswettbewerb, wesentliche Abhängigkeit von wenigen großen Handelsketten. Dazu natürlich der immense Margendruck.' (Int. B)[129]

Related to this is another pattern apparent in the interview data. The majority of the decision makers interviewed emphasize that not only the selection of the distribution channel is a crucial criterion for decisions about product innovations, but that the product status per se plays a role, too.[130] Since the margin attainable for OTCs is — independently of the distribution channel — higher than that of health products, the companies prefer OTCs over health products. In other word, the economic value of the pharmaceutical innovations marginalize health product innovations.

'Man kann sich den Vorteil der OTCs dann leicht ausrechnen: lieber halb so viel Absatz mit 20% Marge als das Doppelte mit 5%.' (D [b])[131]

Pattern 2e: Favoritism of the pharmaceutical over the non-pharmaceutical

The interviews point out that the preference of OTCs over health products is reinforced by the fact that health products enjoy no imitation protection by drug licensing, as OTCs do.[132] It is repeatedly emphasized that this lack of legal protection of innovations influences decision processes, following the logic that the firms rather develop a product that they own the exclusive rights for than one that can easily be imitated by competitors. The danger of imitation is even larger in the mass market than in the pharmacy market, due to the wholesalers' home brands that imitate the original products and market them at competitive prices. The interviewees make clear that whenever possible, the risk of 'sacrificing' an innovative product is avoided. Consequently, the pharmaceutical is preferred; whenever possible, products are developed as pharmaceuticals and (or at least) distributed through the pharmacy.

'Sowieso ist der fehlende Patentschutz der Hauptgrund für die Situation, mit der Sie sich beschäftigen. Man geht in den Mass Market, hat etwas Gutes und wenn es nicht geschützt ist, dauert es genau 3 Monate, bis die Eigenmarken mit einer Kopie auf den Markt kommen, die Preise radikal drücken und das Geschäft kaputt machen. […] Und

[128] 'If – by approaching the wholesale chains — we put our head in the lion's mouth, we must be very clear on the fact that we will be destroyed. […] Clearly we do not perceive ourselves strong enough for that, as we are unprepared in terms of distribution and we would have to build all relevant structures off scratch. You need key account management and all related structures are really different, even if the product remains the same that is also sold in the pharmacy.' (Int. E[a])

[129] 'There is much less potential for product differentiation [in the mass market - AN] as well as a much fiercer price competition, substantial dependence from few big wholesale chains. At the same time there is the immense pressure on margins.' (Int. B)

[130] Interviews B; C; D [b]; E [a] G [b]; I [a].

[131] 'It is easy to calculate the advantages of OTCs in this context: better make half of the sales at a margin of 20% than sell double of it at a 5% margin.' (D [b])

[132] Interviews B; C; D [b]; E [a] G [b]; I [a, b].

auch die Eigenmarken haben mittlerweile einen so guten Ruf, dass der Konsument fast genauso großes Vertrauen hat.[…]Da haben wir bei der Apotheke viel größeren Schutz, da gibt es nicht diese fürchterliche Preiserosion, wie im Mass Market. Da wird man für über 5€ ja kaum noch etwas los.' (Int. G [b])[133]

'Im Grunde gibt es im Mass Market ja nur ein Marketinginstrument und das ist der Preis. Und warum soll ich mit einem innovativen Produkt und ohne Not in einen Markt gehen, der vom Preis bestimmt wird und in dem ich ansonsten keinen Schutz habe. Im Mass Market wird mir das Leben nur vom Preis und von der Gefahr des Nachahmens schwergemacht. […] Warum sollten wir wertvolle Innovation so opfern?' (Int. H [a])[134]

It becomes apparent that exclusiveness of product innovations and their protection from competition are dominant patterns in the decision making processes of the pharmaceutical firms. The pharmaceutical firms avoid open competition with imitators, as they are not used to it. The selection of the distribution channel and the product status aim at bestowing the CHC products with a quasi-exclusiveness, resembling that of the Rx-pharmaceuticals. At the same time, the economic properties of Rx-products and (to a lesser degree) OTCs lay the base for the evaluation of health product innovations and the decision routines. The representative of company C brings the complexity of the routinized decision making process to the point:

'Die Pharmaindustrie ist von den Arzneimitteln her guten Schutz gegen Nachahmer gewohnt, den gibt es bei den Gesundheitsmitteln nicht. Auch die Differenzierungsmöglichkeiten sind nur sehr klein. Es wird mir eigentlich immer klarer: Unser Ziel ist schneller und hoher Profit, was bei den Kompetenzdefiziten der Pharmaindustrie im Gesundheitsmittelmarkt einfach nicht möglich ist. Dadurch fehlt die Plattform, um gute Ideen marktwirtschaftlich sinnvoll umzusetzen, das würde mehr Zeit brauchen und man müsste Flops in Kauf nehmen. OTC-Switches als Innovationsquelle fühlen sich da für die Unternehmensleitung natürlich viel besser an, da muss man nicht vom Gewohnten abweichen.' (Int. C)[135]

The empirical data points out that the majority of the pharmaceutical firms approach the decision making processes form the question of the regulatory product status rather than from the therapeutic attributes of the product. Decision makers in two companies only emphasize that the product status is irrelevant and that instead the satisfaction of the recognized consumer needs is central to their decision pro-

[133] 'The missing patent protection is the main reason for the situation that you are analyzing. One enters the mass market with a good product, yet if it is not protected, it takes exactly three months until the private labels launch the same product, destroying the prices and the business […] Also, the reputation of the private labels has become good enough for consumers to trust them. […] Due to the much better protection in the pharmacy, there is no such terrible price erosions as in the mass market. You can barely sell anything for 5€ there.' (Int. G [b])

[134] 'At the end of the day there is only one marketing tool for the mass market: the price. So, why should I launch an innovative product in a market, of which I know that it is dominated by the price and provides no protection. In the mass market, the price and the danger of being copied are giving me a hard time. […] Why should I sacrifice a valuable innovation there?' (Int. H [a])

[135] 'Stemming from the pharmaceuticals, the pharmaceutical industry is used to very good protection from imitators, which does not exist for health products. Also, being distinguishable is very difficult. It is clear to me: our aim is to make high profits quickly. Facing the competence deficits of the pharmaceutical industry regarding the health products market, this is not feasible. It does not give us the platform we would need for implementing good ideas in an economic way. This would use up much of our time and we would have to accept failure. Therefore, OTC switches as source of innovations appear much more attractive to the management, it requires no departure from what one is used to already.' (Int. C)

cesses.[136] Decision routines are largely decoupled from the regulatory and economic 'advantages' of OTCs that the pharmaceutical firms account for in their decision processes.

> *'Die Zukunft liegt meiner Meinung nach im Erkennen der consumer needs und in dessen Befriedigung - nachgelagert entscheide ich über den Produktstatus. Schließlich definiere ich zuerst ein Produktprofil, das ein Verbraucherbedürfnis befriedigen soll und dann erst überlege ich mir, welchen Status ich wähle. Meiner Meinung nach macht es keinen Unterschied ob das Produkt ein Arzneimittel oder ein Nichtarzneimittel ist und auch für den Verbraucher macht es keinen Unterschied.' (Int. A [b])*[137]

All other interviewees, however, highlight that the product status is the central determinant of their decision processes, the therapeutic properties being secondary.[138] OTCs are the companies' first choice for CHC innovations, as they provide the advantages regarding imitation and margin that are discussed above. Decision routines therefore consider OTCs first and move on to health products only if an OTC cannot be developed. For both product categories, the pharmacy market is considered first, followed by the mass market.

> *'Wir sind als Unternehmen klar auf Profit fokussiert - wo lässt sich der machen? Aldi macht 2%, Beiersdorf vielleicht 10%, andere Mass Market-Unternehmen auch 15%, aber im Pharmageschäft liegen wir bei 20-25%. Das natürlich vor dem Hintergrund des Forschungs- und Zulassungsrisikos. Bei der Überlegung, welche Produkte aufgebaut werden sollen, versuchen wir natürlich, den Markt also top-down zu screenen - wo können wir am meisten Profit machen? Beispiel ZNS-Bereich: wenn wir im Rx-Bereich keine weiteren Innovationsoptionen haben, gehen wir eine Stufe runter, in den apothekenexklusiven Bereich und fragen uns, was wir da machen können. Wenn wir auch da Probleme haben, schauen wir erst auf den Mass Market bzgl. Arzneimittel und erst dann [auf] die Gesundheitsmittel. Gesundheitsmittel sind also meist last choice oder, böse gesagt, Abfallprodukte als strategisches Ziel. […] Nur dann, wenn es Probleme mit der Pipeline gibt, denken Pharmaunternehmen in der Regel ernsthaft über Nichtarzneimittel als zweites Standbein nach; das ist immer erst nachgeordnet. Ganz links in unserem Spektrum steht quasi das onkologische orphan drug für Intensivpatienten, dann kommen Allgemeinarztprodukte, dann die verschreibungsfreien apothekenexklusiven Arzneimittel, dann Arzneimittel im Mass Market, dann apothe-*

[136] Interviews A [a, b]; G [a]. Interestingly, all three interviewees also mention the importance of health products as a strategic stopgap while the marketing authorization of a similar pharmaceutical is pending. Of course, this partly reduces the credibility of their statements.

[137] 'In my opinion, identifying and satisfying consumer needs is the future. In a second step, I decide about the product status only. First of all I define a product profile that is to meet the needs of consumers. Deciding on the regulatory status of this product is the second step only. In my opinion, it makes no difference whether the product is a pharmaceutical or not. For the consumer it makes no difference, either.' (Int. A [b])

[138] Interviews B; C; D [a, b]; E [a, b]; G [b]; H [a, b]; I [a, b].

kenexklusive Gesundheitsmittel und schließlich solche im Mass Market. So staffeln wir auch unsere Prioritäten.' (Int. D [b])[139]

In addition, it is stressed that — if health products are an option at all — they are used to bridge short-term bottlenecks, arising during the marketing authorization process of an OTC.[140] In order to already access the market, one version of the OTC (the same product at a lower dosage, usually) is introduced to the market as a health product. This ensures the continuous presence in the market segment, while waiting for the OTC marketing authorization to be approved.

'[…] wir konzentrieren uns, wenn möglich, auf das Arzneimittel. Allerdings muss man natürlich bedenken, dass eine Arzneimittel-Einführung bedeutet, dass man von der Idee an noch einige Jahre rechnen muss. Da muss man sich natürlich überlegen, ob man sich in der Zwischenzeit mit Gesundheitsmitteln über Wasser halten kann, die ja viel schneller und preiswerter auf den Markt gebracht werden können. Dann ist man schon mal im Markt mit Gesundheitsmitteln und schiebt dann die Zulassung und das Arzneimittel nach.' (Int. H [a])[141]

'Man versucht im Prinzip, den Mass Market nicht nur mit Gesundheitsmitteln zu bedienen, sondern wenn möglich auch regulatorisch nach oben auszuschlagen, durch freiverkäufliche OTCs, und im OTC-Bereich versucht man, durch Schnelligkeit und Timing auch mal eine etwas einfachere regulatorische Version eines Produktes [im Gesundheitsmittelbereich - AN] nachzuschieben, um Entwicklungszeiten zu überbrücken.' (Int. G [a])[142]

A paradox becomes apparent here. The pharmaceutical firms are aware of the health products market and also assign a certain strategic importance to it.[143] At the same time, however, they are not trying to compete with it directly through health product innovations. All companies try to compete with health products through OTCs rather than through health products. Health products play a minor role only: the observable decision routines show that the strategic (and growing) importance of the CHC market perceived by the majority of the firms relates in fact to aggregate

[139] 'Our company is clearly focused on profits - and where can I make them? Aldi makes 2%, Beiersdorf 10% perhaps, other mass market firms 15%, but the pharma business operates at 20-25% profit margins. Of course, this must be seen in the context of the high risk concerning R&D and the marketing authorization. When considering which products to develop, we therefore try to screen the market top-down — where can we make the highest profits? Take, for instance, CNS: if we have no Rx-options for the segment we step down a bit and look what we can do in pharmacy-exclusive segment. If that is also problematic, we screen the mass market for opportunities, starting with pharmaceuticals. Only then we consider health products for the mass markets an option. So, most of the times, health products are last choice or, put negatively, a waste product as the strategic goal. […] Pharmaceutical firms only start thinking seriously about non-pharmaceuticals as a second pillar if there are problems with the pipeline; this always comes subordinately. One could say that on the far left of our product portfolio there is the oncological orphan drug for intensive treatment, next to it to the right are the general pharmaceuticals. Then come the prescription-free pharmaceuticals, followed by the prescription-free pharmacy-exclusive products, the mass market pharmaceuticals, the pharmacy-exclusive health products and finally those in the mass market. That is also how we set up our priorities.' (Int. D [b])

[140] Interviews E [a, b]; G [a, b]; H [a, b]; I [b].

[141] '[…]. if possible, we concentrate on the pharmaceutical. Yet, it must be taken into account that developing a pharmaceutical always means that years go by between the birth of the idea and the actual market introduction. So, one must consider launching a health product in the meantime in order to stay afloat; after all, health products are brought to market much quicker and cheaper. This allows you to be in the market already with a health product and to then introduce the pharmaceutical, once it is approved' (Int. H [a])

[142] 'In principle, what we try is to place not only health products in the mass market but also to use opportunities to upgrade regulatorily by launching OTCs. In the OTC segment we also try to develop health product versions of a product that are regulatorily simpler. Speed and timing allow us to place those products strategically to bridge the development time of the pharmaceutical. (Int. G [a])

[143] Interviews A [a, b]; B; C; E [a]; F; G [a, b]; H [b]; I [b].

market of OTCs and health products. The focus is kept on the pharmaceutical and its classical distribution structures. If a health product is needed to bridge gaps within this segment of the CHC market, one is developed.

Pattern 2f: Consideration for the market power of the pharmacist

Another aspect plays into the decision routines regarding the selection of the distribution channel: the endeavor to maintain the pharmacy as the exclusive distribution channel for the entire CHC-segment. Representatives of all firms highlight that health products *must not* be sold exclusively through the mass market or through the pharmacy and the mass market simultaneously. This has two reasons. First of all — as discussed above — leaving the pharmacy would sacrifice the high revenues obtained in the pharmacy.

A second, equally important consequence would be the pharmacists' rejection of the company's products. Interestingly, the majority of interviewees reported what happened to the company Lichtwehr Pharma in 1998, when it started marketing their products (among them their major product Kwai™) in the mass market.[144] Immediately, pharmacists all over Germany took all Lichtwehr products off their shelves, bringing the company close to bankruptcy.

> *'Das Kwai-Beispiel ist das sicher das beste, es zeigt gut, was passiert, wenn Firmen oder Marken, selbstverschuldet oder nicht, sich von der Apotheke entfernen und in den Mass Market gehen. Der Umsatz in der Apotheke geht dann aber augenblicklich um mindestens die Hälfte zurück und ohne den nützt auch der neue Mass Market-Profit nichts.' (Int. H[b])*[145]

> *'Wir haben das klare Bekenntnis zur Apotheke, auch weil wir um die Spannungen wissen, die entstehen können, wenn man sich in beiden Märkten zu etablieren versucht, Kwai ist da ja immer ein gutes Beispiel.' (I[a])*[146]

> *'Die Geschichte mit Lichtwehr und Kwai hat damals sehr deutlich gezeigt, dass ein falscher Schritt ein ganzes Unternehmen in große Schwierigkeiten bringen kann.' (Int. E[b])*[147]

This shows that the cooperation with the pharmacists as the 'preferred partner' for the distribution of CHC product is also due to the attempt not to lose the pharmacists as customers. The firms' behavior reflects a high market power of the pharmacies and strong historically grown bonds between them and the industry. The anecdote of Lichtwehr Pharma seems to appear in almost all interviews with good

[144] Interviews A [a, b]; B; C; D [b]; E [a]; F; G [a, b]; H [a, b]; I [a].

[145] 'Kwai is certainly the best example for what happens when firms or brands (no matter if self-inflicted or not) depart from the pharmacy and enter the mass market. This lets the pharmacy revenues drop suddenly by at least 50% and without the pharmacy business, the new mass-market profits are useless, as it cannot be compensated.' (Int. H[b])

[146] 'We have a clear commitment to the pharmacy, also because we know about the tensions that can occur when one tries to play in both markets; Kwai is always a good example for that.' (I[a])

[147] 'The story of Lichtwehr and Kwai showed clearly that one wrong move can get an entire company into trouble.' (Int. E[b])

reason: it illustrates the central position of the pharmacist in the innovation processes of the firms. The pharmacists have the power to boycott the products of entire firms.

Accordingly, as the empirical data indicates, the consideration of the exclusive cooperation between the pharmaceutical firms and the pharmacies is deeply anchored in the decision making processes; the fidelity towards the pharmacy is (reinforced by the margins and the 'safety' of this channel) an essential part of the decision routines. Knowing that the pharmacists would punish a partial expansion or a complete transfer of sales to the mass market by dropping the products from their range of goods, the pharmaceutical firms back off from entering the mass market at all.

'Vertriebskanalübergreifender Vertrieb ist sehr schwierig, wegen der starken Position des Apothekers. Wenn ein Apothekenprodukt auch in anderen Kanälen vertrieben wird, dann entsteht für uns ein Channel-Konflikt: es ist eine höchst emotionale Vertriebskanalfrage, da 21.500 unabhängige Apotheker, dann gegen uns sind. Das Festhalten an der Apotheke ist also keine rein rationale und kommerzielle Frage.' (Int. A [b])[148]

'Wenn Arzt oder Apotheker erfahren, dass es ein Produkt auch ohne ihre Beratung im Mass Market gibt, dann spielen sie nicht mehr mit, das ist hoch emotional. Fast nie ist der doppelte Vertriebsweg erfolgreich gewesen. […] Wenn wir beispielsweise mit unserem größten Vitaminprodukt in Deutschland in den Mass Market gehen würden, wäre das sehr gefährlich, weil der Apotheker bei der Preiskonkurrenz mit dem Mass Market nicht mithalten kann und auch gar nicht will. Das Problem weitet sich dann natürlich automatisch auf alle Produkte von uns in der Apotheke aus. Es passiert in der Regel, dass der Apotheker dann nicht nur das eine Produkt, sondern gleich alle Produkte eines Herstellers boykottiert.' (Int. C)[149]

'5% des Geschäfts im Mass Market können die verbleibenden 95% in der Apotheke zerstören. Das lohnt sich bei der Margenschwäche des Mass Markets für uns nicht.' (Int. B)[150]

The market power of the pharmacists places them into a position allowing them to completely block any attempts of pharmaceutical firms to leave the pharmacy market and introduce their health products in the mass market. As the interviewees stress, the reaction of pharmacists to this would most certainly be the delisting of the company's products, independently of how much of the pharmacy-segment is transferred to the mass market.

[148] 'The strong position of the pharmacist makes cross-channel distribution very difficult. When a pharmacy product is also distributed through other channels, we get into a channel conflict: the question of which distribution channel to select is highly emotional, as 21.500 independent pharmacists would suddenly turn against us. Sticking to the pharmacy is therefore not only a rational question but also a commercial one.' (Int. A [b])

[149] 'If physicians and pharmacist learn that a product is sold in the mass market without their prior advice, they stop cooperating, that is highly emotional. Double distribution channels have almost never been successful. One example is Elmex and Aronal. It worked, because the product was distributed outside the pharmacy at first and was later sold through the pharmacy as well. By then pharmacists had already realized the popularity of the product and were happy to include it in their portfolios. Only then, the product was expanded in the market. If we went into the mass market with our biggest vitamin C product, for instance, this would be a dangerous situation. Neither could the pharmacists match up with the price pressure coming from the mass market, nor would they be willing to. Automatically, the problem would expand to all our pharmacy products. What usually happens is that the pharmacist delists not only the one product by boycotts all product of the producer.' (Int. C)

[150] 'Transferring 5% of the business to the mass market can eliminate the remaining 95% in the pharmacy. For us, considering the low-margin mass market, that is not worth it.' (Int B)

Summary, Similarities and Differences

Again, the routine patterns are very homogeneous. No major patterns were identified among just one group of firms, indicating substantial cross-case differences (table 25). It became apparent in the vast majority of interviews that the firms are aware of shortcomings regarding the interdepartmental communication and the effect this has for CHC innovations. Measures are consequently taken in order to coordinate cooperation and open channels of communication.

The picture regarding the hierarchical relation of the segments of the companies and their effect on the CHC dynamics of innovation is rather homogeneous, too. The general tone was that Rx plays — due to its very size — a superior role in the decision making process, while Rx and CHC are at the same time equally represented, being on par with each other when it comes to strategic decision making. In two companies only (D and E) the Rx-segment seems to clearly take on the dominant position, leading to a slight bias of decision making dynamics towards Rx-products.

All firms share a number of decision making routines that impact the dynamics of innovation with respect to health products. On the one hand, the CHC sections of the firms (to which health products belong) enjoy considerable amounts of freedom of decision, as they operate structurally detached from the Rx-segment of the firm. This allows them to enfold the dynamics of innovation needed for CHC products, which are clearly at variance with the requirements for Rx-innovations. This is to be regarded as benefiting the dynamics of innovation of health products as it reduces the danger of a dominance of the Rx business when it comes to the planning and implementing of health products projects.

On the other hand, however, it became apparent that despite the separation of competences between Rx and CHC observable in the firms, the firms manage their CHC segment without further differentiation along product types; OTCs and health products are organized within the same decision making processes. Of course those routines are unfavorable of health products, as pharmaceuticals and non-pharmaceuticals require different dynamics of innovation. If managed within the same structures and along the same decision making processes health products are likely to be subordinated to OTCs, especially in complex decision making processes.

This discrimination of health products against OTCs is strengthened further by the last three patterns identified. Patterns 2d., 2e., and 2f. are also distributed homogeneously across all 9 firms. In general they illustrate a favoritism of the pharmaceutical over health products. High margins came out to be the crucial decision criterion for innovation projects, whereby pharmaceuticals and the pharmacy are naturally preferred over health products and the mass market. Also, the preservation of exclusivity turned out to be a major decision criterion, which contributed to the advantageous position of OTCs and the pharmacy as their distribution channel. Further, the interviews indicate that the decision routines of the firms do (partly due to the

facts above) not consider health products an equivalent to pharmaceuticals but rather as a sometimes useful regulatory compromise. Lastly, it became apparent that the pharmacists enjoy significant market power, being able to block innovation projects for the mass market just by threatening to delist the firms as a consequence. The pharmacists turn out to be key players in the pharmaceutical industry, having considerable influence on the firms' dynamics of innovation.

PATTERN	SIMILARITIES	DIFFERENCES
2a. Systematic coordination efforts to increase the communication between pharma and CHC are made	The majority of the companies have recognized communication deficits between their Rx and CHC departments, effecting CHC innovation dynamics negatively In all those companies routines of communication and coordination are in place, aiming at improving the interdepartmental knowledge exchange	
2b. CHC enjoys (partial) autonomy of decision	The CHC departments of most companies operate largely independently from the Rx-departments	
2c. The hierarchical relation between Rx and CHC is balanced	The CHC departments of most companies except for company E are hierarchically on par with Rx	Decision routines in companies D and E are biased towards Rx-innovations; CHC tends to be at a disadvantage
2d. Profitability as the decisive criterion for innovation decisions	Decision routines of all companies are oriented towards the selection of innovation projects according to their margin => the pharmacy market is preferred over the mass market => OTCs are preferred over health products	
2e. Favoritism of the pharmaceutical over the non-pharmaceutical	All companies favor OTCs over health products, as exclusivity in the market and the regulatory advantages of OTCs are considered crucial for innovation	
2f. Consideration for the market power of the pharmacist	Pharmacists exercise significant power over the decision processes of the firms, as they penalize an expansion to the mass market by delisting products => Loyalty to the pharmacist as the 'preferred partner' is central to the decision processes of all companies	

Table 25: Routines of interaction — cross-case similarities and differences

5.2.1.3. Routines of Combination

Routines of combination influence the recombining and reusing of resources for innovations. Routines of combination can manifest themselves as routines of integration and learning routines. Routines of integration impact the firm's capability of combining resources form different sources to solve a problem, while learning

routines are concerned with the ability to learn experimentally in order to experimentally recombine existing ideas and knowledge as well as to enable new knowledge to enter the organization. As illustrated earlier, routines of combination can take various forms, while they always serve the experimental recombination of organizational resources. Two patterns became apparent in the case studies (table 26).

3. ROUTINES OF COMBINATION	
3a. Interdisciplinary coupling of org. knowledge as to facilitate CHC innovations	**A** [a, b]; **B**; **D** [a]; **E** [a]; **F**; **G** [a]; **I** [a, b]
Exploitation of synergies between CHC and Rx	**A** [a, b]; **D** [a]; **F**; **G** [a]; **I** [b]
Exploitation of interrelations of the CHC and Rx departments	**B**; **D** [b]; **F**; **I** [a, b]
3b. Combination of internal and external knowledge for fostering CHC innovations	
Recognition of the importance of consumer-pull and market-push stimuli for CHC innovations	**A** [a, b]; **B**; **D** [b]; **E** [a, b]; **F**; **G** [b]; **H** [a, b]; **I** [a, b]
3c. Lack of exploratory learning regarding CHC innovations	
Health products as preparation for potential market deregulation	**G** [a, b]

Table 26: Routines of combination — patterns from the case studies

Pattern 3a: Interdisciplinary coupling of org. knowledge as to facilitate CHC innovations

Routines of interaction were identified earlier, regarding the processes of coordination of communication and exchange, as well as the exploitation of interdepartmental synergies. Those routines are beneficial to the firm's dynamics of innovation as they ensure the flow of knowledge within the organization.

At the same time they reflect routines of interdisciplinary coupling of knowledge. The exploitation of synergies between the departments helps the firm combining resources from different parts of the firm.[151] The interdisciplinary coupling of resources through the creation of efficient communication channels contributes to the ability of the firms to recombine resources for innovation.[152] The presence of those routines implies that at least some processes of resource combination are in place in most of the pharmaceutical firms. As mentioned earlier, efficient communication and exchange between the departments of the pharmaceutical firms (Rx and CHC) is essential for health product innovations.

Pattern 3b: Combination of internal and external knowledge for fostering CHC innovations

Another routine pattern is related to the one above. The majority of the interviewees emphasize that their CHC innovations are nourished from two knowledge

[151] Interviews A [a, b]; D [a]; F; G [a]; I [b].

[152] Interviews B; D [b]; F; I [a, b].

sources: internally generated technological knowledge and consumer insights from the markets (collected through the scanning processes that manifest themselves in search routines). According to the data, consumer-pull as well as technology-push factors can be stimuli for CHC innovations.[153]

> *'Der klassische Begriff von Forschung ist in diesem Gebiet gar nicht zentral, sondern die consumer needs. […] Eindeutig ist consumer pull unser Innovationsmotor. […] Wenn man mal ein Patent oder eine Technik hat, die geeignet scheint, schaut man sich das natürlich näher an, zuerst aber schauen wir, ob es Nachfrage gibt. Wir entwickeln nicht einfach Consumer Healthcare-Produkte und schauen dann, ob wir Käufer finden' (Int. B)*[154]

> *'Gesundheitsmittel sind auch bei uns viel stärker consumer-insights-getrieben, der Kernwert einer Innovation ist der Verbrauchernutzen.' (Int. E[a])*[155]

> *'Wir entscheiden das nicht bewusst, was den Anstoß für eine Innovation geben soll, sondern die Frage ist eher, wo sich die innovatorische Nische ergibt. Die kann aus der Technik, aber auch aus dem Konsumenten kommen' (Int. G[a])*[156]

The inclusion of consumer insights into the innovation process of CHC products is remarkable as it shows that the firms are — to some degree at least — willing to experimentally combine resources for innovations. In the core (Rx-) business of the pharmaceutical firms innovations are made solely on the basis of technological and scientific research. Also, OTCs are in most of the cases born out of switches and the pharmaceutical per se is technology driven, rather than demand-driven. In contrast, the empirical data indicates that both sources of knowledge are actively combined. The fact that the firms examined all allow the inflow of knowledge from customer markets for CHC innovations shows that routines are in place that enable the experimental combination of knowledge from different sources. As the literature on innovation routines underlines, this is crucial for innovations. Besides this, the mix of technology-push and consumer-pull strategies manifests once more the independence of the CHC segments of the pharmaceutical firms' Rx segments that is also reflected in the decision making routines. Interview H[b] illustrates that the routines of combination are the result of processes of change, going along with the adaptation to the growing importance of the consumer in the healthcare market.

> *'Ich würde es [den Anteil von Consumer-pull und Technology-push Stimuli für Innovationen - A/N] mit 50:50 beantworten, da hat sich bei uns auch etwas ein Wandel voll-*

[153] Interviews A [a, b]; B; D [a, b]; E [b] F; G [a]; H [b]; I [b].

[154] 'Research in the traditional sense is not central in this domain, but rather the consumer needs. […] Clearly, our innovation engine is consumer pull. […] Of course, if one has a patent or technology that seems useful, one takes a closer look at it. Yet, we analyze first of all, if there is demand for it, instead of just developing a consumer healthcare product and looking for buyers ex post.' (Int. B)

[155] 'In our company, health-products are much more consumer-insights driven, the core value of an innovation is the consumer benefit.' (Int. E[a])

[156] 'We do not decide consciously what initiates an innovation; the question is rather where an innovation niche develops. This can be driven by technology as well as by consumers.' (Int. G[a])

zogen. Früher haben wir verkauft, was wir produziert haben. Heute sagen wir, müssen wir das produzieren, was wir verkaufen können.' (Int. H[b])[157]

However, even though the routines above demonstrate that the firms combine different sources of knowledge for CHC innovations, it remains unclear what effect they really have on the dynamics of innovation concerning health products. A look for learning routines in the firms contributes to understanding the situation.

Pattern 3c: Lack of exploratory learning regarding CHC innovations

In contrast to the routines of integration that were identified, in one company only learning routines are observable, aiming at experimentally exploring the health products market.[158] Both interviewees emphasize that health product innovations and — more importantly — the expansion of their health product segment to the mass market are strategically important for their organization, as it prepares the firm for a potential deregulation of the health markets in the future.[159] It is highlighted that the company is actively and strategically exploring the market in order to profit from learning processes.

'[…] außerdem bietet uns der Mass Market die Gelegenheit, organisatorisch zu lernen und uns auch selbst auf die sicherlich bevorstehenden Umbrüche im deutschen Markt vorzubereiten (die Oligopolstruktur des Mass Market mit Ketten und Großhändlern wird es auch in Deutschland irgendwann geben und da müssen wir wissen, wie man mit denen verhandelt).' (Int. G [a])[160]

'Im Mass Market sind die Deckungsbeiträge niedrig, er ist also nicht gerade lukrativ. Aber wenn man wie wir schon teilweise darin etabliert ist und damit rechnen muss, dass die Käufer weiter in Richtung Mass Market abwandern, lohnt es sich, dort zu bleiben. Sollte es zu mehr Deregulierung kommen, sind wir schon mal als Platzhirsch im Mass Market, das ist sicher auch ein ganz wichtiger strategischer Punkt, der uns dazu veranlasst hat, im Mass Market weiter ordentlich präsent zu sein.' (Int. G [b])[161]

Company G is therefore the sole company in which the statement that the product status is irrelevant for CHC innovation projects is put into action.[162]

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[157] 'I would say that this [the proportion of consumer-pull and technology push stimuli for innovations] is 50:50, a lot has changed in this respect. In the past, we sold what we produced. Today we argue that we may only produce what we can sell.' (Int. H[b])

[158] Interviews G [a, b]

[159] As discussed earlier, the healthcare markets in most countries have been deregulated over the last decades, softening the regulations on selling pharmaceuticals outside pharmacies. If such a deregulation took place in Germany, the position of the pharmacy would be weakened considerably, as the mass market would be opened for all OTCs and prices would fall drastically. In that situation, the focus of the pharmaceutical industry on the pharmacy and the pharmaceutical could turn out disadvantageous.

[160] '[…] the mass market is also an opportunity for organizational learning and for preparing for the changes that are to come about in the German market (also in Germany, the structure of the mass market will turn oligopolistic, with wholesaler chains; we must be prepared and know how to deal with that).' (Int. G [a])

[161] 'The margins in the mass market are low, it is not really lucrative. However, since we are partly established in the market already and since we must expect that consumers migrate further to the mass market, it is worth staying there. If the deregulation should develop further, we are the dominant player in the mass market already. This is another very important strategic aspect that lead us to committing to the mass market and to staying present in it.' (Int. G [b])

[162] Interviews A[a]; G [b]

Otherwise, no clear cross-case patterns of learning routines can be observed. As the preceding discussion shows, the majority of the routines is oriented *against* the experimental formation of resource combinations. The identifiable search routines reflect general curiosity about the extended healthcare market. The decision routines, however, are directed towards the conservation of the traditional core business. This affects learning routines within the core business only: the firms argue in support of the pharmacy as the sole distribution channel for all products, they clearly prefer OTCs over health products and exclusivity through regulatory barriers over open competition. Yet, it certainly excludes routines of *experimental* recombination of resources, which the successful expansion of innovation activities to the health products market (outside the pharmacy in particular) would require. The fact that only company G is willing to exploit the health products in order to strengthen its position in it and to learn for the case the market is to be deregulated, illustrates the lacking ability of the firms to approach the market.

The lack of strong learning routines that becomes apparent naturally diminishes the value of the other two patterns of routines of combination that were identified. Neither the exploitation of synergies, nor the combination of internal and external knowledge for innovations serves the dynamics of innovation of the firms if they are not supported by underlying learning routines.

Summary, similarities and differences

Again, the cross-case patterns of routines of combination that were identified are distributed homogeneously over the cases (table 27).

The routine patterns presented above show a paradox in the behavior of the pharmaceutical firms: on the one hand the majority of the firms couple their organizational knowledge from their departments and actively use consumer insights for their CHC innovation processes. This implies that routines of combination are in place, allowing the firms to experimentally combine their resources for innovations. On contrast, however, the data provides no evidence of deeper learning routines, which would be the requirement for sustainable processes of resource combination. This is illustrated by the fact that only one firm (company G) considers the health products market a starting point for learning processes that could carry future growth while all other firms actively avoid such learning.[163]

[163] Even company G's decision routines are — like those of all other firms — oriented towards highest possible routines and a preference of the pharmaceutical (see patterns 2d. and 2e.). Of course this reduces the value of the learning routines.

PATTERN	SIMILARITIES	DIFFERENCES
3a. Interdisciplinary coupling of org. knowledge as to facilitate CHC innovations	The effort of improving interdepartmental communication made indicates the presence of basic routines of combination	
3b. Combination of internal and external knowledge for fostering CHC innovations	Consumer-pull stimuli for CHC innovations are combined with the traditional technology-based stimuli	
3c. Lack of exploratory learning regarding CHC innovations	No learning routines observable in all companies except G	Company G views the health products market and its activities in it as a preparation for a future deregulation of the healthcare market

Table 27: Routines of combination — cross-case similarities and differences

5.2.1.4. Routines of Diffusion

Routines of diffusion are those routines that influence the diffusion of knowledge within the firm. In contrast to routines of integration, they are less concerned with the mechanisms of integration of knowledge in the organization's segments but rather with the mechanisms that make knowledge available for all actors, through the codification of knowledge (by stocking the knowledge in a language understood by all members of the organization and at a place accessible to all) as well as through its transportation within the firm. One very weak pattern only emerged out the empirical data (table 28).

4. ROUTINES OF DIFFUSION	
4a. Knowledge is formally diffused within the organization and among departments	
Newsletters, centralized collection of innovative ideas	**A** [a]; **B**; **I** [b]

Table 28: Routines of diffusion — patterns from the case studies

Pattern 5a: Formal tools of knowledge diffusion

In company A, B and I formalized channels of communication between the departments of the firm are in place, ensuring a constant exchange of knowledge within the firm. Companies A and I for instance make use of internal newsletters in order to distribute knowledge and ideas to all members of the organization.[164] Similarly, company B installed a central organ collecting internal ideas, dispensing them to the various departments of the firm.[165] Both instruments codify and stock knowledge, making it understandable and accessible for every member of the firm. At the same time the knowledge is transported, ensuring its physical transportation.

[164] Interview A [a]

[165] Interview B

Summary, similarities and differences

Even though the data shows that routines of diffusion are in place in at least three of the pharmaceutical companies examined, the patterns cannot be connected to the dynamics of innovation regarding health products. Those routines can therefore be considered of marginal importance to the analysis.

5.2.2. Cognition and Culture

The empirical data indicates that the organizational culture and managerial cognition of the pharmaceutical firms contribute significantly to the observable dynamics of innovation of the firms (table 29).

5. COGNITION	
5a. The firms feel the duty to conserve its values	**A** [a, b]; **B**; **C; D** [b]; **E** [a, b]; **F**; **G** [b]; **H** [a, b]; **I** [b]
Obligation to adhere to highest scientific standards for all products	**A** [a, b]; **B**; **C; D** [b]; **E** [b]; **F**; **H** [a, b]; **I**[b]
Accepting the moral responsibility and ethics coming along with the production of pharmaceuticals	**A** [a]; **C; D** [b]; **E** [a]; **G** [b]
5b. Ambition to maintain image/reputation	
Commitment to the pharmaceutical and the pharmacy as the basis of industrial reputation	**A** [b]; **B**; **C**; **E** [a] **F**; **G** [b]; **H** [a, b]; **I** [a]
5c. Retention of the exclusive distribution channel pharmacy	**A** [a, b]; **B**; **C; F**; **G** [b]; **H** [a, b]; **I** [b]
Pharmacists as competent sales agents	**A** [a]; **B**; **C**; **F**; **I** [a]
Pharmacies as premium outlets	**A** [b]; **F**; **G** [b]; **H** [a, b]
5d. Commitment to core competences	
Focus on traditional innovation trajectory/Indifference towards health products and the mass market	**A** [b]; **B**; **C**; **D** [a, b]; **E** [a, b]; **F**; **H** [a, b]; **I** [a, b]
5e: Perception of the competition and of the market development	**A** [a, b]; **B**; **E** [a, b]; **F**; **H** [a, b]; **I** [a, b]
Protection through barriers to market entry	**A** [a, b]; **B**; **E** [a, b]; **F**; **H** [a, b]; **I** [a, b]
Competence building hardly possible for outsiders	**A** [a, b]; **B**; **E** [a, b]; **F**; **H** [a]; **I** [a, b]
Credibility is only enjoyed by established players	**A** [b]; **C**; **H** [b]; **I** [b]
No threat from deregulation to the pharmaceutical industry	**A** [a]; **D** [a, b]; **H** [b]; **I** [a, b]

Table 29: Organizational cognition and culture — patterns from the case studies

Pattern 5a: The firm feels the duty to conserve its values

The interviews show that on the cognitive level the firms are heavily attached to the scientific standards of product development that are applied to pharmaceuticals. The high scientific standards that the firms are used to, are deeply anchored in the cognition of decision makers; the firms feel obliged to stick to them without compromise. The pharmaceutical firms hold up the high pharmaceutical quality standards regarding R&D, production and distribution for all product categories. The

majority of the interviewees highlight that no exceptions are made with regard to health products; even though lower regulatory standards are in force for health products than for OTCs (since health products are not pharmaceuticals), the companies apply their pharmaceutical standards to them as well.[166] The interviewees indicate that the scientific standard at which the firms develop products is one of the firms' key values, guiding all innovation activities. As one interviewee puts it:

> *'Bestimmte Prinzipien leiten alle Segmente des Unternehmens und sind nicht kompromissfähig: Arzneimittelsicherheit, mit denselben Anforderungen an CHC und Rx; außerdem muss eine medizinische Rationale hinter all unseren Produkten stehen.' (Int. B)*[167]

It appears from the interviews that integrity, reliability and quality are central values that are to be reflected by all products. The value of new products is consequently measured along this. This places the firms in a situation where the pharmaceutical is automatically the measure of things, as it fulfills those standards. The result is the ambition of the pharmaceutical firms to bestow all products with a sound therapeutic rationale and with credible and reliable health claims. This effort is made, independently of the product category. This situation creates a paradox. Interviewees regularly point out that their company is willing and able to exploit the regulatory niches that health products provide.[168]

> *'Die Pharmaindustrie tickt in Molekülen, ist also strenggenommen für den weiteren Gesundheitsmarkt erstmal ungeeignet. Was sie aber machen kann, um ihre Kernkompetenzen zu nutzen, ist der Ausbau von Produkten und Dienstleitungen um den bestehenden Kompetenzkern herum. Ausgehend von ethischen Arzneimitteln können also durchaus ergänzende OTCs und Gesundheitsmittel in den Markt gebracht werden, um so die Ressourcen des Unternehmens optimal zu nutzen.' (Int. B)*[169]

At the same time, however, it is underlined that this exploitation may under no circumstances jeopardize the scientific substance and quality to which the companies have committed themselves.

> *'Wir pflegen höchste Standards bezüglich der Beleglage unserer Produkte und orientieren die Gesundheitsmittel-Entwicklung an den Arzneimittel-Standards.' (Int. A [b])*[170]

> *'Ein Gesundheitsmittel muss bei uns also durchaus hart und auf Herz und Nieren geprüft werden, es herrscht grundsätzlich eine gewisse Vorsicht - um es neutral zu formulieren und nicht Angst zu sagen.' (Int. E [b])*[171]

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[166] Interviews A [a, b]; B; C; D [b]; E [b]; F; H [a, b]; I[b].

[167] 'There are certain principles that guide all segments of the company and they must not be compromised: product safety of pharmaceuticals for Rx and CHC alike; also, all our products must be backed by a medical rationale.' (Int. B)

[168] As discussed in the chapters on search routines and decision making routines.

[169] 'The pharmaceutical industry is driven by molecules. So strictly speaking, it is unsuited for the health products market. Yet, what the industry can do to develop the core competences further is to expand the range of products and services around them. Based on the Rx pharmaceutical, complementary OTCs and health products can be introduced to the market as to make full use of the organizational resources.' (Int. B)

[170] 'We maintain highest standards regarding the scientific backing of our products and align the development of health products with that of pharmaceuticals.' (Int. A [b])

[171] 'In our company, a health product is tested quite thoroughly. Neutrally formulated, there is a certain caution, if not fear concerning those products.' (Int. E [b])

'Wenn die niedrigen Ansprüche nicht das Ergebnis erfüllen, nämlich ein hochwertiges Produkt, das seine Versprechen hält, dann nutzen wir diese Lücken auf keinen Fall. Wenn wir es umsetzten können, trotz der Bedingungen, dann ja. […] Es gibt Bereiche, wo Arzneimittel einfach nicht das einzig Mögliche ist, beispielsweise Erkältung. Da haben wir ein Nasenspray als Arzneimittel, das abschwellend wirkt, haben aber auch ein Meersalz Nasenspray als Nicht-Arzneimittel auf den Markt gebracht, was dieselbe Indikation hat, aber milder wirkt und dadurch eben andere Verbrauchergruppen anzieht.' (Int. I [b])[172]

Naturally, those ambitions contradict themselves and are hardly combinable. The advantages of health products lie in their relatively quick and cheap development. They are designed to never be substitutes for pharmaceuticals but only supplements.

From the perspective of the pharmaceutical firms, lowering the scientific standards for health products would sacrifice their core value of superior quality and would put their reputation and credibility at risk; yet at the same time, bestowing health products with the same scientific evidence than OTCs would deteriorate their economic value.

'Man muss bedenken, dass das Arzneimittel immer den höheren Stellenwert im Gegensatz zum Gesundheitsmittel hat […]. Das liegt daran, dass es schlicht mit höheren Ansprüchen (Zulassung, etc.) entwickelt worden ist. Es gilt bei uns, soweit die Produktaussagen eine generelle Leitlinie nicht überstrapazieren: wir wissen nicht ganz genau, ob es hilft, aber wir wissen in jedem Fall, es schadet nicht. Das ist eine typische Grenze für ein Pharmaunternehmen und die wird sehr ernstgenommen. Andere Branchen sind da schneller bei der Sache. Genau hier liegen ja die Vorteile der OTCs, wie sie von meinem Unternehmen und sicherlich auch von den meisten anderen Firmen empfunden werden: sie haben alle ihre Historie und sind well-established. Der Erzeuger hat hier kein Rechtfertigungsproblem und hat dadurch natürlich viel weniger Risiko.' (Int. C)[173]

'Die Situation lässt sich allerdings damit erklären, dass wir im Kern eine Arzneimittelfirma sind und der Teil R&D und Regulatorik traditionell einen starken Platz einnimmt; die Sichtweise auf Innovationen und die Ansprüche an sie definieren sich bei uns auf jeden Fall aus dieser Arzneimittel-Historie […].' (Int. E[b])[174]

Quite naturally, because of their diverging scientific standards, health products are not perceived as equal alternatives to OTCs but necessarily as inferior compromises. The interviews underline that the firms perceive pharmaceuticals as superior to non pharmaceuticals in all respects.

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[172] 'If by working with low requirements we do not meet the expected outcome, namely a high quality product that keeps its promises, we exploit that niche under no circumstance. If we can implement all this despite the conditions, then we do it. […] There are segments in which pharmaceuticals are simply not the only possibility, i.e., common cold. We do a nasal detumescing spray as a pharmaceutical in that area, yet we additionally launched a seawater nasal spray as non-pharmaceutical. It has the same indication, yet its mode of action is milder, which addresses different consumer groups.' (Int. I [b]

[173] 'We may not forget that pharmaceuticals always enjoy the higher status, as compared to health products […]. The reason is simply the higher requirements (market access, etc.) that went into their development. As long as we do not cross our guidelines, our principle is that we may not know if the product really helps, yet we must be sure that it does no harm. This is a typical boundary for a pharmaceutical firm and it is taken very seriously. Other industries are less strict in that respect. This is exactly where the advantages of OTCs lie, as they are perceived by this company and probably by most others as well: they have their history and are well-established. The manufacturer has no problem of justification and therefore much lower risks.' (Int. C)

[174] 'The explanation to the situation is that we are a pharmaceuticals company at our roots and that consequently R&D and regulatory have a central position. The perspective on innovations and the requirements they must meet were certainly defined on the background of the pharmaceuticals history[…].' (Int. E[b])

'[…] wir sind Arzneimittel, sind das härtere Produkt, das bessere Produkt. Sonst wären wir ja kein Arzneimittel. […] Wir lancieren Produkte, präferiert Arzneimittel, die einen Mehrwert erzielen und per Definition erfüllen die Arzneimittel ja ganz andere Standards. Besser geprüfte Sicherheit, ein bestimmtes Wirkstofflevel, das ja im Endeffekt garantiert, dass der Verbraucher das bekommt, was er wünscht. Deshalb ja, wir suchen eher nach Arzneimitteln, es hat die höhere Wirkstoffmenge und die bessere Wirkung.(Int. I [b])[175]

'Es gibt eine traditionelle Verhaftung der Unternehmensleitung fast aller Pharmafirmen in dem Selbstverständnis, ein traditionelles Pharmaunternehmen mit traditioneller Pharma-Ethik zu sein. Das ist der Ausgangspunkt für die Analyse [des Wertes von Gesundheitsmitteln].' (Int. C)[176]

The empirical data indicates that health products are not taken fully seriously by the firms, as they operate with softer claims than pharmaceuticals. Expressions like 'erfundene Krankheiten' (Int. D[b])[177] and 'pseudoinnovative Podukteigenschaften' (Int. E[b])[178] in relation to the indications of health products underline the value judgement that the majority of the interviewees make. Similarly, one interviewee calls the health products market 'Trivialsektor' (Int. G[b]).[179]

Further it comes to light that some pharmaceutical firms are very much driven by ethics and a feeling of responsibility.[180] It becomes visible that this flows out of the high regulatory standards applied to all products and the issue of safety and quality resulting from this. It is the notion of ethics and responsibility that is at the basis of the complex regulations regarding the development and production of pharmaceuticals, justifying the status of the pharmaceutical as a 'special good'. The interviewees repeatedly emphasize that their firms feel a responsibility for the patients and their health, which they try to reflect in their innovation activities. Further, they highlight that this creates the obligation for the most ethical behavior. As one interviewee puts it:

'Wir müssen uns aber trotz allem sehr wohl bewusst sein, dass wir eine große Verantwortung tragen. Auf all unseren Produkten steht das Markenzeichen als Absender und darum können wir es uns gar nicht leisten, uns dort irgendwie unklar zu positionieren: wir müssen immer mit den gleichen Normen und Anforderungen arbeiten, die auch für unsere Pharmasparte gelten. […] Man darf eines nicht vergessen, wir arbeiten mit der Gesundheit. Die Gesundheit ist - und das merkt man erst, wenn sie weg ist - das Wichtigste, was der Mensch hat. Das bringt für uns als eines der weltweit führenden Ge-

[175] '[…] we stand for the pharmaceutical, the harder product, the better product. Otherwise, it would not be pharmaceuticals. We launch products, preferably pharmaceuticals, that generate a value-add and per definition the pharmaceuticals fulfill completely different standards. Better safety profile, a certain level of the active ingredient, which is the ultimate guarantor for delivering to the patients what they need. Therefore, yes, we are looking for pharmaceuticals, they have the higher amount of the active ingredient and the better efficacy.(Int. I [b])

[176] 'The management of almost all pharmaceutical firms sticks to the self-concept of being a traditional pharmaceutical firm, acting according to traditional pharmaceutical ethics. This is the starting point for the analysis [of the value of health products].'(Int. C)

[177] 'Invented illnesses' (Int. D [b])

[178] 'Pseudo-innovative product attributes' (Int. E [b])

[179] 'Trivial sector' (Int. G [b])

[180] Interviews A [a]; C; D [b]; E [a].

sundheitsunternehmens eine noch höhere Verantwortung mit sich. Das ethische Handeln steht immer im Mittelpunkt für das, was wir tun.' (Int. A [a])[181]

The central role that ethical and responsible behavior play in the Weltanschauung of the pharmaceutical firms naturally reinforces their focus on pharmaceuticals and the scepticism against health products, as the ethics to which the firms have committed themselves are connected to pharmaceuticals. For the pharmaceutical firms, a departure from the pharmaceutical equals a lowering of their ethical aspirations; lower scientific standards are associated with a less responsible treatment of the patient. The pharmaceutical firms direct their innovation activities along traditional value concepts that almost bestow them with a mission to only develop 'ethical' products. It turns out that the ethics are located above other concerns, ruling out any innovation activities other than pharmaceuticals from the beginning on.

'Der Gesundheitsmittelmarkt würde sich für uns vielleicht eher lohnen, wenn wir unseren hohen Ansprüchen untreu würden und preiswerter entwickeln, billiger produzieren könnten. Aber die Frage stellt sich für uns erst gar nicht, weil wir ein Image, ein Selbstverständnis und eine Ethik haben, die damit nicht vereinbar ist.' (Int. D [b])[182]

'Wenn wir die Arzneimittel-Tradition und -historie nicht hätten, […] wäre auch ein einfacher angereicherter Jogurt mit unserem Image und unseren Leitbildern sicherlich vereinbar.' (E [a])[183]

The interviews show that the firms cognitively differentiate between 'right' and 'wrong' innovations. As the interviews indicate, a key aspect of this differentiation is the scientific validity of the health claims made. The pharmaceutical firms perceive an innovation as 'right' — or ethically uncritical — when its product claims are based on thick scientific evidence (which relates back to the obligation to always meet the highest scientific standards, independently of the product developed). Only then they can be sure that the product statement from the health claim can really be delivered. An innovation with health claims that are only partly proven would be considered dubious; the interviewees indicate that innovation activities that are based on lowered ethical values in terms of lower R&D efforts are 'unethical' and therefore unsuited for a pharmaceutical firm.

'Solche Ansätze wie Becel usw. sind ja für den Markt an sich sehr intelligent, aber die Versprechen, die dort gegeben werden, sind ja gar nicht fundiert und wissenschaftlich belegbar. Das sind mehr Behauptungen als wissenschaftlich belastbare Aussagen. Deshalb mussten Becel und viele Joghurte ja auch schon zurückrudern. Deshalb ist

[181] 'Nevertheless, we must be aware that we carry a high responsibility. Our logo is on all our products and we can therefore simply not afford to position ourselves ambiguously; we must always work on the basis of the same norms and requirements that apply to our pharmaceuticals. […] We may not forget that we work with health. Our health is — and we only realize that when we lost it — the most important good of mankind. For us, as one of the world's leading pharma companies, this brings about an even bigger responsibility. Always, ethical behavior is at the centre of what we do.' (Int. A [a])

[182] 'Perhaps the health products market would be worth more for us if we departed from our high requirements and could develop and produce more cheaply. But we do not pose this question to ourselves in the first place, as we have an image, a self-understanding and ethics that are incompatible with that.' (Int. D [b])

[183] 'If we did not have our pharmaceuticals tradition and history, […] a simple fortified yoghurt would certainly be compatible with our image and guiding principles.' (E [a])

mit der Health Claims Verordnung ja auch etwas geschaffen worden, was diesem Wildwuchs etwas Einhalt gebietet.' (Int. H [a])[184]

'Das wichtigste bei einer Arzneimittelinnovation ist für mich ein klarer Claim, eine einmalige Aussage. Die klinischen Daten - und damit die Forschungsarbeit - sind dafür am allerwichtigsten, nur aus vollständigen und hochwertigen klinischen Daten lassen sich verlässliche Produktaussagen ableiten. Das bedeutet natürlich, dass für uns die Sicherheit auch hier absolut im Vordergrund steht. […] wir orientieren uns so weit möglich an den Arzneimitteln, was Forschung, Sicherheit und den grundsätzlichen Anspruch angeht. Dabei machen wir auch manchmal mehr als die Konkurrenz, Kosmetik oder Lebensmittelhersteller führen oft keine klinischen Studien durch, die viel Geld kosten. Trotzdem ersparen uns die rechtlich-regulatorischen Umstände natürlich einige Aspekte. Auch bei den GM ist der Claim das A und O.' (Int. A[a])[185]

Interestingly, in the above citation, the interviewee from company H calls the health claims directive[186] a measure against the 'Wildwuchs'[187] of earlier times, implying that the increasing popularity and development of health claims for health products over the last decades (at whose regulation the health claims directive aims) equals an uncontrolled rank growth of health statements that needs regulation. This underpins the point that the pharmaceutical firms perceive health products as largely unethical and ultimately irresponsible, unless they are developed like a pharmaceutical.

Pattern 5b: Ambition to maintain image/reputation

Another motive for the companies' scepticism towards health products is their concern for their reputation in the market, which is closely related to the aspects discussed above. The interviewees express that their companies are unwilling to reduce their scientific standards for health products, as it is the high level of scientific accuracy and evidence that makes up the basis of their reputation.[188] The high levels of integrity, reliability and quality that are applied to the product development processes create a reputation that may not be threatened.

'Man hat Angst, sich dem Ruf als ernstzunehmendes Pharmaunternehmen mit Gesundheitsmitteln vielleicht nicht verdirbt, aber doch ankratzt. Da steckt sehrwohl ein Imageproblem.' (Int. C)[189]

[184] 'Such approaches like Becel and so on are certainly very intelligent regarding the market, yet they make promises that are neither scientifically sound nor provable. They are rather assertions that scientifically stressable claims. That is why Becel and many yoghurts already had to backtrack and therefore the Health Claims Directive represents something that can limit this rank growth a bit.' (Int. H [a])

[185] 'What is most important about a pharmaceutical innovation to me is a clear claim, a unique statement. Clinical data - research work therefore - are most important for that, as reliable product claims can only be deducted from complete, high quality clinical data. This means, of course, that safety is most important for us. […] concerning research and safety, we orient our fundamental requirements at the pharmaceuticals as far as we can. In that context we sometimes deliver more than the competition; foods or cosmetics firms often undertake no costly clinical trials. Nevertheless, the legal and regulatory circumstances spare ourselves some aspects of it, of course. Also for health products the claim is most central.' (Int. A[a])

[186] See the discussion on food supplements; European Parliament 2006b.

[187] 'rank growth'

[188] Interviews A [b]; B; C; E [a] F; G [b]; H [a, b]; I [a].

[189] 'One is afraid that health products destroy or at least damage the reputation is a serious pharmaceutical company.' (Int. C)

In the public debate, pharmaceuticals are inextricably linked to the issue of patient safety, which is why the highest regulatory standards are applied to pharmaceutical development and the scientific evidence of their harmlessness. Lowering those standards for the sake of economically exploiting the lower regulatory requirements of health products is seen by the firms as putting at risk their credibility in the market.

> *'Wir wollen niemals etwas machen, wobei die Sicherheit der Verbraucher auch nur im Geringsten in Gefahr gebracht wird. Die 2 wichtigsten assets, die wir haben, sind die Patientensicherheit und unser ausgezeichneter Ruf.' (Int. A [a])*[190]

> *'Das Risiko, das ich sehe, ist dass man die Versprechen, die man macht, nicht halten kann, bzw. die Produktqualität Aufsehen erregt. Das ist die größte Angst der Pharmaindustrie: ein product issue oder ein recall ist das Horrorszenario und hat einen immensen impact auf das Unternehmen, das vom Sicherheitsstandard her nicht attakierbar sein darf; darauf gründet sich der Ruf hauptsächlich. Versprechen und tatsächliches delivery dürfen nicht verwechselt werden. Die anderen machen Studien zu den Gesundheitsmitteln, die man in der Luft zerpflücken kann, das ist nichts im Gegensatz zu Arzneimitteln, das ist nicht so sauber, wie es sein sollte. Deshalb gehen wir bei Nichtarzneimitteln sofort in Habachtstellung. Die haben sicher ihre Position im Alltag des Menschen, aber die werden seine Welt nicht verändern. Außerdem bräuchten wir dann ja auch bei Nichtarzneimitteln compliance, um zu zeigen, wie das Produkt überhaupt wirklich wirkt. Da darf kein Problem auftauchen, die Sicherheitsdenke ist hoch.' (Int. I [b])*[191]

The focus on maintaining the reputation shows once more that health products are developed only if their scientific evidence is at the level of pharmaceuticals. This is a central aspect of the firms' worldview. Of course, this reduces the strategic room for innovations, as per definition health products operate with lower scientific standards than pharmaceuticals. The majority of the interviewees are aware of this situation, claiming that they cannot afford to apply double standards regarding their R&D efforts.[192]

> *'Für uns steht ganz vorne, dass das Produkt dem Verbraucher hilft und seine Versprechen einlöst. Wenn das kein Arzneimittel sein kann, kann ich damit auch leben. Jetzt könnte man sagen, man nutzt die Freiheiten des Gesundheitsmittels aus und bringt schnell und preiswert viele Gesundheitsmittel auf den Markt. Dann müssen wir uns fragen, ob die wirklich wirken, oder nur Placeboeffekte sind. Dann könnte man sagen, dann leben wir eben mit dem Placeboeffekt, ist immer noch ein gutes Produkt. Und da*

[190] 'We never want to something that puts the safety of the consumers at the slightest risk. Our two most important assets are patient safety and our excellent reputation.' (Int. A [a])

[191] 'The risk I see is that we cannot keep the promises one makes or that the product quality causes a stir respectively. That is the biggest fear of the pharmaceutical industry; a product issue or a recall is the horror scenario. It has an enormous impact on the company, whose safety standards may not at all be attackable, as they are the main source of the reputation. Promises made and the actual delivery must not be confused. The others run studies on health products that can easily be plucked into pieces. They are nothing compared to pharmaceuticals, they are not as clean as they should be. That is why we are very cautious when it comes to health products. Certainly, they play a role in the lives of people, yet they will never change their worlds. Additionally we would also need compliance for health products in order to show if the product is really efficient. They must not arise a problem, the need for safety is very high.' (Int. I [b])

[192] Interviews A [b]; B; E [a] F; G [b]; H [a]; I [b]

ist eben die Frage, wie ernst wir unseren OTC-purpose dann nehmen. Der steht dann natürlich tatsächlich im Vordergrund und treibt die Entscheidung.' (Int. I [b])[193]

'Natürlich kann man sich fragen, ob die Standards der klassischen Pharmaindustrie sein müssen, ob man nicht bei den Gesundheitsmitteln auch mit niedrigeren Standards arbeiten kann. Muss die jahrelange Stabilität gewährleistet sein? Muss jeder Bestandteil zertifiziert sein? Muss die Produktion auf diesen Standards laufen? Viele sagen, dass muss es nicht, im schnelllebigen Gesundheitsmittelmarkt. Wir sind der Meinung, dass die Ansprüche eben nicht sinken dürfen, weil es sonst keine verlässlichen Produkte mit hoher Qualität sind, für die der Verbraucher in der Apotheke etwas mehr zahlt.' (Int. H [a])[194]

Interestingly, the firms' concern for their credibility and reputation is getting to the point that innovation activities in the mass market are only thinkable if an independent brand is created for that purpose. The majority of the interviewees points out that their corporate credibility and reputation would be at risk if branded health products appeared in the mass market.[195]

'Das Glaubwürdigkeitsproblem kann man natürlich durch eigene Marken verkleinern oder indem man Generika herstellt. Einige haben das schon versucht, indem sie innerhalb von Consumer Care einzelne Mass Market Schienen aufbauen. […] Wenn ich mit dem dafür notwendigen Euro nichts besseres machen kann, dann ist das eine Überlegung.' (Int. F)[196]

'Ein Pharmaunternehmen kann in Deutschland nur ganz oder gar nicht in der Apotheke vertreiben, es sei denn, es weicht für den Mass Market auf eine andere Marke aus.' (Int. E[a])[197]

As this indicates, the firms are unable to think of their brand and reputation in relation to the mass market for health products, the fear being an over-expansion of their brand, reducing its credibility. As numerous interviewees express, the product range alone is no limitation to the innovation activities, as long as it is sold via the pharmacy.[198] If the decision for investing into a health product is made, it can be any type. Many argue that even Functional Foods would not threaten their firm's credibility — if distributed through the pharmacy. In contrast, however, the mass market is no option at all; an expansion to it is associated with incredibility.

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[193] 'It is central to us that the product helps the consumer and keeps its promises. If the product cannot be a pharmaceutical, I am fine with it. One could now argue that one exploits the freedom of the health products market in order to quickly and cheaply bring health products to the market. What we must ask ourselves, however, is whether those products would really be efficient or just have placebo-effects. Then one could argue that we should live with the fact that it is a placebo-effect only, as the product is still very good. At this point the question arises how seriously we take our OTC purpose really. It is this OTC purpose that would than dominate the decision making.' (Int. I [b])

[194] 'Of course one can ask whether the standards of the traditional pharmaceutical industry are needed, whether lower standards can be applied for health products. Does the drug stability have to be ensured over years? Does every ingredient have to be certified? Does the production have to be run with those standards? Many say that in the fast moving health products market, this does not have to be the case. Yet in our opinion the requirements may not be lowered. Otherwise the products would no longer be reliable and of high quality. It is this for which the consumer pays a mark-up in the pharmacy .' (Int. H [a])

[195] Interviews B; D [a]; E [a]; F; H [b]; I [b].

[196] 'Of course the credibility problem can be reduced by own brands or by producing generics. Some have tried that already by developing several mass market segments within consumer care. […] If there is nothing better I can do with a dispensable Euro, than it is worth giving it a thought.' (Int. F)

[197] 'In Germany, a pharmaceutical company can only distribute completely or not at all through the pharmacy, the only exception being an evasion to an own brand for the mass market.' (Int. E[a])

[198] Interviews D [a]; F; H [b]; I[a, b].

'Auch die Glaubwürdigkeit und die Belastbarkeit der Marke spielt für uns eine Rolle. - Was kann die Marke tragen und wie Glaubwürdig ist das Gesundheitskonzept der Marke am Ende noch, wenn sie so stark in den Lebensmittelmarkt eindringt.' (Int. D[a])[199]

'Ich würde sagen, innerhalb der Apotheke bis zum FF hin alles gehen kann. Ja, unter eine apothekenexklusiven Marke könnte ich mir sogar einen Joghurt vorstellen. Die Apotheke ist die Eintrittshürde.' (Int. H[b])

Yet, the commitment to the pharmacy goes beyond the considerations of credibility only.

Pattern 5c: Retention of the exclusive distribution channel pharmacy

On the cognitive level, the aspiration of quality and ethics reinforces the decision against the mass market as a distribution channel for health products. This adds to the economic considerations about the distribution channel embedded in the decision routines of the firms.

Firstly, following their aspiration of providing the highest possible quality, the pharmaceutical firms see the pharmacy as the only channel of distribution that can transport the complexity of their products and ensure patient safety through professional advice. The quality of the products is therefore not only a question of highest possible R&D and production standards, but also of qualified consultancy by a professional.[200] In other words, the industrial ethics are applied to the marketing activities of the firms as well.

'Wir brauchen einen Absatzmittler, der die Kompetenz hat, unsere komplexen Produkte zu verkaufen, auf diese Beratungsleistung können und dürfen wir nicht verzichten' (Int. I [a])[201]

'Wir glauben sehr sehr stark an Patientensicherheit und wir glauben, dass die Patientensicherheit am besten gewährleistet ist, wenn unsere Produkte von einem Apotheker verkauft werden. Das kann auf unterschiedliche Art und Weise sein, in Deutschland sind wir streng, man muss sich das Produkt vom Apotheker geben lassen. Wir glauben, dass es nur einen Mehrwert gibt, wenn ein Experte (Apotheker oder PTA [Pharmazeutisch-technische Assistenz - A/N]) unsere Produkte erklären kann, die Nebenwirkungen einschätzen und mit den individuellen Patientencharakteristika (Schwangerschaft etc.) abgleichen kann. Die Beratung, die der Apotheker mit dem Produkt verkauft, halten wir für besonders wichtig für die Arzneimittelsicherheit.' (Int. A [a])[202]

Additionally, according to the empirical data, the considerations regarding the reputation impact the choice of the distribution channel. The majority of the inter-

[199] 'The credibility and resilience of the brand also play a role. What can the brand carry and how credible is its health concept in the end, when it penetrates the foods market so strongly.' (Int. D[a])

[200] Interviews A [a]; B; C; F; I [a]

[201] 'We need an intermediary organ in sales, one that has the competence to sell our complex products. We must not and are unwilling to relinquish this consultancy.' (Int. I [a])

[202] 'We strongly believe in patient safety and believe that patient safety is best ensured when our products are sold by a pharmacist. This can take various forms, in Germany we are very strict and the pharmacist must hand the product over to the consumer. We believe that a value can only be generated if an expert (a pharmacist or a pharmaceutical assistance) explains our product, can estimate its side-effects and align them with the individual patient characteristics (pregnancy and so on). We perceive the consulting that the pharmacist sells with the product as particularly important for drug safety.' (Int. A [a])

viewees highlight that their firms aim at maintaining their image further by limiting their distribution of health products to the pharmacy. It is stressed that the distribution channel underlines the credibility of the pharmaceutical firms, as it is associated with more integrity than the mass market.

> *'Bei der Vertriebskanalwahl geht es immer um die Positionierung, das ist für alle Produkte dasselbe. Es macht eben einen Unterschied, ob ich mein Produkt im Fachmarkt oder im Mass Market vertreibe. Wir haben uns für den Fachmarkt entschieden, die Apotheke. Man möchte sich ein gewisses Image, eine gewisse Preisstruktur oder ein gewisses Servicelevel aneignen, das läuft eben auch über den Vertriebskanal. In dieser Hinsicht ist die Apotheke unser preferred partner, da die Qualität der Produkte und der Lagerung gewährleistet wird. […] Außerdem reflektiert die Apotheke mit ihrem guten Image natürlich auch auf unsere Produkte zurück, unser Image profitiert von der Apotheke als Vertriebskanal.' (Int. F)*[203]

> *'Beim AM ist es so, wie vorhin gesagt: es ist ein besonderes Gut, hat einen hohen Wert und muss also auch wertig distribuiert werden. Die Wertigkeit in der Apotheke ist natürlich eine ganz andere als im Mass Market, wo teilweise eine echte Verramschung der Produkte stattfindet. Besonders auch dann, wenn Arzneimittel etwas komplexer und beratungsbedürftig sind, müssen wir auf jeden Fall auf den Apotheker setzen. Aus demselben Grund versuchen wir auch Gesundheitsmittel [über die Apotheke], wertiger zu vertreiben und höhere Preise zu erzielen, als es im Mass Market möglich wäre.' (Int. G [b])*[204]

At the same time, the data suggests that some pharmaceutical firms are actively exploiting the strong position that the pharmacy has among german consumers.[205] As one interviewee underlines:

> *'Der traditionelle Glaube an die Apotheke herrscht aber auch beim Verbraucher vor, Apotheken stehen für Qualität und Zuverlässigkeit und alles was mit Gesundheit zu tun hat, sucht der Verbraucher dort zuerst. Das ist ein immenser Vorteil für uns als Pharmaunternehmen, wenn es um die Vertriebskanalwahl geht.' (Int. C)*[206]

This relates back to and supports the argument of the consumers' trust in the pharmacy as a source of resource dependences made earlier. It shows how the strong position of the pharmacy in the German healthcare market is reflected by the firms' perception of market realities.

The focus on the pharmacy also displays the ambition of the pharmaceutical firms to produce and distribute premium products only.[207] It becomes apparent that -

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[203] 'The selection of the distribution channel is all about positioning, this is the same for all products. It makes a difference if I sell my product in a specialty market or in the mass market. We opted for the specialty market, the pharmacy. One wants to build up a certain image and price structure, or a specific service level; this can also be achieved through the distribution channel. In this regard, the pharmacy is our preferred partner, as it ensures the quality of the products and their storage. […] Additionally, the good image of the pharmacy reflects on our products, of course. Our image benefits from the pharmacy as our distribution channel.' (Int. F)

[204] 'As I said before, the pharmaceutical is a special good with a high value and it must therefore be distributed in a valuable way. Of course, the values of the pharmacy is completely different from that of the mass market, where sometimes products are marketed highly under value. Particularly when a pharmaceutical is more complex and requires instructions for use, we must in any case rely on the pharmacist. Because of the same reasons we try to sell health products in a valuable way [through the pharmacy], aiming at yielding higher prices than in the mass market.' (Int. G [b])

[205] Interviews B; C; H [a, b]; G [b].

[206] 'The traditional belief in the pharmacy also prevails among consumers. Pharmacies symbolize quality and reliability and the consumer searches there first if they need anything related to health. As a pharmaceutical company, this is an enormous advantage for us when we need to decide on the distribution channel.' (Int. C)

[207] Interviews A [b]; F; G [b]; H [a, b].

in addition to the superior quality of their products — the firms need the pharmacy in order to realize the product value. The pharmacy is regarded as the only adequate channel of distribution for the products, not least because the required price premium can only be attained there. As one interviewee puts it:

> *'Unsere Produkte sind Premiumprodukte, was durch den Apothekenvertrieb unterstrichen wird; ein klassisches Beispiel aus dem Markt ist Cetebe™: Marktführer im Vitaminbereich, Positionierung im Premiumbereich, Packungspreis von 8 oder 9€. Vergleichbare Produkte im Mass Market mit preiswerterer Vitamin C-Formulierung, aber ansonsten dem gleichen Nutzen bekommen Sie im Drogeriemarkt für 1,99€. Im Mass Market würde Cetebe™ mit dem so viel höheren Preis nicht bestehen. Der Markenwert könnte nicht realisiert werden. […] die Apotheke ist ein Premium-Outlet, der Vertriebskanal wird mit Wertigkeit verbunden.' (Int. A[b])*[208]

Interestingly, it is here where all aspects of the discussion come together. The data shows the connection between the economic aspects of health products and the cognitive aspects impacting the firms' behavior. The firms find themselves in in a situation of no room for strategic maneuvering. They invest large sums in product development for OTCs and health products alike, in order to meet the quality standards to which they committed themselves. Usually, those high production and development costs push them towards launching the product as an OTC, as this yields the highest margins. Health products tend to be second choice only. In any case, however, there is no way around the pharmacy, as the margins in the pharmacy market lie far below those of the mass market.

> *'Wenn wir eine Innovation haben, überlegen wir uns sehr wohl, wo diese besser platziert ist und wie sie am besten vermittelt wird. Und diese Position hat in der Regel eben der Apotheker. Wir betreiben schließlich einen riesenhaften Aufwand bei der Produktion und der Qualitätssicherung, das müssen wir auch vergütet bekommen. Und eben das passiert nur in der Apotheke. Deshalb ist es für eine Pharmafirma, für eine richtige Pharmafirma immer so schwer, rauszukommen und den Markt zu erweitern.' (Int. H[a])*[209]

> *'Wir haben schließlich einen Anspruch an unsere Produkte, der sich durch alle Aspekte zieht und das kostet mich eben mehr, als wenn ich das nicht mache. Und diesen Mehrwert muss ich auch irgendwo vergütet bekommen und das passiert schließlich nur über einen Fachkanal und meist am besten über das Arzneimittel.' Int. H[b])*[210]

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[208] 'Our products are premium products, which is underlined by the distribution through the pharmacies. A classical example from the market is Cetebe™: market leader in the vitamin segment, positioned in the premium segment, 8€ or 9€ per unit. Comparable products in the mass market contain cheaper vitamin C-formulations but apart from that they have the same benefits. You can get those in drug stores for 1.99€. Under those conditions, Cetebe™ would, due to its higher price, not survive in the mass market. The brand value could not be realized. […] the pharmacy is a premium outlet which is associated with values.' (Int. A[b])

[209] 'When we have an innovation we think very intensively where it would be placed best and where it is marketed best. Usually, the pharmacist is in the best position in this context. After all, we make an enormous effort regarding the production and product quality, which requires compensation. This precisely is only happening in the pharmacy. Therefore it is always f˝difficult for a pharmaceutical company, a real pharmaceutical company, to get out of this and expand its markets. The more regulated the market becomes, also outside the pharmacy, the more difficult this becomes.' (Int. Ha)

[210] 'After all, we have requirements for our products that affect all aspects of them and this costs me more than if I did not have them. It is this value added that I must be compensated for at some point. This happens only in a speciality channel of distribution and most of the times via the pharmaceutical.' Int. H[b])

Obviously, the situation is unlikely to change as long as a change of thinking stays away. Only if the pharmaceutical firms departed from the high universally applied quality standards in which they believe, could health products become economically attractive and an expansion of innovation activities would be worth it, even to the mass market. The representative of company F illustrates this dilemma well, underlining the cognitive distance of the pharmaceutical industry from a strategic shift towards health products that became apparent in the majority of the cases:

> *'Die Produkte haben unterschiedliche Wertekataloge: OTCs müssen allein schon bei der Produktion viel stärker kontrolliert werden als foods, das schafft schon grundsätzlich ganz andere Kostenstrukturen. Die ganz grundsätzlichen Werte sind natürlich für alle unsere Produkte die Qualität, die Haltbarkeit, usw. Da ist es schwierig, ein Pharmaunternehmen so weit zu kriegen, zu sagen, man möchte Durchschnittsqualität für bestimmte Produkte. Das ist vielleicht für die Produktanwendung ok, aber im Gesamtrahmen nicht. Da haben wir immer wieder Diskussionen, wenn wir feststellen, dass für den Konsumenten und die Produktion eigentlich das Niveau X reicht, wir aber einen Standard haben, der sehr viel mehr hergibt, aber auch etwas mehr kostet. Da fällt es uns als Pharmafirma sehr schwer, auf den niedrigeren Minimalanspruch runterzugehen, das passiert nicht. Solch eine Diskussion fällt anderen Industrien natürlich viel leichter.' (Int. F)*[211]

Pattern 5d: Commitment to core competences

Another cross-case pattern becoming apparent in the interview data relates to the firms' commitment to their core competencies. It illustrates a deep attachment to the core competences on which the success of the industry has historically been based.[212] This alone is hardly remarkable and probably to be found in any successful organization. What is noteworthy, however, is the fact that the majority of the firms is consciously opting against competence-building even though they are aware of the need to build up new competences that would come along with innovation activities in the health products market. The declared intention of the majority of the firms examined is to conserve their core competences rather than to expand them.

> *'Schuster bleib bei Deinen Leisten, das ist das Motto. Wo sind die capabilities, mit denen ich arbeiten kann? Die Frage ist, ob wir die Vorteile, die beispielsweise Unilever bei den Gesundheitsmitteln nutzen kann, auch mit unseren capabilities nutzen können. Wahrscheinlich hat die Lebensmittelindustrie Kompetenzen, die im Mass Market leichter einzusetzen sind (beispielsweise das key account management und die Menge an unterschiedlichen Produkten, die gehandelt werden, das gibt die nötige Marktmacht gegenüber den Handelsketten), als die unseren; unsere Stärke liegt eher in der Qualität und der Forschung. Diese Hardware bringt einen nur bis zu einem ge-*

[211] 'The products have different sets of values: OTCs must be controlled much stricter than foods, this already applies to their production. This alone produces fundamentally different cost structures. Of course, the basic values for all our products are quality, sustainability and so on. It is hard to get pharmaceutical firms to the point where they say they want average quality for some of their products. That might be ok for the product application, but is is unacceptable as a larger principle. We have this discussion repeatedly wen we realize that for the consumers and the production a level X is sufficient, while we have a standard that allows for more and costs much more. As a pharmaceutical company we have difficulties to reduce our requirements to a minimum, its does not happen. Such discussions are much easier in other industries, of course.' (Int. F)

[212] Interviews A [b]; B; C; D [a, b]; E [a, b]; F; H [a, b]; I [a, b].

wissen Punkt, von dem an die Marktvorteile die sie bringt, abnehmen. Irgendwo da ist die Grenze für die Pharmaindustrie.' (Int. F)[213]

'Und die Muskeln, die unser Unternehmen spielen lassen kann, sind halt eben F&E und das Premiumsegment, da ist ein Engagement beispielsweise im Functional Foods Markt unpassend.' (Int. A[b])[214]

'Die Frage, die wir uns stellen ist einfach: where to play, how to win? Das heißt für uns nicht, dass, nur weil der Konsument verschiedene Produkte akzeptiert, wir auch überall spielen müssen. Fokus ist im Laufe der Zeit aufgrund unserer capabilities immer eher der Bereich Gesundheit/Krankheit und nicht so sehr die anderen Bereiche (Wellness, Lifestyle - A/N), wo wir dann auch schnell nicht mehr die capabilities haben oder sie entsprechend aufbauen müssten.' (Int. F)[215]

The data indicates that the firms want to focus on their traditional field of activity only, ignoring the health products market as an option for growth. The majority of the interviewees is well aware that the concentration of competences of their firm is due to the history and the traditional focus on pharmaceuticals.

'Wenn wir die Arzneimitteltradition und -historie nicht hätten, dann wäre ein Umdenken leichter. Dann wäre auch ein einfacher angereicherter Jogurt mit unserem Image und Denken sicherlich vereinbar.' (Int. E[a])[216]

'Unsere Policies bzgl ethischen Verkaufs und Qualität sind natürlich klar durch Pharma und unsere Tradition in dem Bereich geprägt.' (Int. I[b])[217]

It becomes apparent that the rejection of health products and the mass market is a result of a simple weighting of the benefits gained from the traditional innovation trajectory against the efforts it would take to invest in the new market. Against the high profitability of OTCs and the pharmacy as the major distribution channel, an expansion of activities to health products and (even lesser so) to the mass market are not considered worth a structural change.

What becomes visible is a certain indifference of the pharmaceutical firms towards health products, flowing out of the dynamics discussed above. In particular this is the case regarding health products in the mass market. Even though the firms are well aware of the market and its dynamics, the decision is made to focus on the traditional markets. This indifference is also reflected by the fact that the majority of the interviewees expresses that the foods industry (among others) is better equipped

[213] 'Stay with what you know, that is our motto. Where are the capabilities that I can leverage? The question is whether we can exploit our capabilities for health products in the same way companies like Unilever do it. Probably, the foods industry has competences that are easier to apply in the mass market (key account management for instance and the number of different products that are marketed and that provide the necessary market power vis à vis the wholesale chains) than ours. Our strength is the quality and R&D. This hardware only gets us to a certain point and from there on the value of the competences decreases. Somewhere there is a boundary for the pharmaceutical industry regarding the ability to combat the mass market.' (Int. F)

[214] 'The muscles we can flex are R&D and the positioning in the premium segment. In this context getting involved in the Functional Foods market, for instance, would be inappropriate.' (Int. A[b])

[215] 'The question we pose is simply: where to play, how to win? This means that we do not want to play everywhere only because the consumer accepts different products. Over time, our capabilities have made us focus on the segment of health/illness, rather than the other areas (Wellness, Lifestyle - A/N) in which we would not have or would have to build up sufficient capabilities .' (Int. F)

[216] 'If we did not have our pharmaceuticals tradition and history, […] a simple fortified yoghurt would certainly be compatible with our image and guiding principles.' (E [a])

[217] 'Certainly, our policies regarding ethical sales and quality are clearly impacted by pharma and our tradition in the area.' (Int. I[b])

with the resources needed to innovate and thrive in the market. Interestingly, an envious undertone of any sort is missing, underlining that the health products market beyond the pharmacy is consciously left to other industries

'Die Kernkompetenz eines Arzneimittelherstellers ist die Forschung, die Produktsicherheit und die Qualität. Wir könnten ohne Probleme einen Joghurt mit hochwertigem Vitamin C und einer wissenschaftliche belegten Wirkung entwickeln. Aber wir hätten große Probleme damit, ihn geschmacklich und optisch ansprechend und überzeugend zu gestalten. Da ist die Lebensmittelindustrie wieder besser und wird weiterhin Vorteile haben, weil Functional Foods etc. eben vom Lebensmittel ausgehen; das Lebensmittel und sein Geschmack sind die Basis, der Gesundheitsnutzen nur die Garnitur.' (Int. A[b])[218]

Pattern 5e: Perception of the competition and of the market development

Another cross-case pattern identified in the interview data contributes to the explanation of the indifferent attitude towards the expansion of innovation activities to the extended healthcare market. As the interview data shoes, the pharmaceutical firms do not perceive the gradual strengthening of the foods industry and other players in the health products market as a serious competitive threat, neither today nor in the future.[219] The majority of the interviewees consider the entrance of food firms into the pharmacy market unlikely. Even if it was to happen, many of them argue, it would remain limited to health products.

This perspective on the competition reflects a rather strong feeling of safety that the pharmaceutical firms have regarding their competitive position. As the interviews show, this feeling of safety is based on the assumption and the belief that the barriers to market entry are too high for external firms to overcome. Many interviewees point out that the high regulatory pressure, the quality standards and the complex relation between the industry and the pharmacist are unlikely to be mastered by external players.[220] It is perceived as highly unlikely that food firms (Nestlé, Unilever and Danone are amongst the firms mentioned most often) are to overcome those barriers, aiming at developing OTCs and competing with the pharmaceutical firms in the pharmacy.

'Ich glaube, dass die Geschäftsmodelle so unterschiedlich sind, dass das nicht schnell passieren wird. Nestlé verkauft 99% seiner Produkte an Retailers. Das ist natürlich etwas ganz anderes, als Absatz zu machen durch Rabattvertragsverhandlungen mit Krankenkassen oder durch politische Verhandlungen über Impfstofflieferungen für die Epedemienprävention. Ich halte es nicht für sehr wahrscheinlich, Unilever oder Proc-

[218] 'The core competences of a pharmaceutical company are R&D, product safety and quality. We could without any problem develop a fortified yoghurt containing a high quality vitamin C and backed by scientific proofs of efficacy. Yet, we would have a hard time making the yoghurt taste and look good. In this domain the foods industry is better equipped and will persist to have advantages as Functional Foods and others are based on foods. The food and its taste are the basis, the health benefit is only decoration.' (Int. A[b])

[219] Interviews A [a, b]; B; E [a, b]; F; H [a, b]; I [a, b].

[220] Interviews A [a, b]; B; E [a, b]; F; H [a]; I [a, b].

ter and Gamble müssten schon eine Menge dazulernen, um das zu können.' (Int. A[a])[221]

'So schwierig es für eine Pharmafirma ist, in den Mass Market einzusteigen, so schwierig ist für ein Lebensmittelunternehmen der Einstieg in die Apotheke. Die Markteintrittbarrieren sind sicherlich nicht so gut sichtbar wie beim umgekehrten Fall der Pharmaindustrie im Mass Market. Beispielsweise müsste die Lebensmittelindustrie erstmal mit dem emotionalen Verhalten des Apothekers umzugehen lernen, bei dem man nicht einfach für ein Listing zahlen kann, sondern individuelle Kundenpflege betreiben muss.' (Int. I[b])[222]

The feeling of safety contributes to the explanation of the indifference of the pharmaceutical firms towards the health product (mass) market. It lets the pharmaceutical firms remain passive against the foods industry as a potential new competitor. This perceived safety reflects the protected position that the pharmaceutical industry has traditionally enjoyed in the market. Due to the high regulatory requirements imposed on the drug development process, entry to the market for pharmaceuticals has always been particularly difficult. The data indicates that this is - from the part of the pharmaceutical firms - experienced as a protection from external competition.

A number of interviewees also point out the importance of the pharmacist in this context. They argue that the complex relation between the pharmacy and the industry that they know how to deal with cannot easily be managed by external players. Food firms would, the argument goes, neither be able to quickly build the competences needed for dealing with the pharmacy and the structures of the distribution channel, nor have sufficient credibility for successful product launches in the pharmacy.[223]

'Nestlé zum Beispiel wäre in der Apotheke für uns weniger eine Gefahr, weil die in der Apotheke sicher nicht die Arzneimittel anpacken werden, sondern nur Gesundheitsmittel. Zu unseren großen, ernsthaften Indikationen im Arzneimittel-Bereich wird Nestlé erstmal nicht kommen, dafür fehlt die Glaubwürdigkeit beim Apotheker und beim Konsumenten. Ich würde von einer Schokoladenfirma kein Herzmittel kaufen.' (Int. I[b])[224]

'Ich glaube nicht, dass andere Industrien, viel tiefer in den Markt eindringen würden, weil sie ein Glaubwürdigkeitsproblem hätten. Außerdem: Nestlé oder Unilever bei-

[221] 'I think that the business models are so different from each other that this will not happen soon. Nestlé sells 90% of their products to retailers. Of course, this is fundamentally different from selling to sick funds in the context of rebate agreements or having to conduct political talks regarding vaccines supplies for epidemics prevention. I do not thinks it is very probably, Unilever or Proctor and Gamble would have to learn a lot in order to become able to do that.' (Int. A[a])

[222] 'No matter how hard it is for a pharma company to enter the mass market, a foods company experiences the same difficulties when trying to succeed in the pharmacy market. The barriers to entry are certainly not as visible as in the reverse case of the pharmaceutical industry in the mass market. For instance, the foods industry would first of all have to learn to deal with the emotional behavior of the pharmacists, who you cannot pay for listing your products but whom you have to approach by personal customer management.' (Int. F)

[223] Interviews A [b]; C; H [b]; I [b].

[224] 'Nestlé for instance would be less of a danger to us in the pharmacy, as they would certainly not touch pharmaceuticals, but health products only. For the time being, Nestlé will not be able to compete with us in our big and serious indications, they are lacking the credibility with the pharmacists and the consumers. I would not buy a cardiovascular drug from a chocolate manufacturer.' (Int. I[b])

spielsweise hätten große Vertriebskanalprobleme, wenn sie in der Apotheke agieren würden.' (Int. A[b])[225]

Considering the enormous progress many foods firms have made in the field of health products over the last years, this attitude is noteworthy. As discussed earlier, the fact that some firms like Nestlé operate small pharmacy-segments for health products already, having accumulated knowledge and competences in the borderline area of nutrition and health, suggest the assumption that for them the step to the high-margin pharmacy-market or even to the OTC-market becomes increasingly small.

The interview data also provides insights regarding the perspective of the pharmaceutical firms on the market changes that might result from deregulation. Numerous interviewees express that a deregulation of the German healthcare market would - if it came about - not threaten their market position and competitiveness.[226] They consider a strategic (preemptive) move to the mass market therefore unnecessary.

'Selbst dann, wenn die Deregulierung der Märkte dann wirklich kommen sollte, ist das [eine präventive Ausweitung auf den Mass Market - A/N] nicht nötig, glaube ich. Mit unserem Portfolio sind wir die ersten, die angerufen werden von Rossmann, dm usw., die sagen: „Eure Produkte hätten wir gerne". Das ist auch mit allen anderen Top-Herstellern so, denke ich. Ich glaube, die Kontakte kriegen wir sehr schnell. Wenn das so kommen würde, müsset man vielleicht überlegen, ob man einen Key Account Manager von FMCG einstellt, der die Jungs bei dm schon kennt und weiß, wie die ticken. Solange ich mit denen aber keine Berührungspunkte habe, ehrlich gesagt, will ich mit denen auch gar nicht erst groß Kontakte aufbauen, weil ich muss auch nicht der erste sein, der da am Ende drin ist. Am Ende des Tages bekommt man die Kontakte ganz schnell, weil die auch einfach Sortiment haben wollen.' (Int. I[b])[227]

'Wir sehen in der Regel, dass, wenn dereguliert wird, der Mass Market sehr stark unter Druck kommt, weil dann auch die OTCs den Markt fluten. Darum haben wir beschlossen, dass wir mit dem Mass Market für die sicherlich auch in Deutschland anstehende Deregulierung langfristig strategisch falsch aufgestellt sind.' (Int. A[a])[228]

The fact that the firms do not even perceive the potential deregulation of the healthcare markets as a threat to their competitiveness shows once again that they perceive their current and future situation as stable.[229] Under those conditions, of

[225] 'I do not think that other industries could enter the market more intensively, as they would have a credibility problem. Also: Nestlé or Unilever, for instance, would have serious problems with their distribution channels if they went into the pharmacy (Int. A[b])

[226] Interviews A [a]; D [a, b]; H [b]; I [a, b]

[227] 'Even if the deregulation of the markets really came about one day, I do not think this [a preventive expansion to the mass market - A/N] would be needed. With our portfolio we are the first ones to be called by Rossmann, dm and the others, who would say: ''we would like to have your products.'' This is the same with all other top-manufacturers, I think. I think we would get the contacts very quickly. If all that happened, one would perhaps have to think about whether to hire a key account manager from FMCG, who knows the guys at dm already and how they think. As long as there are no points of contact with them, to be honest, I do not really want to establish a relation in the first place, as I do not have to be the one who is in the market first. At the end of the day one gets the contact very quickly, because they just want to buildup their portfolio.' (Int. I[b])

[228] 'What we usually see is that when the market is deregulated, the mass market gets under high pressure, as the OTCs flood the market. Therefore we decided that in the long term the mass market is not the right strategic field to play for us, when the deregulation comes about in Germany.' (Int. A[a])

[229] This corresponds to the discussion of lack of exploratory learning routines and deregulation above.

course, an expansion of innovation activities to the health products market is not needed. Instead the firms leave the market to other industries.

> *'Ich glaube, das kann in 5 oder 10 Jahren passieren, dass Firmen wie Unilever, Danone oder Nestlé den Apothekenmarkt entdecken, sie finden ihn ja heute schon sehr interessant. Dann werden die aber sicher ein Unternehmen, das schon im Apothekenmarkt etabliert ist, kaufen, um so die Eintrittshürden zu nehmen. Unter dem Dach einer Firma X, die unbekannt ist, würden die die Produkte dann vermarkten. […] Aber deswegen wird kein Pharmaunternehmen sagen, bevor die kommen, machen wir es selber, daran glaube ich nicht.' (Int. H[b])*[230]

Summary, similarities and differences

Interestingly, the cross case patterns regarding the cognitive aspects of the dynamics of innovation show the same homogeneity as the routine patterns presented earlier (table 30).

What all cases have in common is a commitment to the highest scientific standards and quality of product development. Those are key values of the pharmaceutical firms that are applied to all products developed, regardless of their regulatory status. What became apparent is a preference of pharmaceuticals over health products, as pharmaceuticals require the highest standards, while for the development of health products less scientific evidence is needed. As the data shows, the commitment to the highest scientific standards naturally leads to a focus on OTCs and (even more so) on the pharmacy market. Further, the firms feel a moral responsibility towards the patients, forcing them to deliver a maximum of product reliability and quality. This again contributes to the commitment to the scientific standards of pharmaceuticals, further deteriorating the perceived value of health products and the mass market for them.

The second cross-case pattern identified relates to the image and reputation of the firms examined. The majority of the firms feel that their reputation is based on the value and quality of their products. They feel that applying double standards would not only threaten their corporate values of always delivering the best quality but also their reputation. Interestingly, it appeared that those double standards are only thinkable if an independent brand is created for the distribution of health products outside the pharmacy.

The retention of the pharmacy as the exclusive distribution channel for their products is another cross-case pattern that is closely related to the above. It turned out that the majority of the firms remain loyal to the pharmacy because they see the pharmacist as the only sales agent competent enough to distribute their products.

[230] 'I think it can happen in 5 or 10 years from now that firms like Unilever, Danone or Nestlé discover the pharmacy market, as they already find it interesting today. But if that happened they would certainly buy a firm that is already established in the pharmacy market, thereby skipping the entry barriers. Under the protection of a company X that is not well known, they would then market the products. […] But this alone will not make a pharmaceutical firm enter this market on its own as they fear the new competition.' (Int. H[b])

Also, the pharmacy is seen as a premium outlet, allowing the firms to present their products as the premium products that they are.

The fourth cross-case pattern identified relates to the commitment to their core competences that could be observed in almost all cases. It turned out that the firms voluntarily focus on their traditional innovation trajectory (the pharmacy market and OTCs), leaving the health products market (its mass market segment in particular) to other players. The data showed that the firms almost feel indifferent about the mass market for health products, the reason being their success in their traditional fields of activity.

The fifth and last cross-case pattern addressed the perception of the market and their competitive position in it that the majority of the firms share. It became clear that most firms feel highly protected by the high barriers to entry to the market for pharmaceuticals. This is the reason why they are fearless of a potential move of the foods industry from the mass market for health products to the to health products in the pharmacy or even to OTCs. This contributed to the explanation of the firms' indifference towards the mass market for health products.

PATTERN	SIMILARITIES	DIFFERENCES
5a. The firms feel the duty to conserve its values	All firms commit themselves to the highest scientific standards for all product categories. The majority of the firms feels a moral responsibility towards patients => only pharmaceuticals fulfill the ethical requirements.	
5b. Ambition to maintain image/ reputation	The majority of the firms sees health products developed at a lower standard than OTCs as well as the mass market as a threat to their reputation ==> double standards' for OTCs and health products are not acceptable.	
5c. Retention of the exclusive distribution channel pharmacy	Most firms want their products to be distributed by a sales agents who understands their complexity => the pharmacist as the ideal partner The majority of the firms claim their products to be premium products => pharmacy-distribution to underline this.	
5d. Commitment to core competences	In light of the perceived unattractiveness of health products and the mass market, the majority of the pharmaceutical firms focuses on their traditional field of activity. Most firms are indifferent about the health products outside the pharmacy, leaving it to other players; building up competences to enter the market is not considered worth it.	
5e. Perception of the competition and of the market development	Most firms feel safe from competition from the mass market; a move of today's players in the health products mass market to the pharmacy is considered unlikely, due to the high barriers to market entry => firms feel no need to become engaged in the mass market at least preventively The majority of firms sees the potential deregulation of the healthcare market as no threat to their competitiveness => firms feel no need to become engaged in the mass market at least preventively	

Table 30: Organizational cognition and culture — cross-case similarities and differences

Discussion

The interview data provides deep insights into the routines of the pharmaceutical firms and their cognitive fundament. Overall, the analysis clearly shows that both the routines as well as the perceived values and culture of the pharmaceutical firms produce rigidities regarding an expansion of innovation activities to the health products market.

The search routines of the pharmaceutical firms identified display a general concern about and interest in the extended healthcare market. They firms employ a number of tools to systematically scan the developments of the market as well as the activities of the core players in it. The most widely used tool is internal market research. Also, a number of firms systematically import external knowledge health

products by hiring former FMCG employees to their consumer care departments. Of course those routines represent no rigidity but rather a step towards the health products market.

This openness towards health products is also reflected by the routinized efforts to install communication structures facilitating the exchange and cooperation between the pharma departments of the firms and their CHC counterparts. Similarly, the routine patterns display that most of the firms seek to support their CHC departments by organizing them along separate structures (as to allow them to unfold the different dynamics of innovation they require) and equating them hierarchically with the Rx-departments.

Also, some of the routines of combination that were identified aim at supporting the CHC business of the pharmaceutical firms: synergies and departmental interrelations between Rx and CHC are exploited, and internal and external knowledge is combined for innovations. This reflects the attempt of the pharmaceutical firms to position their CHC products close to the consumer. Clearly this is an indicator for the firms' awareness of the dynamics of the healthcare market and the focus on consumers as an autonomous demanders for healthcare products. Also, the routines can be seen as an indication for the will of the firms to strengthen the consumer-markets for their products.

Yet, as the analysis of the other cross-case patterns of routines shows, the above routines are rather superficial, unable to initiate a real departure of the pharmaceutical firms from their core markets towards the extended healthcare market. While they might strengthen the dynamics of innovation regarding CHC, health products (as an element of CHC) remain disadvantaged. Instead, the routines give preference to OTCs, producing rigidity concerning health products. The reason for this is the deep entrenchment of the firms' innovation routines in the world of pharmaceuticals. This includes several decision routines that turned out to be central to the firms' dynamics of innovation. All of them produce innovation routines that favor pharmaceuticals over health products and the pharmacy over the mass market, the result being the preferred development of pharmacy-bound or pharmacy-exclusive OTCs. Health products are the second choice only and — if developed at all — they are exclusively distributed through the pharmacy.

Firstly, treating profitability as the decisive criterion for innovation decisions leads to rigidity as it puts high margins at the centre of decision processes. Of course, the drastic differences in selling prices and margins across Rx-products, OTCs and health products give good reasons to put the issue of profitability at the centre of decision making process. One may not forget that the majority of the firms' portfolios is Rx-products, which yield very high margins. The routines display that those margins set the bar for profitability. High margins are, however, only attainable through the pharmacy-sale of products or through the product status, privileging the development of pharmaceuticals and their sale in pharmacies. Relatively to Rx-products,

pharmacy-bound OTCs yield the highest margins, while those of mass market health products are lowest. The cross-case patterns show that most firms decide for both ways of ensuring high margins.

Further, product exclusivity and the question of the product status are core determinants of the decision routines. Reflecting their pharmaceuticals-tradition, a decisive criterion for innovation decisions is the exclusivity of products, the aim being to avoid direct competition.[231] Again, this is made possible by developing OTCs and by keeping the pharmacy as the distribution channel. Similarly, the data from the interviews shows that the product status per se is a relevant aspect of decision processes. The decision routines of most firms feature a preference of the pharmaceutical, the reason being the dynamics discussed above. Health products are perceived as a bridge-solution only, useful in situations where the OTC is not developed yet. This illustrates that the commitment to health products reflected by some routines is not lived by the pharmaceutical firms. The economic advantages of pharmaceuticals lead to decision routines clearly in favor of pharmaceuticals.

This shows that central aspects of the decision routines of the firm produce rigidity when it comes to the question of developing more health products, even for the pharmacy. As a matter of fact, the decision criteria of the firms can only be met by pharmacy-bound or pharmacy-exclusive OTCs; relatively, health products always perform badly. The reasons for this lie in the regulatory and market conditions. The decision routines of the firms reflect those conditions. Naturally, this impedes a reorientation towards health products.

Also, the strong position of the pharmacist within the innovation system is reflected by the decision routine of the firms. Being afraid of the negative reaction of the pharmacist to the introduction of products to the mass market, the firms simply remain loyal to the pharmacy at any cost. This boosts the position of the pharmacist further and pushes the pharmaceutical industry even farther from leaving the pharmacy market.

What strengthens the rigidity significantly is the lack of exploratory learning becoming apparent from the interview data. The absence of learning processes with respect to health products, their mass market or scenarios of market deregulation can be interpreted as the ultimate proof of routine rigidity of the pharmaceutical industry. After all, learning routines that ensure the experimental recombination of resources and the generation of knowledge are a necessary condition for change and adaptation.

As this shows, the routines of the pharmaceutical firms feature strong rigidities. Ironically, some strong decision routines overrule the efforts made to strengthen the position of the CHC business. This dilemma becomes even visible within the de-

[231] This is the case with patented Rx-products. As they dominate the portfolios of the pharmaceutical firms this degree of protection is the standard situation for most of their innovations. The decision routines consequently treat exclusivity as a major determinant for development projects. Even though OTCs cannot be patented, their marketing authorization provides some protection. Health products on the other hand can easily be imitated.

cision routines that aim at creating autonomy of decision for the CHC-departments: while in most of the firms the Rx- and CHC-departments operate autonomously along different structures, the differentiation is not continued within the CHC-structures. Instead, OTCs and health products are developed together, sharing the CHC-structures. While the overall structural differentiation between Rx and CHC might strengthen the dynamics of innovation of the CHC departments as a whole, health products cannot be developed independently of OTCs. This clearly impedes a shift towards health products and indicates once more that routine rigidity is present in the pharmaceutical firms.

The analysis shows further that the on the cognitive level rigidities prevail as well, underpinning the organizational routines. Again, all cross-case patterns identified illustrate the rootedness of the pharmaceutical industry in pharmaceuticals. Just like in the case of routines, the regulatory standards and the logic of innovation of Rx-products is reflected in the firms' cognition. The perceived duty to conserve their core values, the need to maintain their reputation and the commitment to core competences illustrate that. Again, the situation puts the pharmaceutical industry in a dilemma: as long as the basic values and beliefs of the firms put the adherence of pharma-standards of product development at the centre of their 'mission', health products cannot become an option. There are two reasons for this: firstly, health products can — by definition — never meet the standards at which pharmaceuticals are developed. Even if they are developed and produced at the level of pharmaceuticals, they cannot obtain a marketing authorization and can therefore never have the same 'value' as pharmaceuticals. The second reason relates back to the market. Of course, firms can put the same effort in the development of health products as they do for pharmaceuticals. In fact, as the interviews show, most firms do that. However, this renders health products highly unprofitable. Again, this locks the pharmaceuticals in their traditional innovation trajectory. If health products are developed at all, they are only distributed through the pharmacy.

The firms' attempts to protect their reputation by sticking to the highest scientific standards for all products clearly contributes to the rigidity. Similarly, the firms' belief in the pharmacy as a premium outlet and the pharmacist as a competent sales agent strengthens the inflexibility towards health products.

Interestingly, the cognitive aspects of the firms' behavior lead to a voluntarily rejection of the health products (mass) market. The firms prefer a focus on their traditional innovation trajectory over entering new areas of growth, preferring to leave the market to other players over running the risk of threatening its reputation and market position by entering. As the analysis shows, this behavior is driven by a lack of interest in the market and a feeling of safety from competition in the firms' traditional markets. The disinterest in the market is certainly a result of the strong market position and success in the core market and the impossibility to combine the own requirements for an 'ethical' health products innovation with market realities. As the

interviews show, the feeling of safety, however, is a result of the high barriers to market entry to which the pharmaceutical industry is used. The firms perceive it unlikely that players to whom they left the mass market for health products accumulate sufficient amounts of knowledge to enter the pharmacy market for health products or perhaps even OTCs.

6. Discussion of the Findings

The analysis was driven by the hypothesis that rigidities must prevail in the sectoral system of innovation the pharmaceutical industry is embedded in. The assumption was that those rigidities hamper the sectoral dynamics, hindering the industry from innovating in the health products market. The hypothesis was translated into a research question that guided the empirical study:

> *In how far does inertia present in the pharmaceutical industry hinder the sectoral firms from extending their boundaries and adapt their innovation activities further to the extended healthcare market?*

In accordance with the theoretical framework, the pharmaceutical industry was analyzed along four categories of inertia identified by the literature: resource dependence and incumbent reinvestment incentives (resource rigidity) as well as firm routines and firm cognition (routine rigidity) (figure 20).

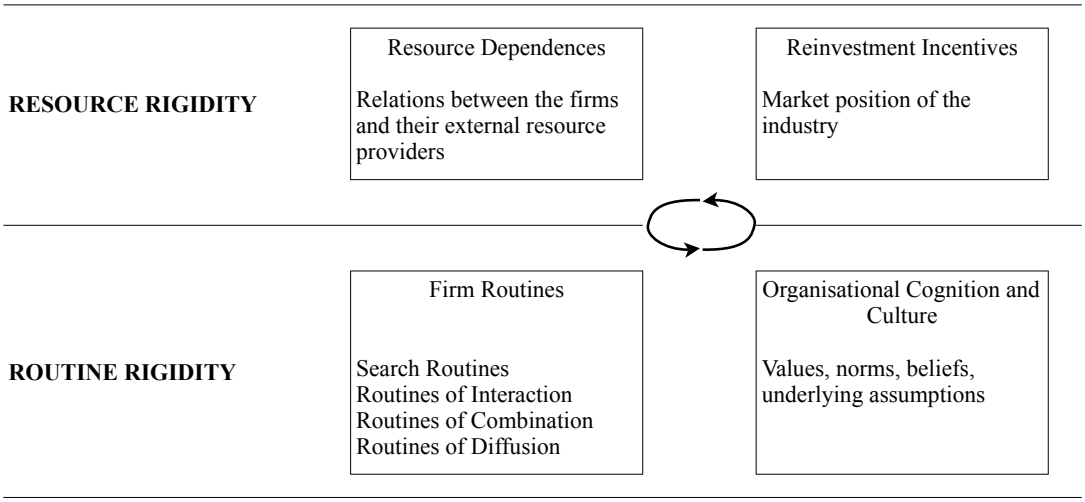

Figure 20: Theoretical framework for the empirical analysis (own illustration; also displayed above as figure 9)

The findings from the analysis were presented in detail and shortly discussed above. Rigidities were identified in all four categories (see table 31). Firstly, the regulatory framework in which the industry is embedded produces resource dependences impeding the adaptation of the OTC-business to the new areas of the second healthcare market, as well as the expansion of the existing health products segment to the mass market. This is reinforced by the dependences on the customer markets, being highly loyal to the pharmaceutical and the pharmacy as well as by the (regulatorily induced) strong position of the pharmacist in the market.

Secondly, the pharmaceutical industry enjoys a strong market position that is based on an almost exclusive focus on Rx-innovations. Naturally, the industrial resources are therefore allocated in accordance with the regulatory regime for pharmaceuticals. In the light of the different resource requirements of health products, this

produces no reinvestment incentives for the pharmaceutical industry. Above all, the industry enjoys — based on the traditional innovation trajectory and the corresponding resources — ongoing success in the market, which strengthens the rigidities regarding a strategic reorientation towards new markets.

Thirdly, the firm routines examined display strong rigidities, too. The routines aggravate the departure from pharmaceuticals towards health products and from the pharmacy to the mass market, illustrating the deep entrenchment of the pharmaceutical firms in their tradition as producers of pharmaceuticals and partners of the pharmacy. The organizational routines, decision making routines in particular, turned out to be strongly impacted by the industry's traditional dynamics of innovation. This produces a favoritism of innovations in the classical market for self-medication over turning towards the health products (mass) market. The firms have difficulties adapting their behavior to the changed conditions; their innovation routines are not dynamic in the sense that they are geared to pharmaceutical innovations, without being able to depart from this. The decisive criteria for innovations that are reflected in the routines are still those that only pharmaceutical firms can fulfill, as they mirror the regime under which the firms have learned to innovate: highest possible margins, maximal product exclusivity, loyalty to the pharmacy and a strong sense for the product status. Even though the firm routines feature some attempts to strengthen the position of health products internally, it became apparent the in the end the routines leave no space for reorientation.

Lastly, the worldview of decision makers in the pharmaceutical firms illustrates that below the routine level guiding their behavior, there is also a deeper, close cognitive relation to the traditional innovation trajectory of the industry. Health products are simply not believed to be an adequate alternative for OTCs, as they do not fulfill the standards and regulatory requirements of pharmaceuticals. Yet the pharmaceutical firms perceive fulfilling those requirements completely as the minimum standard for any product development. The firms rather concentrate on their core values and markets than expanding their innovation activities, as they fear that an expansion to the mass market would threaten their values, credibility and finally their reputation. According to their principles of 'ethical' innovations, health products are only an option if they are developed, produced and distributed at the same degree of quality and scientific accuracy as pharmaceuticals. It turned out that those ethics rule out any other innovations than pharmaceuticals from the very beginning on. Any other innovation would be considered 'wrong', as it would deviate from the standards the industry has traditionally worked with; cognitively, the firms differentiate between 'right' and 'wrong' innovations, based on the values and beliefs that drive their behavior.

RESOURCE DEPENDENCE

- The regulatory conditions aggravate an adaptation of the core business of the pharmaceutical industry to the developments in the second healthcare market
  - Regulatory inflexibility of OTC development: long and expensive development process, prescription requirement for new substances, regulated distribution => highly limited opportunities of innovation beyond classical OTCs
  - Regulatory standards of Rx-products apply to the development process of OTCs, yet the market is less 'protected' from competition => economic unattractiveness of OTCs in the mass market => dependence on the pharmacy market as distribution channel
- The regulatory conditions applying to health products represent no barriers to innovation in the field, yet they produce an economic unattractiveness of the mass market for health products, strengthening dependences on the small existing segment of pharmacy-exclusive health products
  - The low regulatory standards of health products allow selling prices in the mass market that are much below those of OTCs => only pharmacy-exclusive health products may be economically attractive to producers
- German consumers support the dependence of the pharmaceutical industry on the pharmacy and pharmaceuticals
  - Consumers prefer pharmacies for the purchase of healthcare products and are highly loyal to them
  - Consumers' level of trust in pharmaceuticals is higher than in non-pharmaceuticals

LACKING REINVESTMENT INCENTIVES

- The dynamics of innovation of the pharmaceutical industry are characterized by the dominance of pharmaceuticals, Rx-products in particular, giving no reason to induce a strategic shift towards health products => no reinvestment incentives
  - Resources are allocated according to the regulatory requirements applying to pharmaceuticals
    - High R&D intensity
    - Low marketing and advertising intensity
    - The physician and the pharmacy as the established sales agents and distribution channel
- The industry enjoys ongoing success in its traditional area of operation, benefiting from a strong market position => no reinvestment incentives

RIGID FIRM ROUTINES

- Although routines of interaction grant the CHC departments autonomy of decision, no structural separation between OTCs and health products is made within the CHC departments (pattern 2b)
- The decision routines of the firms favor pharmaceuticals over non pharmaceuticals and the pharmacy over the mass market
  - Profitability is a major decisive criterion for innovation decisions (pattern 2d)
  - The preservation of product exclusivity and the product status are of relevance to the decision processes (pattern 2e)
  - The market power of the pharmacist is reflected in the decision routines => loyalty to the established distribution channel (pattern 2f)
  - No clear routines of exploratory learning are observable regarding health products and their market => a lack of learning processes contributes to rigidity (pattern 3c)
  - No clear routines of knowledge diffusion are observable, contributing to routine rigidity (pattern 4a)

RIGID MANAGERIAL COGNITION

- The cognitive patterns of the pharmaceutical industry lead to a focus on the traditional innovation trajectory (pharmaceuticals, pharmacy market) and away from an expansion of innovation activities
  - The firms feel the duty to conserve their core values (pattern 5a): they feel obliged to adhere to the highest scientific standards at which Rx-products are developed in order to meet their moral and ethic responsibility => health products are perceived inappropriate in this context
  - The firms attempt to maintain their reputation, which is based on the industrial ethics and highest scientific standards, by avoiding (regulatorily simpler) health products innovations (pattern 5b)
  - The firms maintain the pharmacy as the traditional distribution channel as they perceive the pharmacy as a premium outlet and the pharmacist as a competent sales agent => complex pharmaceutical products require this quality of the distribution channel (pattern 5c)
  - The firms view themselves in a safe position regarding their competitiveness and the barriers to market entry protecting them => a 'preventive' expansion of innovation activities with respect to pharmacy-exclusive health products or the mass market is considered unnecessary (pattern 5d, e)

Table 31: Overview of the rigidities identified

The findings clearly show that the sectoral dynamics of innovation produce resource and routine rigidities leading to inertia in relation to health products. The data indicates that the systemic dynamics of innovation hold the pharmaceutical industry in its traditional innovation trajectory. Facing the changes in the healthcare market, pharmaceutical firms in Germany are unfitted to strategically adapt to them and expand their innovation activities beyond pharmacy-exclusive health products to the mass market.

This, however, shall not imply that the pharmaceutical industry is completely unaware of the developments taking place in the second healthcare market and the opportunities arising from them. Quite in contrast, the interviewees underlined that the second healthcare market in general is of importance to them and that they are interested in its development. A number of routine patterns reflect this openness towards health products: search routines are in place, scanning the health products market via various tools and importing knowledge on the market by hiring former employees with a FMCG background; routines of interaction strengthen the communication between the Rx and CHC departments as to water down the separation between R&D and marketing, ensuring knowledge diffusion that would be beneficial to the innovation activities of the CHC departments; the autonomy and hierarchical equality of CHC in relation to Rx is promoted as to give CHC the freedom to innovate independently from the Rx-business; routines of combination bring about interdisciplinary coupling of knowledge and the combination of internal and external knowledge for allowing CHC innovations to break out of the traditional trajectories.

Yet, interestingly, the analysis shows that those efforts made are clearly overruled by the rigidities, ultimately producing inertia regarding health products. It became apparent that the efforts made to boost the innovation activities of the CHC departments benefit OTCs only and leave the attitude towards health products largely unchanged, the reason being the preference for pharmaceuticals over non-pharmaceuticals on all levels of the firms. The lacking structural separation between health products and OTCs within the CHC departments of the firms reflects this on the structural level. It shows that the two product categories are not treated as independent from each other, which they would if health products were perceived as a real opportunity; instead, health products and OTCs are managed in the same structures, naturally giving priority to OTCs. In the end, the pharmaceutical industry is in a somewhat paradoxical situation that represents the core of the inertia: the regulatory regime on health product provides opportunities for innovation that the industry could exploit. However, this is possible at a certain expense only. The industry is neither well prepared for innovating in the mass market, nor is it really willing to adapt to the new market. Firms are unwilling to reduce the scientific and quality standards of pharmaceuticals for the sake of developing health products, as they feel an ethical responsibility towards the consumer.

Developing health products at the scientific level of pharmaceuticals, however, renders health products completely uneconomical in the mass market, leaving — if at all — only the pharmacy-market to the industry. This is reinforced by resource dependences flowing from the drastically lower profitability of health products in the mass market than in the pharmacy and the loyalty of the customer markets to the pharmacy. At the same time, the firm routines favor OTCs over health products and the pharmacy market over the mass market, as product profitability, product status and the loyalty to the pharmacist are key determinants of the routinized behavior. Also, in terms of resources the industry is badly equipped for health products and their distribution in the mass market. As long as the dominance of pharma remains on all levels of the firm, health products are considered inadequate and remain limited to the pharmacy market. Additionally, even within the pharmacy market, the resource composition and routines of the firms drag the industry to OTCs rather than health products.

The findings show that the inertia is produced by the sectoral environment of the pharmaceutical firms and the firms alike: dependences on external resource providers (institutions and markets) and the firm-internal structures (resource allocations, routines, cognition) rigidify the industrial dynamics together, producing inertia. This shows that the inertia flowing out of the dynamics of innovation is constituted by multiple system dynamics at a time. They hold the industry in its innovation trajectory from different quarters, constituting the particular complexity of the inertia. At the same time, the different sources of inertia are highly interconnected, mutually impacting and causing each other. In addition to these findings, five additional insights can be obtained from the them that merit a separate discussion:

1. Rigidities prevail in all four domains analyzed simultaneously.
2. The categories of inertia are causally interlinked and building on each other.
3. The categories of inertia are connected by feedback mechanisms.
4. The categories of inertia are linked through self-reinforcing dynamics.
5. The industry's behavior is highly homogeneous.

Those insights contribute to the deeper understanding of the industrial innovation dynamics and the inertia resulting from them.

Rigidities prevail in all four domains analyzed simultaneously

Interestingly, the findings prove not only the presence of inertia in the pharmaceutical industry, thereby validating the hypothesis derived from theory. What the data also illustrates is that inertia is present throughout all of its levels: evidence for rigidity was found in all four categories that were analyzed (figure 21). This underlines the weight of the inertia in the pharmaceutical industry and its relevance for the sectoral system of innovation as a whole. Otherwise — if rigidities were identified in

less than four categories — the presence of inertia could be doubted. Having shown how the rigidities are 'distributed' allows to track inertia across its four layers, it provides insights into the building blocks of inertia responsible for the behavior of the pharmaceutical industry towards the health products market. The analysis showed not only *that* the industry suffers from inertia but it can also demonstrate *where* exactly it is located and *how* it functions.

What is interesting in this context, is the simultaneity of the rigidities. Taking a snapshot perspective on the pharmaceutical industry, the analysis could show that all layers of inertia operate at the same time, indicating that they must not be seen independently but in context of each other. The interview data illustrates how all four rigidities impact the firms' decisions at the same time; it reveals how the regulatory pressure, the resource composition, as well as the established decision routines and the values and beliefs of the industrial players together shape the innovation activities. It is this simultaneous interplay of various system dynamics that make up the inertia of the pharmaceutical industry regarding health products.

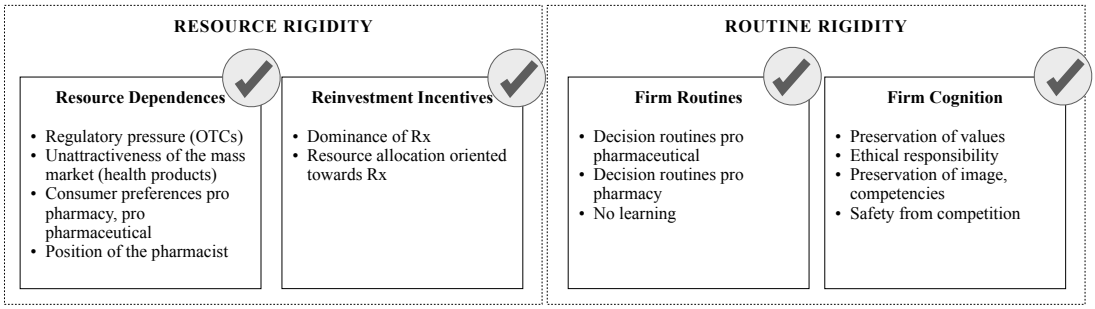

Figure 21: Evidence for rigidities among the categories of inertia (own illustration)

Moreover, the evidence for rigidities across all categories underpins the systemic nature of inertia as conceptualized in the theoretical framework (see figures 8 and 9) — inertia of the pharmaceutical industry is the result of firm-external and firm-internal dynamics at the same time. While the resource dependences represent the impact that the firms' external environment has on their innovation activities, the (lacking) reinvestment incentives as well as the rigid firm routines and cognition illustrate the firm-internal aspects of inertia.

The categories of inertia are causally interlinked and building on each other

In addition to this the findings show how the layers of inertia are sequenced; they indicate that the four aspects of inertia are casually interlocking and building on each other. Casual links exist between resource rigidities and routine rigidities, reflecting the logic of inertia where routine rigidities are (at least partly) born out of resource rigidities (figure 22).

Two examples illustrate this particularly well: the role of institutions in the industry as well as the position of the pharmacist in it. As the analysis was able to

show, the sectoral institutions represent the most powerful source of inertia, impacting all of its layers and being highly influential on all levels of the systemic dynamics of innovation.

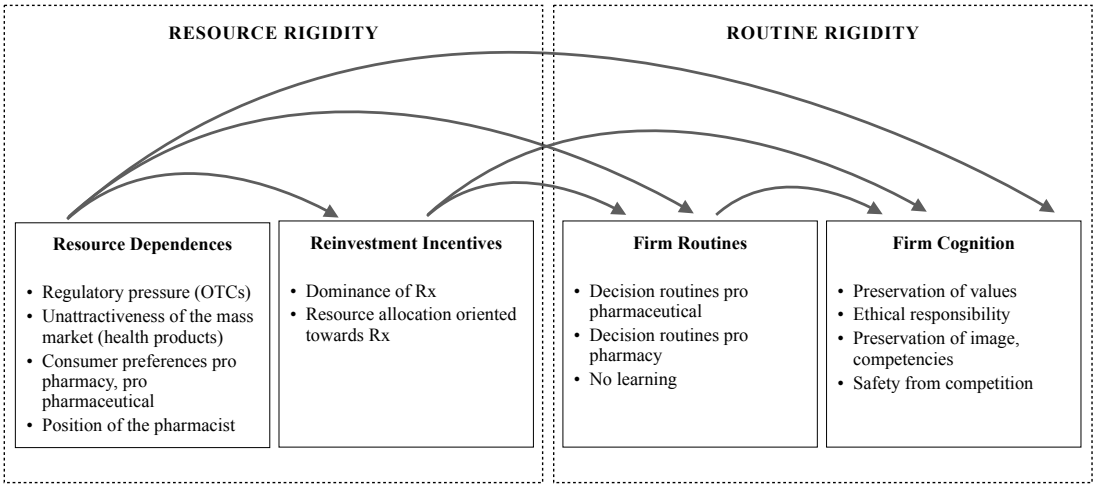

Figure 22: Bidirectional links between the categories of inertia: casual links (own illustration)

Firstly, the regulations on the development and production of pharmaceuticals function as the major external force determining the innovation activities of the pharmaceutical industry. The legal status of pharmaceuticals as a 'special good' obliges firms to develop them at the highest standards. Due to those standards, the OTC-segment of the pharmaceutical industry, representing the borderline to the health products market, cannot be expanded to the new market segments: the degree of novelty of an innovation is regulatorily highly restricted. Moreover, high margins are needed to generate a return on the high development costs of OTCs caused by the regulatory standards. This ties the pharmaceutical industry to the pharmacy as their exclusive distribution channel: pharmacies are highly accepted among German consumers; the trust in the pharmacy as the best outlet for healthcare products is high. Price premiums can therefore only be generated in the pharmacy.

At the same time, the relatively liberal regulatory conditions applying to health products facilitate innovations in this field. Ironically, however, the lack of regulatory protection makes health products economically less attractive than OTCs, as the superior scientific standards applying to OTCs allow producers to obtain higher margins for them than for health products. While this is not always the case in the pharmacy-market, the margins of health products in the mass market are drastically lower than for OTCs.

Secondly, while the regulatory frame conditions produce resource dependences on the part of OTCs, the regulatory attractiveness of health products suggests that pharmaceutical firms should intensify their activities (at least) with respect to pharmacy-exclusive health products. Yet, due to the traditional focus of the pharmaceutical industry on pharmaceuticals the industrial resources are allocated according to the regulatory requirements. The strong regulatory influence on the industrial dynam-

ics of innovation is thereby carried into the resource allocation of the industry, contributing to rigidity; the dynamics of innovation are clearly oriented towards pharmaceuticals. Naturally, the concentration of resources in the domain of pharmaceuticals produces no incentives to building up the resources that would be needed for health products innovations. Moreover, in the light of the regulatory protection from competition of pharmaceuticals (Rx-products in particular), the pharmaceutical industry is even less urged to reinvest in changes. In other words, the strong influence of institutions on the sectoral dynamics of innovation manifests itself — transmitted through the regulatory standards imposed on the industry by the systemic environment — also in the positioning of the industry in the market. As the analysis shows, the industry resources allocated in accordance with the regulatory frame conditions are better suited for pharmacy-exclusive health products than for those outside the pharmacy. This clearly contributes to the rigid dynamics of innovation regarding the extended healthcare market.

Thirdly, the regulatory regime is equally reflected by the routines structures of the pharmaceutical industry in Germany. Except for search routines that indicate some openness towards health products, all other cross-case patterns display innovation routines that benefit the exploitation of the traditional innovation trajectory rather than the exploration of the new healthcare markets. Again, the motive behind the routines guiding the decision making and interaction processes of the pharmaceutical firms is the concern for product safety, R&D standards and the quality of the products. This shows that the regulation on which the dynamics of innovation of the pharmaceutical industry are necessarily based have formed the routinized behavior of the sectoral firms, rigidifying the dynamics of innovation further.

Lastly, the analysis unveiled that at the cognitive level underlying the routinized behavior of the firms, the regulatory conditions manifest themselves as core values and traditions of the pharmaceutical industry. Quality, scientific excellency as well as product and patient safety are the core elements of the regulatory regime on pharmaceuticals. They turned out to be the core values of the pharmaceutical industry that determine their worldview. Products deviating from those values — namely health products — are therefore considered of lower value than pharmaceuticals.

The regulatory conditions at the basis of the industrial innovation activities are reflected by the other aspects of the system, producing rigidities on multiple levels of the sectoral dynamics of innovation. The pharma-oriented resource allocation of the pharmaceutical industry is clearly the result of the regulatory regimes as well as a reaction to the mechanisms of regulatory protection that is in place. Further, the routines of the pharmaceutical firms are again a consequence of the omnipresence of safety and quality regulations in the majority of operations in the firms. Lastly, the cognitive logic guiding the firms' behavior represents the deepest entrenchment of the regulatory regime in the dynamics of innovation: the norms and values that guide

the firms' innovation activities directly reflect the regulatory landscape of pharmaceuticals.

Similarly, the pharmacy turned out to have a significant impact on the rigidity of the pharmaceutical industry is the distribution structures, causing inflexibility on all levels of the system. While its role in the system is — as everything — highly impacted by the regulatory regime, it also impacts the different categories of rigidity on its own. As discussed above, the regulation places pharmacies at the centre of the dynamics of innovation as almost all pharmaceuticals must be distributed through them. While this already produces dependences on the part of the pharmaceutical industry, the higher margins attainable in the pharmacy strengthen them further. Of course, the pharmacy-oriented resource allocation of pharmaceutical firms has been the logical step following it.

Of course, the strong, regulatorily induced position of the pharmacists bestows them with considerable amounts of power. Consequently, the routines and cognition of the pharmaceutical industry mirror this. Pharmacists are key systemic players who can even blockade the industry: as the decision routines of the pharmaceutical firms display, remaining loyal to the pharmacy is a fundamental condition for innovating, as otherwise the pharmacist could delist the company's products. This mirrors the resource dependence with respect to the pharmacy, yet on the level of organizational routines. Further, the pharmacy is perceived by the pharmaceutical firms as the only reliable sales agent who is able to distribute products as complex as pharmaceuticals. The initial position of the pharmacist as a result of their regulatory role is reflected by the categories of inertia; the pharmacist's market power and their ability to block the systemic dynamics of innovation is translated into all aspects of rigidity.

The categories of inertia are connected by feedback mechanisms

At the same time, the findings show that the links between the categories of inertia are bidirectional: not only are routine rigidities born out of resource rigidities, but routine rigidities also affect the resource rigidities of the industry. Those feedback mechanisms that are in place produce a mutual dependence between the rigidities (figure 23).

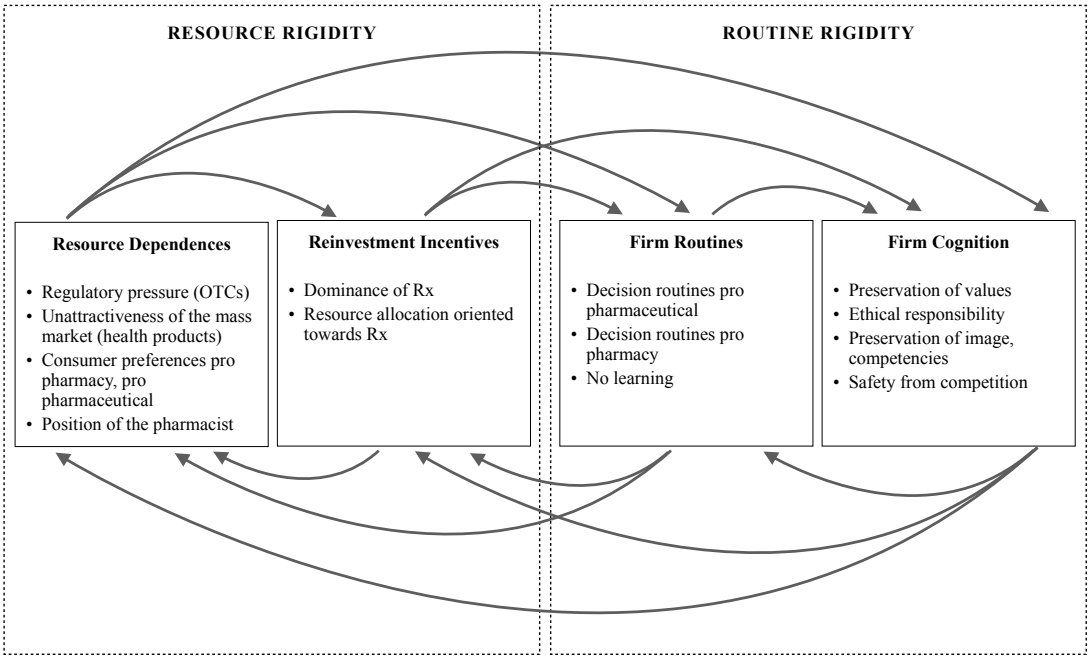

Figure 23: Bidirectional links between the categories of inertia: feedback mechanisms (own illustration)

Again, the linkages are not linear in the sense that the feedback runs through all phases, from category 4, through 3 and 2, to category 1. Rather, the categories are linked by multiple direct links. As the findings show, the firms' values and norms cognitively guide their innovation activities; they reflect the other three categories of inertia. It is the managerial cognition of the pharmaceutical firms that affects the other layers of inertia in turn as it is transferred to them. What this means is that neither the routines, nor the reinvestment incentives or resource dependences can be viewed independently of the firms' cognitive settings. For instance, the decision routines in favor of the pharmaceutical and the pharmacy are not only the result of the resource rigidities that are in place. They are at the same time reinforced by the cognitive settings that are at the basis of the firms' dynamics. How could the decision routines possible be or become more health products friendly if the decision makers act on the basis of norm and values in favor of pharmaceuticals and the related ethics?

Similarly, the resource allocation of the industry is unlikely to change as long as the routines and cognition reinforce the status quo. Surely, the rigidities in this domain could be overcome, if the routine rigidities were to change. Yet, the data shows how the question of whether or not adapting the production to the standards of health products (which would be a prerequisite for overcoming one aspect of resource rigidity) is dependent on the basic understanding of the value of pharmaceuticals and the moral responsibility of the producers.[232]

[232] 'Of course one can ask whether the standards of the traditional pharmaceutical industry are needed, whether lower standards can be applied for health products. Does the drug stability have to be ensured over years? Does every ingredient have to be certified? Does the production have to be run with those standards? Many say that in the fast moving health products market, this does not have to be the case. Yet in our opinion the requirements may not be lowered. Otherwise the products would no longer be reliable and of high quality. It is this for which the consumer pays a mark-up in the pharmacy .' (Int. H [a])

Also the resource dependences resulting from regulation are reinforced by the other categories of rigidities. Clearly the resource dependences alone could be overcome by the industry, they are not entirely responsible for the inertia. Yet, it became apparent in the analysis that the lacking reinvestment incentives only reinforce those rigidities: why exploit the regulatory niches regarding health products when the resources in place produce sufficient outcomes without them? As this shows, the close linkages between the four layers of inertia are responsible for the feedback mechanisms among the rigidities, producing bidirectional connections among them.

While unveiling the casual bonds between the rigidities provided insight into the construction of inertia (routine rigidity follows resource rigidity), the feedback mechanisms show how the inertia functions in practice, how it is 'lived' by the industry. As the interviews show, the basis for decision making is the sets of values and norms the firms share. Many interviews expressed this by arguing that first of all, their values are not negotiable and incompatible with health products. The argument was continued by the decision principles, the resource situation and lastly the regulatory conditions as further reasons for rejecting the health products market. This shows the 'backwards' connection between the resource categories. They operate as feedback mechanisms between the categories of rigidity.

The categories of inertia are linked through self-reinforcing dynamics

Another insight obtained from the analysis is closely connected from the ones discussed above: self-reinforcing dynamics are at work between the layers of inertia, increasing the complexity of the rigidities from category to category (figure 24). This finding is similar to the causal links between the categories, yet it addresses another aspect of it. It reveals that in addition to the fact that the categories are based on each other, their complexity differs, allowing to rank them accordingly. While the regulatory framework and the resulting resource dependences of the pharmaceutical industry represent the 'first step' of inertia (no innovation without compliance to the regulations), the rigid firm cognition represent its last step, reflecting all other rigidities. The data from the interview shows this clearly. The values and beliefs of the managers interviewed reflect the regulatory maxims as well as the business (in terms of resource allocations as well as routine structures) that has been historically growing out of them: the industry submits itself to the regulatory framework and orients its resources towards the regulatorily most attractive aspect, namely Rx-products. In the light of the industry's success the industry under these conditions, investments in reorientation are unattractive, even though the changes in the market would require them. Further, organizational routines have developed within the firms, reflecting and reinforced by the regulatory requirements and the traditional business model that emerged out of it. The result is routine rigidity. Lastly, the managerial cognition combines all previous aspects in itself, representing the last and most complex category of inertia.

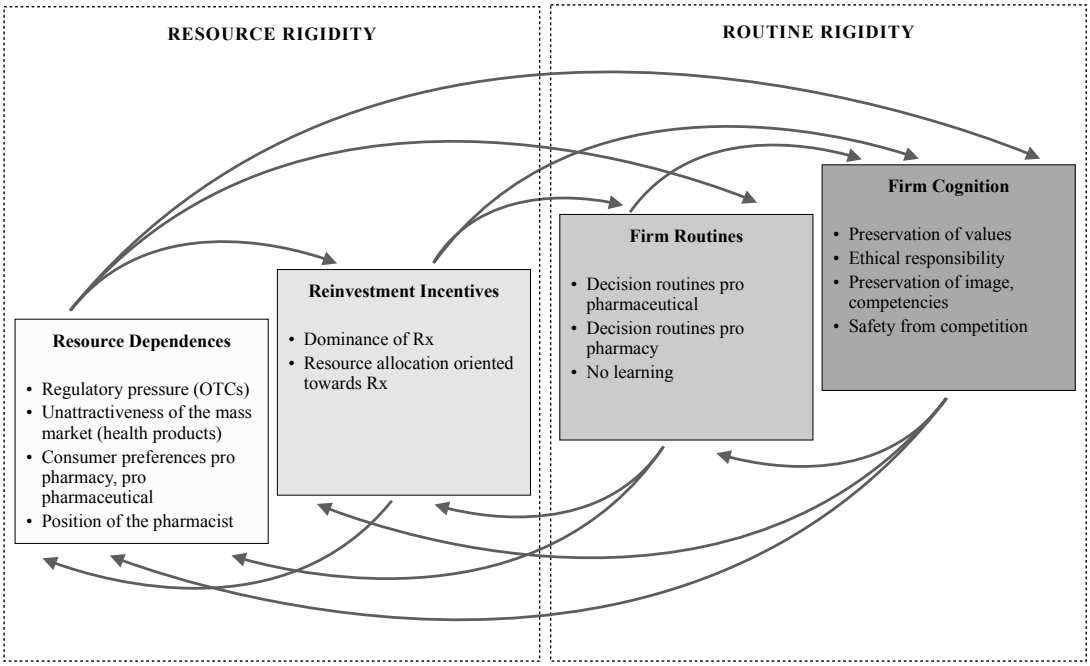

Figure 24: Self-reinforcing effects between the categories of inertia (own illustration)

What this tells us is that the inertia must not only be seen as a chain of four dynamically linked and mutually dependent categories, but that along the categories their complexity increases (figure 24 visualizes this).

The industry's behavior is highly homogeneous

The findings from the analysis also show that the pharmaceutical industry features a high degree of homogeneity with respect to the sectoral dynamics. Homogeneously, the pharmaceutical firms concentrate their innovation activities on pharmaceuticals for the most part; among the R&D intensive, globally acting pharmaceutical corporations, no exceptions exist. The resource allocation discussed in the analysis is characteristic of the pharmaceutical industry in Germany, again displaying a high degree of homogeneity among firms. The case studies illustrate that the homogeneous dynamics of innovation are supported by organizational routines and cognition. The cross-case patterns of firms routines and managerial cognition that became apparent from the interview data are very homogeneously distributed among the cases; in only very few cases individual firms deviated from the overall pattern identified. The resulting dynamics of innovation are rather monotonous: the pharmaceutical firms in Germany are cohesively avoiding an adaptation to the changes in the health-care market.

This is an interesting insight from the empirical study, which can be related to the points made above. The fact that the pharmaceutical firms in the sectoral system of innovation are all subject to the same tight regulatory creates basic dynamics of innovation that are common to all actors. Due to the strict regulations, the basic realm of what innovations are feasible is the same for all, while the firm-specific dy-

namics of innovation are secondary. This certainly differentiates the pharmaceutical industry from other less regulated sectors, as it leads to a high degree of homogeneity at the basis of the sectoral dynamics.

Additionally, however, all firms analyzed react in the same way to this situation, none of them attracting attention by dealing differently with the changes in the healthcare market than the others. This is noteworthy, as one would usually expect to see some of the firms in the sample to be pioneers and some to be laggards, while the majority remains in between.

7. Summary and Conclusion

7.1. Contributions of the Research

This research started out with the principal research question, seeking to understand the behavior of the pharmaceutical industry regarding the new segments of the healthcare market. The aim of the research was firstly to close the research gap regarding the understanding of the innovation activities of the pharmaceutical industry in the new market. Secondly, the research aimed at contributing to shortcomings of the sectoral systems of innovation literature by shedding light on the boundaries of sectoral systems of innovation and the barriers to sectoral transformation and change. Three sub-questions to the principal research question developed out of the initial problematic and the research gaps identified. The research was structured along them.

1. What guides the dynamics of innovation of the pharmaceutical industry?
2. What imposes limits to the innovation activities of the pharmaceutical industry?
3. Under what conditions can the industrial boundaries not be overcome?

The findings discussed above allow to answer to all three research questions, thereby contributing to closing the research gaps identified.

7.1.1. Implications for the research questions

Regarding the first research question the analysis showed that the innovation activities of the pharmaceutical industry are driven by the focus on R&D-intensive prescription medicines. In this context, the main determinant of the industrial dynamics of innovation is the regulatory framework for pharmaceuticals. As the analysis of industrial rigidities showed, regulations are omnipresent, impacting any step of the innovation process and the value chain of pharmaceuticals. Consequently, the regulatory sphere influences all other aspects of the industry: the resource allocations as well as the routines and the managerial cognition of pharmaceutical firms.

Even though those insights were obtained in the context of the analysis of inertia, they help answering the first research question, laying the basis for understanding the innovation dynamics of the pharmaceutical industry. It became clear that the industry's innovation activities gravitate around its core business, namely pharmaceuticals and — more precisely — prescription medicines. The logic is simple: regulatorily, Rx-medicines are highly attractive, providing opportunities for innovation. Even though they are expensive to develop, they are protected by patents and yield extraordinarily high margins. At the same time the patents and the high R&D intensity serve as barriers to entry to the market, increasing the attractiveness of the market segment for the incumbents.

Logic suggests that the pharmaceutical industry has therefore traditionally concentrated on this business, building up resources and structuring its activities accordingly. As the industry analysis showed, the resource allocation of the industry perfectly reflects the needs of Rx-pharmaceuticals. Looking at the growth rates and the financial situation of the major firms suggests that the focus on Rx-pharmaceuticals has paid out.

Regarding the second question, the analysis clearly showed that it is inertia that imposes limits to the innovation activities of the pharmaceutical industry. It was shown that rigidities are present in the pharmaceutical industry, impacting the ability and willingness of the firms to react to the changes taking place in the healthcare markets: the traditional, historically grown structures of the pharmaceutical industry are in fact producing rigid dynamics that keep up the status quo.

This is an important result: it shows that in deed the innovation activities of an industry can be limited, making an expansion to new markets impossible and proves the theoretical link that was made between sectoral systems of innovation and inertia right. Rigidities are present in all four categories of the theoretical framework for the empirical analysis. Together, those four layers of inertia produce complex industrial structures impeding a strategic reorientation and adaption to the changes taking place in the health products market. Change and transformation is therefore not necessarily the result of market changes. This supports the implicit assumption behind the research questions, namely that there might be structures and dynamics that drag the pharmaceutical industry away from the health products market.

What is most insightful, however, is the answer to the third research question, provided by the analysis. As discussed above, the research was able to show that it is inertia that imposes limits to the adaptability of the pharmaceutical industry to changing market conditions. Yet, this alone is insufficient to explain under what conditions those industrial boundaries cannot be overcome. As the findings imply, the sectoral boundaries are not simply the result of the presence of inertia. Rather, it is the interconnection between its various elements and their relation to the larger system that produce insurmountable inertia. The simultaneity of the rigidities, the casual connection, self-reinforcing dynamics and feedback mechanisms between them as well as the outstanding homogeneity of their occurrence across the industry produces a very high complexity of inertia (figure 25).

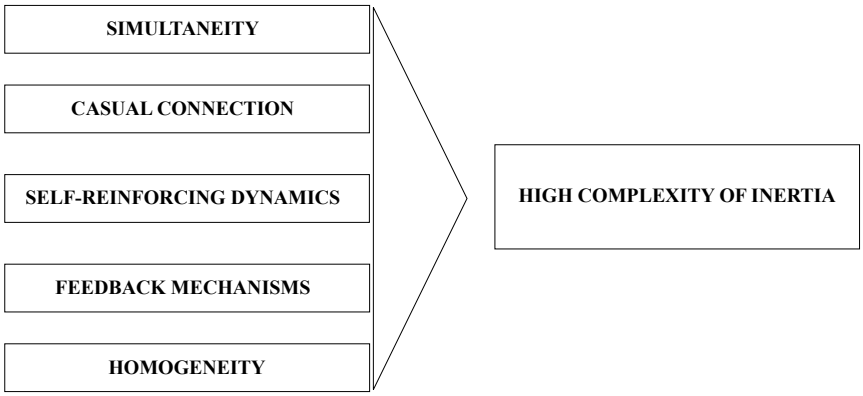

Figure 25: Complexity of inertia in the pharmaceutical industry

This implies that a central condition for industries to be unable to overcome their boundaries is the presence of highly complex inertia, resulting from the simultaneous presence of multiple rigidities that are dynamically interlinked. Apparently, this determines the strength of inertia and ultimately its persistence. What underpins this conclusion from the data is the fact that after all, singular rigidities, existing independently and isolated from each other are likely to be overcome by the firms. For instance, if in the case of the pharmaceutical industry, resource rigidities towards health products existed while the firms' routines produced dynamics benefiting the expansion of innovation activities to the health products market, the resource rigidities could probably be overcome.

The behavior of the pharmaceutical industry towards the biotech sector supports this assumption. As discussed in the introduction, the industry has shown strong dynamism and the ability to adapt regarding the growth of biotechnology. The successful integration of biotechnology into the dynamics of innovation illustrates that the industry is not per se unable to absorb environmental changes, exploit them and reorient. The initial problematic is therefore not a general one but the adaptability of industries rather depends on the individual situation. This provoked the assumption that industries are not necessarily able to expand innovation activities to all adjacent markets and sectors alike.

In the light of the knowledge on the pharmaceutical industry obtained in this study, it becomes apparent that the sectoral dynamics of innovation of the pharmaceutical industry produce less rigidities with respect to adaptation processes to the biotech sector. Even though the 'biotech revolution' drastically changed the R&D processes for pharmaceuticals, it never beard the risk of touching the core of the dynamics of innovation of the pharmaceutical industry, if incorporated into the sector. By extending its innovation activities to biotechnology, the pharmaceutical industry could even strengthen its core business — pharmaceuticals — without having to adapt too much.

Looking back at the biotechnology revolution and the incorporation of biotech in the pharmaceutical industry, the 'biotechnology-pharmaceutical overlap' (McK-

elvey and Orsenigo 2001: 3) and the absence of rigidities are somewhat inherent to the system. When biotechnology experienced the first waves of growth, biotech firms

> '[…] were organized very much like academic units and they deeply embodied some fundamental academic principles like the importance attributed to publication and to work at the frontier of knowledge. However, these organizational principles (in terms of norms, incentives, practices) had to be made consistent with their commercial nature too. Thus, secrecy and the search for broad property rights became crucial features of these new firms. Moreover, financial constraints coupled with their high burn rates have made "time to patent" a characteristic feature of the research style of these companies.' (McKelvey and Orsenigo 2001: 28)

This underlines the assumption of 'shared structures' between biotech and pharma that have produced no rigidities that could make adaptation processes of the pharmaceutical industry impossible. After all, both sectors share highest regulatory standards, basic research and intellectual property rights as the basis of their work and commercial success (see McKelvey and Orsenigo 2001: 40; Casper et al. 1999: 20). Also, both industries operate in highly similar regulatory frameworks in terms of complexity and the role they play for innovation.

The analysis suggests that this is why no such barriers exist in the case of biotech at the boundaries to health products. Overall, the extension of innovation activities to the biotech sector allows pharmaceutical firms to make use of their pharmacy- and pharmaceuticals-oriented resources. Knowing about the favoritism of the pharmaceutical and the traditional distribution structures rooted in the routines and cognition of the pharmaceutical industry, it can be assumed that they are less likely to turn into rigidities when facing the need to adapt to the biotech sector.

As McKelvey and Orsenigo (2001: 29) emphasize, in addition to the similarities of biotechnology and pharma that made the early fusion possible, complementarities existed that have contributed to the adaptation of the pharmaceutical industry. In their early stages, biotechnology firms lacked knowledge that the pharma companies could provide, such as expertise on clinical research, testing and approval processes and commercial know-how. Pharmaceutical companies could perfectly complement biotech with their skill set and integrate the industry in its structures. As Gassmann et al. (2008) put it,

> '[…] pharmaceutical and biotechnology companies seem to prefer a coexistence rather than direct competition. While biotechnology companies provide early-stage input into the collaborations via new technologies or compounds, the pharmaceutical companies provide their broad and extensive marketing channels and sales force.' (24)

This is not to say that the process of adaptation to the biotech market was and still is automatic and free of rigidities whatsoever. In contrast, it required substantial reorganization processes of the in-house R&D of the pharmaceutical companies, as well as development of the knowledge base in order to perform well (see i.e. Casper et al. 1999: 14; McKelvey and Orsenigo 2001: 32). However, the analysis of the

pharmaceutical industry shows that this is no coincidence, as the pharmaceutical industry is apparently more 'fitted' for the integration of biotechnology into its innovation activities; it is closer and more related to the biotechnology sector than to the health products market. This is the reason why rigidities are at least weaker or even absent in some domains. Of course, the knowledge on the rigidities of the pharmaceutical industry towards biotechnology is limited at this point and the conclusions drawn are obtained indirectly only, without having examined the biotech sector in detail. However, it can clearly be stated that the rigidities towards biotechnology are less complex than in the case of health products, as many structural and cognitive similarities exist that could be leveraged.

The two situations are different with regard to the complexity and simultaneity of the rigidities and the dynamic interrelations between them. Surely, the transition of the pharmaceutical industry towards biotechnology was never stuck in the way it is regarding the health products market. Tables 32 and 33 visualize the argument. While the pharmaceutical industry experiences strong inertia regarding the health products market in all categories, the inertia is absent or at least present at a lower degree when it comes to adapting to the biotechnology sector.[233]

CATEGORY	RIGIDITY
External resource-providers: dependences on the institutional/regulatory regime	●
⟳	
The market position and resource allocation: no reinvestment incentives	●
⟳	
Dynamics of Innovation rooted in firm routines: rigid firm routines	●
⟳	
Dynamics of Innovation flowing from firm cognition: rigid managerial cognition	●

Table 32: Rigidities of the pharmaceutical industry regarding the health products market (● Rigidity ○ Weak/no rigidity) (own illustration)

[233] Tables 32 and 33 focus therefore not on the absolute but on the relative strength of inertia; they represent no absolute measures of measured strength of the inertia in the individual categories.

CATEGORY	RIGIDITY
External resource providers: support from the institutional/regulatory regime	○
↻	
The market position and resource allocation: exploitation of the resources, little reinvestment needed	○
↻	
Dynamics of Innovation rooted in firm routines: focus on pharmaceuticals and the pharmacy market	○
↻	
Dynamics of Innovation flowing from firm cognition: focus on pharmaceuticals and the pharmacy market	○

Table 33: Rigidities of the pharmaceutical industry regarding the biotechnology sector (● Rigidity ○ Weak/no rigidity) (own illustration)

In fact, it may be assumed that only the presence of all rigidities and the resulting complexity of inertia really produces sectoral inertia. Most certainly, the disappearance or change of only one of the rigidities regarding the involvement of the pharmaceutical industry in the health products market would change the situation, allowing the pharmaceutical firms to approach the new market. Changes in the distribution structure for instance, such as gradual steps towards a deregulation of the German healthcare market could already cause a decrease of sectoral inertia: seeing the barriers to market entry being reduced by deregulation, pharmaceutical firms would probably feel less safe, which could cause a paradigm shift towards an increased acceptance health products market.

It is this inertia that sets boundaries to the industrial innovation activities. As the example of biotechnology has shown, this is only proven true for the health products market and cannot be generalized. Yet, the example of the health products market illustrates that an industry is not necessarily expanding its activities to adjacent markets, even not when they are growing dynamically. Instead, boundaries persist if complex networks of rigidities are in place that direct the industrial actions.

7.1.2. Practical implications for the industry

The analysis unveiled the close ties between the pharmaceutical industry and the pharmacists in Germany, flowing from the strong position of the pharmacists that is regulatorily induced and bestows them with considerable market power. All prescription pharmaceuticals and most of the non-prescription products must be distributed through pharmacies, which makes them a central element in the distribution chain, leading to a 'natural dependence' of the industry on them. However, it became apparent that the dependence goes further, as the pharmacists enjoy and make use of an enormous bargaining power that keeps the manufacturers in the pharmacies. At

the same time the pharmacies represent something like a safe haven for the industry: barriers to entry and margins are high, the pharmacy landscape is complex (20.000 independent pharmacies) and the ties between the industry and the pharmacy are old and historically grown (including the pharmacy salesforce). Establishing an alternative distribution channel would be difficult for the industry as in any case the pharmacists could obstruct it.

This produces an extraordinarily high dependence of the industry on its major distributor and raises the question in how far the pharmaceutical industry in Germany is capable of coping with structural changes that recently, many have seen looming on the horizon (see i.e. Rumm and Böcking 2013; Schmidt 2008). As Rumm and Böcking (2013) argue, a deregulation of the pharmacy market — following the British model, for instance — would lead to a sharp increase in competition among pharmacies, to the emergence of pharmacy chains as well as to the death of a large number of the independent pharmacies in Germany. This would certainly change the distribution structures, forcing pharmaceutical firms to build up key account structures for marketing in wholesale-like structures and resisting fierce competition on price (as a result of the liberation and the harsh competition between the pharmacy chains).

This indicates that the status quo of the pharmaceutical industry bears substantial risks. In the light of the industrial structures and the resulting inertia it is highly questionable whether such adaptations could be set into motion by the industry. It raises the question whether the industry is — despite its inertia regarding the health products market — strategically prepared for substantial changes in its innovation environment. As many of the interviews indicated, the dependence on the pharmacy in terms of the save haven as well as in terms of the bargaining power of the pharmacists is easily accepted by the industry and is not thought of as a challenge or a threat.

On a higher level, this indicates that the industry is in general not equipped for dealing with a deterioration of the regulatory barriers to the pharmaceuticals market that serve as a protection shield for them. What if the firms that have established themselves in the health products market gain enough know-how to push forward into the pharmaceuticals space? Again, the analysis unveiled no alarmed behavior of the industry, which is worrisome. After all, the strategic maxim should be to keep competition as far away from the own sphere of influence as possible, which should include cutting it off from accumulating too much know how on the own core business.

Another insight from the research that has raises further questions is the apparent lack of knowledge spillovers between the country organizations. All pharmaceutical firms in which interviews were conducted are major global players, most of them raining among the world's top 10 manufacturers. Those companies operate in all European markets and even though Germany is the biggest among them, they have

experience in markets such as the United Kingdom, where access to and distribution of pharmaceuticals has already been liberalized. The interviews have shown that accordingly, the national businesses in more liberal markets market more health products than in Germany or launch products as non-pharmaceuticals that would be classified as OTCs in Germany. Interestingly enough, no learnings seem to be gained from those markets to be processed and integrated into the strategy by the German organizations of those firms. Even though the interviews showed that there is awareness for the different practices in the national markets, it did not become apparent that strategic implications for the (future) operations in Germany are deducted from them. This indicates that the pharmaceutical industry is so closely attached to the national systemic structures and dynamics (at least in Germany) that the boundaries of the innovation activities and the internal learning processes remain absent across national borders.

Additionally, a sense of responsibility, the obligation to stick to the highest scientific standards in order to ensure patient safety and the related perceived inferiority of non-pharmaceuticals became apparent as the main cognitive motives of the pharmaceutical industry, guiding the strategic orientation. Those motives should be valid across the national organizations of the pharmaceutical players, which would lead to a univocal response to the growth of the health products markets. Instead, the fact that the operations differ across the national markets suggests that this is not the case. This is not to say that the firms ignore their standards completely in some countries, yet it shows that at least the (national) systemic conditions in which the business is run have a substantial influence on the innovation activities. It is the regulation on pharmaceuticals that drives the system dynamics; the firms behave differently in different countries, their behavior being fully dependent on these regulatory frameworks. The question is whether this is not representing exactly the threat to credibility and image that the German subsidiaries expressed as their major concern regarding the health products space. Even if the German organization 'sticks to the rules', how does that benefit the credibility of the company as a whole if the procedures are so different in other countries?

The pharmaceutical industry is in a difficult situation regarding the health products market. It is neither well equipped for strategically reorient towards health products, nor is it willing to so. Interestingly, the cognitive aspects of the industry's behavior displayed a certain inability of the decision makers to think their way into health products and see them as a strategic challenge that needs to be eliminated, either through limiting its influence externally or to get into open competition. It somehow matches the historically grown regulated industry structures that the idea of open competition on such a new terrain is foreign to the firms.

As a result, of those historically grown structures the industry is positioning itself as close as possible to its traditional core business and core competences, which is opportunistic at most and successful only if the status quo remains unchanged.

The interviews showed clearly that the firms' behavior is completely logical from their point of view and consistent with the external and internal circumstances.

7.1.3. Implications for the sectoral systems of innovation approach

In addition to contributing to the understanding of the innovation dynamics of the pharmaceutical industry, the analysis provides insights into the functioning of sectoral systems of innovation. Several conclusions can be drawn from the analysis that contribute to the understanding of sectoral systems of innovation.

Sectoral boundaries can be static

The dynamics of innovation of the pharmaceutical industry in Germany clearly set boundaries to adaptation processes towards the expanded healthcare market. The adequate extension of the innovation activities to health products and their mass market is thereby rendered difficult. The pharmaceutical industry has — from a sectoral perspective — clear boundaries that determine its current field of activity as well as the ability to expand it to new areas of interest. So far, this is in accordance with the literature on sectoral system of innovation that is aware of the systemic boundaries that the system elements can constitute (see i.e. Malerba 2002: 254; see also Bresnahan and Malerba 1997; Malerba et al. 1999).

Yet, it is also illustrated that sectoral boundaries are not always changing or able to change, once one or more elements of the system are altered. This result contributes to the understanding of sectoral systems of innovation and to closing the research gap identified. The literature conceptualizes sectoral boundaries as never static or fixed, but rather as being able to adapt to a changing environment (Malerba 2001: 250, 2005b: 67). Sectoral systems of innovation are thought to be a product of their components, developing and changing through co-evolutionary processes: once a system component changes, a 'domino-effect' occurs, whereby all other actors in the system change and adapt accordingly.

The automatism of the co-evolutionary development of sectoral systems of innovation that the literature assumes is apparently absent in the pharmaceutical industry, indicating that sectoral systems of innovation can be locked in and that industrial transformation is in deed impossible under certain conditions. The co-evolutionary processes of change can in fact be interrupted and no automatism of change should be assumed. Of course, in the long run any system is likely to change, proving the evolutionary logic of the approach. In the short and medium run however, this might not take place; even in case one or more system components change — as in the case of the pharmaceutical industry — sectoral boundaries can persist.

Inertia sets system boundaries

The issue of boundaries is discussed by the literature and also the notion of dynamic interdependencies is covered: '[i]nterdependencies and complementarities

define the real boundaries of a sectoral system' (Malerba 2002: 250). Nevertheless, the results of this research add to the understanding of sectoral systems of innovation. They confirm the presence of boundaries, yet additionally they illustrate that inertia can hold them in place; the dynamics of innovation that carry the growth and development of sectoral systems of innovation (the literature views them as the very core of the systems) can create inertia when the sectoral system of innovation faces changes.

Moreover, the analysis proves the impact that inertia can have on sectoral systems of innovation. It provides not just evidence that system boundaries can be static in general, but it also shows that it is inertia that can block the development of sectoral systems of innovation. Relating back to the sectoral systems of innovation approach and the issue of boundaries, this shows that the inertia constitutes boundaries to the pharmaceutical industry as a sectoral system of innovation. The sectoral boundaries develop out of the rigidities inherent to the dynamics of innovation of the pharmaceutical firms. They allow no change or expansion of the innovation activities towards health products. This proves the theoretical framework right, in which the concept of inertia was integrated into the sectoral system of innovation approach, as to test the system for rigidities.

As the sectoral systems of innovation literature argues, processes of learning and knowledge generation are at the centre of sectoral systems of innovation, representing the engine for sectoral growth and development (see i.e. Malerba 2002; Malerba and Orsenigo 2000). The dynamic interrelations between the system players set those processes into motion.

According to the analysis, those processes are absent in the pharmaceutical industry with respect to health products. The few health products innovations in the pharmacy market are born out of the opportunity to employ the existing resources for developing pharmacy-exclusive health products, rather than out of the strategic ambition to gain new knowledge and develop a new market. This is illustrated by the fact that pharmacy-exclusive health products are at most seen as short term bridge-solutions while waiting for an OTC; mass market products are not even considered an option at all. The organizational routines and cognitive patterns are too focused on pharmaceuticals to allow any knowledge generation in the direction health products.

Again, the behavior of the pharmaceutical industry towards biotechnology serves as an example supporting that point, as its shows that in general the industry is able to undergo learning processes and systematically acquire knowledge for adaptation. Otherwise, the pharmaceutical industry would have been unable to exploit the biotech revolution for its purposes. The difference to the situation regarding health products is — again — the fact that the Rx-segment of the industry carried the learning processes. As the analysis shows, the learning and knowledge generation at the centre of the pharmaceutical system of innovation is limited to the pharmaceuticals segment, Rx in particular.

This shows that the inertia runs to the heart of the sectoral system of innovation and underpins the argument that that the adaptability of sectoral systems of innovation depends on the complexity of rigidities within and between the actors in the system. Evidence suggests that if multiple, dynamically interconnected rigidities are present in a sectoral system of innovation, its boundaries cannot be overcome easily.

In this context, a crucial insight provided by the research is that the same dynamics that constitute, energize and hold up the sectoral system of innovation are also responsible for its inertia. It suggests that the systemic dynamics can go into at least two directions at the same time, strengthening the system on the one hand and slowing its development down on the other. Turning back to the sectoral systems of innovation literature, this insight supports parts of the logic, as it underlines that sectoral systems of innovation should not be viewed as a combination of separate dynamics but as a more complex system of links and interdependencies that constitute the system and its development. Yet on the other hand, knowing that the systemic dynamics can constitute firm system boundaries contradicts once more the argument of Malerba and others that systemic boundaries are never static or fixed (see i.e. Malerba 2002, 2003, 2005b; Malerba and Orsenigo 2000).

Sectoral inertia depends on the systemic conditions

Of course, whether or not inertia sets really static boundaries to a sectoral system of innovation depends on the specific conditions under which inertia occurs. As stated above (figure 25), it is the dynamic connection of the rigidities and their simultaneous occurrence that produce insurmountable system boundaries

It was discussed above that an industry can behave differently with respect to different markets. Processes of adaptation take place in some cases, innovations in the new field being the result. In others, this does not happen. Projected onto sectoral systems of innovation, this implies that one sectoral system of innovation can behave differently with respect to different environmental changes. It indicates that the sectoral dynamics of innovation have different effects on the adaptability of the sectoral system of innovation, depending on the changes the industry faces.

The presence of sectoral inertia and static boundaries is therefore a function of the parameters outlined earlier: the simultaneous presence of all categories of inertia as well as their dynamic interconnections (figure 26). The more rigidities are present and the more related they are amongst each other, the less likely it is that the system can overcome its inertia and extend the sectoral boundaries.

RESOURCE RIGIDITY	RESOURCE DEPENDENCE	● / ○
	REINVESTMENT INCENTIVES	● / ○
ROUTINE RIGIDITY	FIRM ROUTINES	● / ○
	FIRM COGNITION	● / ○
SIMULTANEITY		yes/no
CASUAL CONNECTION		yes/no
SELF-REINFORCING DYNAMICS		yes/no
FEEDBACK MECHANISMS		yes/no
HOMOGENEITY		yes/no

Figure 26: Assessment framework for sectoral inertia (● Rigidity ○ Weak/no rigidity) (own illustration)

Consequently, the adaptability of sectoral systems of innovation to exogenous shocks such as market changes cannot be estimated for a system as a whole. As the previous discussion showed, sectoral systems of innovation can have multiple boundaries at a time, each of them behaving differently when facing external changes. If that was not the case, the pharmaceutical industry could not behave differently regarding biotechnology and health products. In other words, there is never *the one* sectoral boundary that explains sectoral behavior completely. Rather, sectoral inertia must be evaluated in the specific sectoral context. Analyzing a sector along the assessment framework for sectoral inertia, scanning the relevant categories identified throughout this study (figure 26) helps evaluating the exact boundaries in place and their strength. The condition for inertia to be present in sectoral systems of innovation is the simultaneous presence of multiple rigidities in the system. Those rigidities impede — if they are mutually dependent and interlocking — adaptation processes of the system.

Inertia as a function of the distance between the systemic core and its periphery

In the context of the results, inertia can be seen as a function of the 'misfit' between the sectoral dynamics of innovation and the environmental changes to which they would have to adapt. As the analysis has shown, the industrial rigidities arise out of the dynamics at the core of the industrial activities. It became evident that the needs of the new market do not match the traditional structures and thinking of the system players, being unable to break the inertia. This is reflected on all levels of inertia, ranging from the industrial resources that are unfitted for developing health products, up to the routines and cognition, illustrating a lack of understanding for health products.

The notion of a 'misfit' between what the sectoral dynamics of innovation have historically taught the system to do and what the environmental changes require is at the basis of inertia (see Gilbert 2005: 742). Taken to another level, this can be thought of as a distance between the system's core and its periphery, the core being the traditional business around which inertia has developed and the periphery being the new markets bordering the system. A question when evaluating systemic inertia is therefore where the centre of the system lies and how far the new market is from it. Again, the different reaction of the pharmaceutical industry to biotechnology and health products supports this thought: biotechnology is easily integrated into the industrial innovation activities, as it is closely related to the Rx-segment. Health products on the other hand, are much more distant from that. The boundaries of the system are reached when the systemic dynamics of innovation have languished completely.

Figuratively speaking, the core of the system could be imagined as a point somewhere in the system, yet not in its middle. It is the traditional centre of the sector, the historically grown core business of the firms in the sector and the related system dynamics. The result is varying distances to the system's periphery. The concept of sectoral inertia may serve as a tool of measuring this distance.

This notion of the 'spread' of a sectoral system of innovation and the question of where the system's centre of gravity is located add to the sectoral systems of innovation approach to industrial boundaries. It implies that sectoral boundaries are stronger, the larger the distance is between the core of the sector and the adjacent market in question and supports the point that there can never be just one system boundary. Environmental changes at the very periphery of the sectoral system of innovation should therefore be less likely to be absorbed by the sectoral system of innovation than changes close to the sectoral core, simply because they are further away from the traditional trajectory along which the industry have developed and from which the complex rigidities arise.

Geography can constitute the boundaries of sectoral systems of innovation

The analysis provided substantial insights into the pharmaceutical industry in Germany from a sectoral perspective. The results contribute to understanding the interplay between the industrial actors in the sectoral system of innovation. For the sake of feasibility, out of personal interest and due to the interesting particularities of the German pharmaceuticals market, the research was limited to Germany. This was in accordance with theory: the sectoral systems of innovation literature claims national and local influences to be present in sectoral systems of innovation, as there is always a geographic component to innovation activities. Sectoral systems of innovation can, according to theory, have some national characteristics that may constitute boundaries; '[g]eographical boundaries are an important element to be considered in most analyses of sectoral systems' (Malerba 2002: 260).

Yet, the analysis unveiled that sectoral and national system of innovation can be almost congruent. It showed that all aspects of the system can be influenced — if not dominated — by national institutions. This raises the question what a sectoral system of innovation really is if — as in the case of the pharmaceutical industry — its nature and configuration is determined along national borders.

This is interesting, as adds to the sectoral systems of innovation literature, which fails to discuss the congruence of the national and the sectoral sphere. Even though the pharmaceutical industry must certainly be considered a special case in this respect (few or no industries are more regulated), it illustrates that the concept of sectoral systems of innovation as a whole can be stretched to its limits: obviously, the pharmaceutical industry is not one sector, even though the firms are globally acting and operating in all major national markets. Instead, it turned out that the national dynamics define the sectoral system of innovation, resulting in a somewhat paradoxical situation where all national subsidiaries behave different in their individual markets while they are at the time centrally managed.

7.2. Limitations of the Study and further Research

Even though the research was able to contribute to the understanding of the pharmaceutical industry and the concept of sectoral systems of innovations, some questions remained open or appeared during the study, requiring further research. Also, for the sake of feasibility, some questions could not be considered, which may be taken up by studies to come.

Despite the contributions the research has made regarding sectoral dynamics in Germany, it produced additional questions regarding the relation between the national and the sectoral sphere that are worth researching more in detail. Certainly, the strong national influence of sectoral systems of innovation that was identified in the pharmaceutical industry needs to be analyzed further. In order to better understand the relation between the two types of systems it would be worth researching how they can coexist in one industry. In cases like the pharmaceutical industry, where are the exact boundaries between the sectoral and the national sphere? How can the two regimens co-exist and when does one of them overrule the other? Where exactly do they overlap? How do they influence each other?

As this research was limited to Germany, it cannot answer those questions. However, it would be worth revisiting the issue on the basis of a cross-national comparison in order to obtain knowledge on the role of the geographic domain. This would provide deeper insights into the relation between the national regulatory frameworks and the nature of sectoral inertia. Furthermore, it would contribute to understanding how the different national subsidiaries adapt to the local conditions while they are at the same time managed by a global mother.

In this context, another interesting issue is the role of the pharmacists within the sectoral dynamics. Their (regulatorily induced) position enables them to obstruct system change. They therefore represent an essential component of the industrial inertia, contributing to its complexity. This notion of a blockade-actor in the system is an interesting starting point for further research. How dependent can sectoral systems of innovation in general be on such players? How does a system react once such a central player changes or disappears? Is this affecting inertia? Those considerations are not only of important to the sectoral systems of innovation approach in general, but also to better understanding the pharmaceutical industry. After all, the analysis has shown that deregulation of the pharmacy market is the biggest threat to the status quo of the industry.

This research contributed to understanding the role of inertia in sectoral systems of innovation. It provided insights into the dynamics that hinder a sector from adapting to changing market conditions, showing that industries can be highly rigid and that sectoral systems of innovation are not necessarily following co-evolutionary processes of development. As a result, the notion of distance between the systemic core and its periphery was developed. It was suggested to employ the assessment framework for sectoral inertia in order to 'measure' this distance, as to get an understanding of the complexity of inertia and the strength of the sectoral boundaries. Yet, what remains to be analyzed is how this distance can be changed or overcome. What, for instance, happens in the very long run? Does the centre of gravity of a sectoral system of innovation and the corresponding inertia remain forever, or can natural processes decomposition be identified? This would be interesting to know, as the results of this research naturally cover the short and medium run only.

Another idea suggests itself at this point that needs further consideration: the strength of the system's centre of gravity can also be imagined as a function of the homogeneity of the sectoral dynamics of innovation. The literature underlines the heterogeneity of the actors in sectoral systems of innovation, including sectoral firms. The actors in a sector are expected to behave heterogeneously, thereby constituting the sectoral dynamics that drive development and growth.

Based on the high degree of homogeneity observable it could be argued that the boundaries of a sectoral system of innovation are stronger the more homogeneous the system dynamics are. This would imply that changes at a system's periphery are dependent on the heterogeneity of the dynamics at the system's centre. Put differently, very homogeneous system dynamics provide no points of contact for new inputs form outside the system, they are not permeable. Those systems naturally have strong boundaries as their impermeability limits their ability to adapt. In contrast, it could be argued that heterogeneous dynamics of innovation provide more possibilities for systemic processes of adaptation. Even though they may not be free of rigidities, they are certainly more likely to adapt to changes in their environment.

In order to further test the hypothesis that the persistence of systemic boundaries and the complexity of inertia are dependent on the sectoral homogeneity further, it would be worth looking at the small and medium-sized pharmaceutical firms in Germany. Those were left out of the analysis, as they are highly heterogeneous, highly specialized niche players, unrepresentative of 'big pharma'. However, based on this research, analyzing and comparing them to big pharma could turn out interesting, as it could provide insights on how groups of highly heterogeneous actors react to system change.

8. Appendices

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8.2. Abstracts

Die Arbeit beschäftigt sich - am Beispiel der Pharmaindustrie - mit Trägheit innerhalb von *Sektoralen Innovationssystemen* und dessen Einfluss auf die systemische Anpassungsfähigkeit an den Systemgrenzen. Ziel ist, aus sektoraler Sicht die passive innovatorische Position der Pharmaindustrie gegenüber der jüngeren Entwicklung des Gesundheitsmittelmarktes zu verstehen und die zu kurz greifenden Erklärungsansätze der Sektoralen Innovationssysteme zu ergänzen. Dabei steht die Frage im Mittelpunkt, wie sich über die bestehenden Ansätze der Anpassungsfähigkeit von Sektoren im *sectoral systems of innovation framework* hinaus, die in der Pharmaindustrie zu beobachtende Unfähigkeit einer Industrie sich an veränderte Marktbedingungen an ihren Grenzflächen anzupassen, erklärt werden kann. Aufbauend auf einen theoretischen Bezugsrahmen, der dem Konzept der sektoralen Innovationssysteme die Theorie der organisationalen Trägheit (*organizational inertia*) zur Seite stellt, gibt die Arbeit Einblick in die Ressourcenallokationen und Handlungsroutinen der Pharmaindustrie.

Die Dissertation zeigt, dass sowohl die Ressourcen (intern, sowie extern/strukturell), die als Basis für die Innovationsaktivitäten der Industrie dienen, als auch die Routinen, die die Handlungen der Akteure leiten, gänzlich auf das Arzneimittel und den Arzneimittelmarkt abgestellt sind. Es besteht eine Abhängigkeit von dynamisch miteinander verknüpften Ressourcen und Routinenstrukturen, die Trägheit entstehen

lässt (*resource rigidities [resource dependences, lacking incumbent reinvestment incentives]* und *routine rigidities [organizational routines, managerial cognition]*) und eine Ausweitung der Innovationsaktivitäten weg vom Arzneimittel- und hin zum Gesundheitsmittelmarkt erschwert.

Damit gibt die Arbeit am Bespiel der Pharmaindustrie Einblick in das Zusammenspiel zwischen sektoraler Dynamik und der Anpassungsfähigkeit von Industrien auf exogene Veränderungsprozesse. Es wird deutlich, dass die Systemstrukturen in Bezug auf Anpassungsprozesse am Rande des etablierten Aktionsbereichs trotz ihrer grundsätzlichen Dynamik von Trägheit geprägt sein können. Dabei ist es jedoch nicht das Vorhandensein einzelner Faktoren dieser Trägheit, sondern die gleichzeitige Präsenz aller Faktoren, also Ressourcen- und Routinenrigidität, sowie deren kausale Verknüpfung, Rückkopplungseffekte, und die selbstverstärkenden Effekte zwischen ihnen, die die Industrie lähmen.

Die Forschungsergebnisse lassen vermuten, dass sektorale Innovationssysteme über klare Grenzen verfügen können, die von denselben Prozessen innerhalb des Sektors definiert und aufrecht gehalten werden, die seine Dynamik begründen. Es wird deutlich, dass - im Gegensatz zum Ansatz der sektoralen Innovationssysteme - sektoraler Wandel aus dem System heraus behindert werden kann und so die Grenzflächen zu benachbarten Sektoren und Märkten undurchlässig werden.

Using the pharmaceutical industry as an example, this dissertation focuses on inertia in *sectoral systems of innovation* and on their impact on the behavior of sectoral systems of innovation at their boundaries. The central question is how the inability of an industry to adapt to changing environmental conditions at its boundaries can be explained. This goes beyond and supplements the partially narrow conceptual approaches towards the adaptability of industrial sectors to environmental changes provided by the sectoral systems of innovation framework. The analysis draws on the observable passive behavior of the pharmaceutical industry beyond pharmaceuticals, in the dynamically developing health products market.

The analysis is based on a theoretical framework that complements the sectoral systems of innovation perspective by the theory of organizational inertia, providing insights into the resource allocation and routine structures of the industry and the resulting inertia.

The research results show that the industrial resources (internal and external/ systemic), constituting the basis of the innovation activities, as well as the routines that guide the actors' behavior gravitate around pharmaceuticals and the pharmaceuticals market. Dependences among dynamically connected resources and routines are in place that produce inertia (*resource rigidities in terms of resource dependences and lacking incumbent reinvestment incentives as well as routine rigidities in terms of organizational routines and managerial cognition*) and hamper the expansion of the innovation activities beyond pharmaceuticals to health products.

By unveiling those rigidities the dissertation provides insights into the interplay between sectoral dynamics and the adaptability of industries to exogenous change. The analysis shows that systemic structures can — despite their dynamics — be highly inert regarding the adaptation to changes taking parts at their boundaries. Yet, it is not only the presence of some of the rigidities that constitute systemic inertia, but their simultaneous presence, as well as the causal relations, bidirectional links (feedback mechanisms and causal links) and self-reinforcing effects between them.

The research results indicate that sectoral systems of innovation can have clear boundaries. They are constituted and held up by the same dynamics that are responsible for the systemic dynamics. It becomes apparent that systemic change can be inhibited by the system itself, manifesting the systemic boundaries. Those insights contribute to the sectoral systems of innovation approach to change that emphasizes the systemic flexibility, lacking explanatory approaches for a systemic inability to expand sectoral boundaries.

8.3. Legal texts cited

1. Arzneimittelgesetz (AMG)
2. Heilmittelwerbegesetz (HWG)
3. Verordnung über den Betrieb von Apotheken (ApBetrO)
4. Nahrungsergänzungsmittelverordnung (NemV)
5. Sozialgesetzbuch
6. Novel Food Verordnung
7. Diätverordnung (DiätV)
8. Lebensmittel-, Bedarfsgegenstände- und Futtermittelgesetzbuch (LFGB)
9. Medizinproduktegesetz (MPG)

1. ARZNEIMITTELGESETZ

§ 2: Arzneimittelbegriff

(2) Als Arzneimittel gelten

1. Gegenstände, die ein Arzneimittel nach Absatz 1 enthalten oder auf die ein Arzneimittel nach Absatz 1 aufgebracht ist und die dazu bestimmt sind, dauernd oder vorübergehend mit dem menschlichen oder tierischen Körper in Berührung gebracht zu werden,
   1.a. tierärztliche Instrumente, soweit sie zur einmaligen Anwendung bestimmt sind und aus der Kennzeichnung hervorgeht, dass sie einem Verfahren zur Verminderung der Keimzahl unterzogen worden sind,
2. Gegenstände, die, ohne Gegenstände nach Nummer 1 oder 1a zu sein, dazu bestimmt sind, zu den in Absatz 1 bezeichneten Zwecken in den tierischen Körper dauernd oder vorübergehend eingebracht zu werden, ausgenommen tierärztliche Instrumente,
3. Verbandstoffe und chirurgische Nahtmaterialien, soweit sie zur Anwendung am oder im tierischen Körper bestimmt und nicht Gegenstände der Nummer 1, 1a oder 2 sind,
4. Stoffe und Zubereitungen aus Stoffen, die, auch im Zusammenwirken mit anderen Stoffen oder Zubereitungen aus Stoffen, dazu bestimmt sind, ohne am oder im tierischen Körper angewendet zu werden, die Beschaffenheit, den Zustand oder die Funktion des tierischen Körpers erkennen zu lassen oder der Erkennung von Krankheitserregern bei Tieren zu dienen.

§ 21 Zulassungspflicht

(1) Fertigarzneimittel, die Arzneimittel im Sinne des § 2 Abs. 1 oder Abs. 2 Nr. 1 sind, dürfen im Geltungsbereich dieses Gesetzes nur in den Verkehr gebracht werden, wenn sie durch die zuständige Bundesoberbehörde zugelassen sind oder wenn für sie die Europäische Gemeinschaft oder die Europäische Union eine Genehmigung für das Inverkehrbringen gemäß Artikel 3 Abs. 1 oder 2 der Verordnung (EG) Nr. 726/2004 auch in Verbindung mit der Verordnung (EG) Nr. 1901/2006 des Europäischen Parlaments und des Rates vom 12. Dezember 2006 über Kinderarzneimittel und zur Änderung der Verordnung (EWG) Nr. 1768/92, der Richtlinien 2001/20/EG und 2001/83/EG sowie der Verordnung (EG) Nr. 726/2004 (ABl. L 378 vom 27.12.2006, S. 1) oder der Verordnung (EG) Nr. 1394/2007 erteilt hat. Das gilt auch für Arzneimittel, die keine Fertigarzneimittel und zur Anwendung bei Tieren bestimmt sind, sofern sie nicht an pharmazeutische Unternehmer abgegeben werden sollen, die eine Erlaubnis zur Herstellung von Arzneimitteln besitzen.

(2) Einer Zulassung bedarf es nicht für Arzneimittel, die

1. zur Anwendung bei Menschen bestimmt sind und auf Grund nachweislich häufiger ärztlicher oder zahnärztlicher Verschreibung in den wesentlichen Herstellungsschritten in einer Apotheke in einer Menge bis zu hundert abgabefertigen Packungen an einem Tag im Rahmen des üblichen Apothekenbetriebs hergestellt werden und zur Abgabe im Rahmen der bestehenden Apothekenbetriebserlaubnis bestimmt sind,

1.a. Arzneimittel sind, bei deren Herstellung Stoffe menschlicher Herkunft eingesetzt werden und die entweder zur autologen oder gerichteten, für eine bestimmte Person vorgesehene Anwendung bestimmt sind oder auf Grund einer Rezeptur für einzelne Personen hergestellt werden, es sei denn, es handelt sich um Arzneimittel im Sinne von § 4 Absatz 4,

1.b. andere als die in Nummer 1a genannten Arzneimittel sind und für Apotheken, denen für einen Patienten eine Verschreibung vorliegt, aus im Geltungsbereich dieses Gesetzes zugelassenen Arzneimitteln A als Zytostatikazubereitung oder für die parenterale Ernährung sowie in anderen medizinisch begründeten besonderen Bedarfsfällen, sofern es für die ausreichende Versorgung des Patienten erforderlich ist und kein zugelassenes Arzneimittel zur Verfügung steht, hergestellt werden oder B als Blister aus unveränderten Arzneimitteln hergestellt werden oder C in unveränderter Form abgefüllt werden,

1.c. zur Anwendung bei Menschen bestimmt sind, antivirale oder antibakterielle Wirksamkeit haben und zur Behandlung einer bedrohlichen übertragbaren Krankheit, deren Ausbreitung eine sofortige und das übliche Maß erheblich überschreitende Bereitstellung von spezifischen Arzneimitteln erforderlich macht, aus Wirkstoffen hergestellt werden, die von den Gesundheitsbehörden des Bundes oder der Länder oder von diesen benannten Stellen für diese Zwecke bevorratet wurden, soweit ihre Herstellung in einer Apotheke zur Abgabe im Rahmen der bestehenden Apothekenbetriebserlaubnis oder zur Abgabe an andere Apotheken erfolgt,

1.d. Gewebezubereitungen sind, die der Pflicht zur Genehmigung nach den Vorschriften des § 21a Abs. 1 unterliegen,

1.e. Heilwässer, Bademoore oder andere Peloide sind, die nicht im Voraus hergestellt und nicht in einer zur Abgabe an den Verbraucher bestimmten Packung in den Verkehr gebracht werden, oder die ausschließlich zur äußeren Anwendung oder zur Inhalation vor Ort bestimmt sind,

1.f. medizinische Gase sind und die für einzelne Personen aus im Geltungsbereich dieses Gesetzes zugelassenen Arzneimitteln durch Abfüllen und Kennzeichnen in Unternehmen, die nach § 50 zum Einzelhandel mit Arzneimitteln außerhalb von Apotheken befugt sind, hergestellt werden,

1.g. als Therapieallergene für einzelne Patienten auf Grund einer Rezeptur hergestellt werden,

2. zur klinischen Prüfung bei Menschen bestimmt sind,

3. Fütterungsarzneimittel sind, die bestimmungsgemäß aus Arzneimittel-Vormischungen hergestellt sind, für die eine Zulassung nach § 25 erteilt ist,

4. für Einzeltiere oder Tiere eines bestimmten Bestandes in Apotheken oder in tierärztlichen Hausapotheken unter den Voraussetzungen des Absatzes 2a hergestellt werden,

5. zur klinischen Prüfung bei Tieren oder zur Rückstandsprüfung bestimmt sind oder

6. unter den in Artikel 83 der Verordnung (EG) Nr. 726/2004 genannten Voraussetzungen kostenlos für eine Anwendung bei Patienten zur Verfügung gestellt werden, die an einer zu einer schweren Behinderung führenden Erkrankung leiden oder deren Krankheit lebensbedrohend ist, und die mit einem zugelassenen Arzneimittel nicht zufrieden stellend behandelt werden können; dies gilt auch für die nicht den Kategorien des Artikels 3 Absatz 1 oder 2 der Verordnung (EG) Nr. 726/2004 zugehörigen Arzneimitteln; Verfahrensregelungen werden in einer Rechtsverordnung nach § 80 bestimmt.

(2a) Arzneimittel, die für den Verkehr außerhalb von Apotheken nicht freigegebene Stoffe und Zubereitungen aus Stoffen enthalten, dürfen nach Absatz 2 Nr. 4 nur hergestellt werden, wenn für die Behandlung ein zugelassenes Arzneimittel für die betreffende Tierart oder das betreffende Anwendungsgebiet nicht zur Verfügung steht, die notwendige arzneiliche Versorgung der Tiere sonst ernstlich gefährdet wäre und eine unmittelbare oder mittelbare Gefährdung der Gesundheit von Mensch und Tier nicht zu befürchten ist. Die Herstellung von Arzneimitteln gemäß Satz 1 ist nur in Apotheken zulässig. Satz 2 gilt nicht für das Zubereiten von Arzneimitteln aus einem Fertigarzneimittel und arzneilich nicht wirksamen Bestandteilen sowie für das Mischen von Fertigarzneimitteln zum Zwecke der Immobilisation von Zoo-, Wild- und Gehegetieren. Als Herstellen im Sinne des Satzes 1 gilt nicht das Umfüllen, Abpacken oder Kennzeichnen von Arzneimitteln in unveränderter Form, soweit

1. keine Fertigarzneimittel in für den Einzelfall geeigneten Packungsgrößen im Handel verfügbar sind oder

2. in sonstigen Fällen das Behältnis oder jede andere Form der Arzneimittelverpackung, die unmittelbar mit dem Arzneimittel in Berührung kommt, nicht beschädigt wird.

Die Sätze 1 bis 4 gelten nicht für registrierte oder von der Registrierung freigestellte homöopathische Arzneimittel, die, soweit sie zur Anwendung bei Tieren bestimmt sind, die der Gewinnung von Lebensmitteln dienen, ausschließlich Wirkstoffe enthalten, die im Anhang der Verordnung (EU) Nr. 37/2010 als Stoffe aufgeführt sind, für die eine Festlegung von Höchstmengen nicht erforderlich ist.

(3) Die Zulassung ist vom pharmazeutischen Unternehmer zu beantragen. Für ein Fertigarzneimittel, das in Apotheken oder sonstigen Einzelhandelsbetrieben auf Grund einheitlicher Vorschriften hergestellt und unter einer einheitlichen Bezeichnung an Verbraucher abgegeben wird, ist die Zulassung vom Herausgeber der Herstellungsvorschrift zu beantragen. Wird ein Fertigarzneimittel für mehrere Apotheken oder sonstige Einzelhandelsbetriebe hergestellt und soll es unter deren Namen und unter einer einheitlichen Bezeichnung an Verbraucher abgegeben werden, so hat der Hersteller die Zulassung zu beantragen.

(4) Die zuständige Bundesoberbehörde entscheidet ferner, unabhängig von einem Zulassungsantrag nach Absatz 3 oder von einem Genehmigungsantrag nach § 21a Absatz 1 oder § 42 Absatz 2, auf Antrag einer zuständigen Landesbehörde über die Zulassungspflicht eines Arzneimittels, die Genehmigungspflicht einer Gewebezubereitung oder über die Genehmigungspflicht einer klinischen Prüfung. Dem Antrag hat die zuständige Landesbehörde eine begründete Stellungnahme zur Einstufung des Arzneimittels oder der klinischen Prüfung beizufügen.

§ 48: Verschreibungspflicht

(1) Arzneimittel, die

1. durch Rechtsverordnung nach Absatz 2, auch in Verbindung mit den Absätzen 4 und 5, bestimmte Stoffe, Zubereitungen aus Stoffen oder Gegenstände sind oder denen solche Stoffe oder Zubereitungen aus Stoffen zugesetzt sind,
2. nicht unter Nummer 1 fallen und zur Anwendung bei Tieren, die der Gewinnung von Lebensmitteln dienen, bestimmt sind oder
3. Arzneimittel im Sinne des § 2 Absatz 1 oder Absatz 2 Nummer 1 sind, die Stoffe mit in der medizinischen Wissenschaft nicht allgemein bekannten Wirkungen oder Zubereitungen solcher Stoffe enthalten,

dürfen nur bei Vorliegen einer ärztlichen, zahnärztlichen oder tierärztlichen Verschreibung an Verbraucher abgegeben werden.

§ 43 Apothekenpflicht, Inverkehrbringen durch Tierärzte

(1) Arzneimittel im Sinne des § 2 Abs. 1 oder Abs. 2 Nr. 1, die nicht durch die Vorschriften des § 44 oder der nach § 45 Abs. 1 erlassenen Rechtsverordnung für den Verkehr außerhalb der Apotheken freigegeben sind, dürfen außer in den Fällen des § 47 berufs- oder gewerbsmäßig für den Endverbrauch nur in Apotheken und ohne behördliche Erlaubnis nicht im Wege des Versandes in den Verkehr gebracht werden; das Nähere regelt das Apothekengesetz. Außerhalb der Apotheken darf außer in den Fällen des Absatzes 4 und des § 47 Abs. 1 mit den nach Satz 1 den Apotheken vorbehaltenen Arzneimitteln kein Handel getrieben werden. Die Angaben über die Ausstellung oder Änderung einer Erlaubnis zum Versand von Arzneimitteln nach Satz 1 sind in die Datenbank nach § 67a einzugeben.

(3) Auf Verschreibung dürfen Arzneimittel im Sinne des § 2 Abs. 1 oder Abs. 2 Nr. 1 nur von Apotheken abgegeben werden. § 56 Abs. 1 bleibt unberührt.

§ 44 Ausnahme von der Apothekenpflicht

(1) Arzneimittel, die von dem pharmazeutischen Unternehmer ausschließlich zu anderen Zwecken als zur Beseitigung oder Linderung von Krankheiten, Leiden, Körperschäden oder krankhaften Beschwerden zu dienen bestimmt sind , sind für den Verkehr außerhalb der Apotheken freigegeben.

(2) Ferner sind für den Verkehr außerhalb der Apotheken freigegeben:

1.
   - 1.a. natürliche Heilwässer sowie deren Salze, auch als Tabletten oder Pastillen,
   - 1.b. künstliche Heilwässer sowie deren Salze, auch als Tabletten oder Pastillen, jedoch nur, wenn sie in ihrer Zusammensetzung natürlichen Heilwässern entsprechen,
2. Heilerde, Bademoore und andere Peloide, Zubereitungen zur Herstellung von Bädern, Seifen zum äußeren Gebrauch,
3. mit ihren verkehrsüblichen deutschen Namen bezeichnete
   - 3.a. Pflanzen und Pflanzenteile, auch zerkleinert,
   - 3.b. Mischungen aus ganzen oder geschnittenen Pflanzen oder Pflanzenteilen als Fertigarzneimittel,
   - 3.c. Destillate aus Pflanzen und Pflanzenteilen,
   - 3.d. Presssäfte aus frischen Pflanzen und Pflanzenteilen, sofern sie ohne Lösungsmittel mit Ausnahme von Wasser hergestellt sind,
4. Pflaster,

5. ausschließlich oder überwiegend zum äußeren Gebrauch bestimmte Desinfektionsmittel sowie Mund- und Rachendesinfektionsmittel.

(3) Die Absätze 1 und 2 gelten nicht für Arzneimittel, die

1. nur auf ärztliche, zahnärztliche oder tierärztliche Verschreibung abgegeben werden dürfen oder
2. durch Rechtsverordnung nach § 46 vom Verkehr außerhalb der Apotheken ausgeschlossen sind.

§ 45 Ermächtigung zu weiteren Ausnahmen von der Apothekenpflicht

(1) Das Bundesministerium wird ermächtigt, im Einvernehmen mit dem Bundesministerium für Wirtschaft und Technologie nach Anhörung von Sachverständigen durch Rechtsverordnung mit Zustimmung des Bundesrates Stoffe, Zubereitungen aus Stoffen oder Gegenstände, die dazu bestimmt sind, teilweise oder ausschließlich zur Beseitigung oder Linderung von Krankheiten, Leiden, Körperschäden oder krankhaften Beschwerden zu dienen, für den Verkehr außerhalb der Apotheken freizugeben,

1. soweit sie nicht nur auf ärztliche, zahnärztliche oder tierärztliche Verschreibung abgegeben werden dürfen,
2. soweit sie nicht wegen ihrer Zusammensetzung oder Wirkung die Prüfung, Aufbewahrung und Abgabe durch eine Apotheke erfordern,
3. soweit nicht durch ihre Freigabe eine unmittelbare oder mittelbare Gefährdung der Gesundheit von Mensch oder Tier, insbesondere durch unsachgemäße Behandlung, zu befürchten ist oder
4. soweit nicht durch ihre Freigabe die ordnungsgemäße Arzneimittelversorgung gefährdet wird.

Die Rechtsverordnung wird vom Bundesministerium für Ernährung, Landwirtschaft und Verbraucherschutz im Einvernehmen mit dem Bundesministerium und dem Bundesministerium für Wirtschaft und Technologie erlassen, soweit es sich um Arzneimittel handelt, die zur Anwendung bei Tieren bestimmt sind.

(2) Die Freigabe kann auf Fertigarzneimittel, auf bestimmte Dosierungen, Anwendungsgebiete oder Darreichungsformen beschränkt werden.

(3) Die Rechtsverordnung ergeht im Einvernehmen mit dem Bundesministerium für Umwelt, Naturschutz und Reaktorsicherheit, soweit es sich um radioaktive Arzneimittel und um Arzneimittel handelt, bei deren Herstellung ionisierende Strahlen verwendet werden.

§ 50 Einzelhandel mit freiverkäuflichen Arzneimitteln

(1) Einzelhandel außerhalb von Apotheken mit Arzneimitteln im Sinne des § 2 Abs. 1 oder Abs. 2 Nr. 1, die zum Verkehr außerhalb der Apotheken freigegeben sind, darf nur betrieben werden, wenn der Unternehmer, eine
zur Vertretung des Unternehmens gesetzlich berufene oder eine von dem Unternehmer mit der Leitung des Unternehmens oder mit dem Verkauf beauftragte Person die erforderliche Sachkenntnis besitzt. Bei Unternehmen mit mehreren Betriebsstellen muss für jede Betriebsstelle eine Person vorhanden sein, die die erforderliche Sachkenntnis besitzt.

§ 75 Sachkenntnis

(1) Pharmazeutische Unternehmer dürfen nur Personen, die die in Absatz 2 bezeichnete Sachkenntnis besitzen, beauftragen, hauptberuflich Angehörige von Heilberufen aufzusuchen, um diese über Arzneimittel im Sinne des § 2 Abs. 1 oder Abs. 2 Nr. 1 fachlich zu informieren (Pharmaberater). 2Satz 1 gilt auch für eine fernmündliche Information. 3Andere Personen als in Satz 1 bezeichnet dürfen eine Tätigkeit als Pharmaberater nicht ausüben.

(2) Die Sachkenntnis besitzen

1. Apotheker oder Personen mit einem Zeugnis über eine nach abgeschlossenem Hochschulstudium der Pharmazie, der Chemie, der Biologie, der Human- oder der Veterinärmedizin abgelegte Prüfung,
2. Apothekerassistenten sowie Personen mit einer abgeschlossenen Ausbildung als technische Assistenten in der Pharmazie, der Chemie, der Biologie, der Human- oder Veterinärmedizin,
3. Pharmareferenten.

(3) Die zuständige Behörde kann eine abgelegte Prüfung oder abgeschlossene Ausbildung als ausreichend anerkennen, die einer der Ausbildungen der in Absatz 2 genannten Personen mindestens gleichwertig ist.

2. HEILMITTELWERBEGESETZ

§1

(1) Dieses Gesetz findet Anwendung auf die Werbung für
1. Arzneimittel im Sinne des § 2 des Arzneimittelgesetzes,
   1.a. Medizinprodukte im Sinne des § 3 des Medizinproduktegesetzes,
2. andere Mittel, Verfahren, Behandlungen und Gegenstände, soweit sich die Werbeaussage auf die Erkennung, Beseitigung oder Linderung von Krankheiten, Leiden, Körperschäden oder krankhaften Beschwerden bei Mensch oder Tier bezieht, sowie operative plastisch-chirurgische Eingriffe, soweit sich die Werbeaussage auf die Veränderung des menschlichen Körpers ohne medizinische Notwendigkeit bezieht.

(2) Andere Mittel im Sinne des Absatzes 1 Nr. 2 sind kosmetische Mittel im Sinne des § 4 des Lebensmittel- und Bedarfsgegenständegesetzes. Gegenstände im Sinne des Absatzes 1 Nr. 2 sind auch Gegenstände zur Körperpflege im Sinne des § 5 Abs. 1 Nr. 4 des Lebensmittel- und Bedarfsgegenständegesetzes.

(3) Eine Werbung im Sinne dieses Gesetzes ist auch das Ankündigen oder Anbieten von Werbeaussagen, auf die dieses Gesetz Anwendung findet.

(4) Dieses Gesetz findet keine Anwendung auf die Werbung für Gegenstände zur Verhütung von Unfallschäden.

(5) Das Gesetz findet keine Anwendung auf den Schriftwechsel und die Unterlagen, die nicht Werbezwecken dienen und die zur Beantwortung einer konkreten Anfrage zu einem bestimmten Arzneimittel erforderlich sind.

(6) Das Gesetz findet ferner keine Anwendung beim elektronischen Handel mit Arzneimitteln auf das Bestellformular und die dort aufgeführten Angaben, soweit diese für eine ordnungsgemäße Bestellung notwendig sind.

§2

Fachkreise im Sinne dieses Gesetzes sind Angehörige der Heilberufe oder des Heilgewerbes, Einrichtungen,
die der Gesundheit von Mensch oder Tier dienen, oder sonstige Personen, soweit sie mit Arzneimitteln, Medizinprodukten, Verfahren, Behandlungen, Gegenständen oder anderen Mitteln erlaubterweise Handel treiben oder sie in Ausübung ihres Berufes anwenden.

§4

(1) Jede Werbung für Arzneimittel im Sinne des § 2 Abs. 1 oder Abs. 2 Nr. 1 des Arzneimittelgesetzes muß folgende Angaben enthalten:
1. den Namen oder die Firma und den Sitz des pharmazeutischen Unternehmers,
2. die Bezeichnung des Arzneimittels,
3. die Zusammensetzung des Arzneimittels gemäß § 11 Abs. 1 Satz 1 Nr. 6 Buchstabe d des Arzneimittelgesetzes,
4. die Anwendungsgebiete,
5. die Gegenanzeigen,
6. die Nebenwirkungen,
7. Warnhinweise, soweit sie für die Kennzeichnung der Behältnisse und äußeren Umhüllungen vorgeschrieben sind,
   7.a. bei Arzneimitteln, die nur auf ärztliche, zahnärztliche oder tierärztliche Verschreibung abgegeben werden dürfen, der Hinweis "Verschreibungspflichtig",
8. die Wartezeit bei Arzneimitteln, die zur Anwendung bei Tieren bestimmt sind, die der Gewinnung von Lebensmitteln dienen.

Eine Werbung für traditionelle pflanzliche Arzneimittel, die nach dem Arzneimittelgesetz registriert sind, muss folgenden Hinweis enthalten: "Traditionelles pflanzliches Arzneimittel zur Anwendung bei ... (spezifiziertes Anwendungsgebiet/spezifizierte Anwendungsgebiete) ausschließlich auf Grund langjähriger Anwendung".

(1a) Bei Arzneimitteln, die nur einen Wirkstoff enthalten, muß der Angabe nach Absatz 1 Nr. 2 die Bezeichnung dieses Bestandteils mit dem Hinweis: "Wirkstoff:" folgen; dies gilt nicht, wenn in der Angabe nach Absatz 1 Nr. 2 die Bezeichnung des Wirkstoffs enthalten ist.

(2) Die Angaben nach den Absätzen 1 und 1a müssen mit denjenigen übereinstimmen, die nach § 11 oder § 12 des Arzneimittelgesetzes für die Packungsbeilage vorgeschrieben sind. Können die in § 11 Abs. 1 Satz 1 Nr. 3 Buchstabe a und Nr. 5 des Arzneimittelgesetzes vorgeschriebenen Angaben nicht gemacht werden, so können sie entfallen.

(3) Bei einer Werbung außerhalb der Fachkreise ist der Text "Zu Risiken und Nebenwirkungen lesen Sie die Packungsbeilage und fragen Sie Ihren Arzt oder Apotheker" gut lesbar und von

den übrigen Werbeaussagen deutlich abgesetzt und abgegrenzt anzugeben. Bei einer Werbung für Heilwässer tritt an die Stelle der Angabe "die Packungsbeilage" die Angabe "das Etikett" und bei einer Werbung für Tierarzneimittel an die Stelle "Ihren Arzt" die Angabe "den Tierarzt". Die Angaben nach Absatz 1 Nr. 1, 3, 5 und 6 können entfallen. Satz 1 findet keine Anwendung auf Arzneimittel, die für den Verkehr außerhalb der Apotheken freigegeben sind, es sei denn, daß in der Packungsbeilage oder auf dem Behältnis Nebenwirkungen oder sonstige Risiken angegeben sind.

(4) Die nach Absatz 1 vorgeschriebenen Angaben müssen von den übrigen Werbeaussagen deutlich abgesetzt, abgegrenzt und gut lesbar sein.

(5) Nach einer Werbung in audiovisuellen Medien ist der nach Absatz 3 Satz 1 oder 2 vorgeschriebene Text einzublenden, der im Fernsehen vor neutralem Hintergrund gut lesbar wiederzugeben und gleichzeitig zu sprechen ist, sofern nicht die Angabe dieses Textes nach Absatz 3 Satz 4 entfällt. Die Angaben nach Absatz 1 können entfallen.

(6) Die Absätze 1, 1a, 3 und 5 gelten nicht für eine Erinnerungswerbung. Eine Erinnerungswerbung liegt vor, wenn ausschließlich mit der Bezeichnung eines Arzneimittels oder zusätzlich mit dem Namen, der Firma, der Marke des pharmazeutischen Unternehmers oder dem Hinweis: "Wirkstoff:"geworben wird.

§ 10

(1) Für verschreibungspflichtige Arzneimittel darf nur bei Ärzten, Zahnärzten, Tierärzten, Apothekern und Personen, die mit diesen Arzneimitteln erlaubterweise Handel treiben, geworben werden.

(2) Für Arzneimittel, die dazu bestimmt sind, bei Menschen die Schlaflosigkeit oder psychische Störungen zu beseitigen oder die Stimmungslage zu beeinflussen, darf außerhalb der Fachkreise nicht geworben werden.

3. APOTHEKENBETRIEBSORDNUNG

§ 17 Erwerb und Abgabe von Arzneimitteln und Medizinprodukten

(1) Arzneimittel dürfen nur von zur Abgabe von Arzneimitteln berechtigten Betrieben erworben werden.

(1)a. Arzneimittel dürfen, außer im Falle des § 11a des Apothekengesetzes und des Absatzes 2a, nur in den Apothekenbetriebsräumen in den Verkehr gebracht und nur durch pharmazeutisches Personal ausgehändigt werden. Satz 1 ist auf apothekenpflichtige Medizinprodukte entsprechend anzuwenden.

(3) Der Apothekenleiter darf Arzneimittel und Medizinprodukte, die der Apothekenpflicht unterliegen, nicht im Wege der Selbstbedienung in den Verkehr bringen.

4. NAHRUNGSERGÄNZUNGSMITTELVERORDNUNG

§ 1 Anwendungsbereich

(1) Nahrungsergänzungsmittel im Sinne dieser Verordnung ist ein Lebensmittel, das

1. dazu bestimmt ist, die allgemeine Ernährung zu ergänzen,
2. ein Konzentrat von Nährstoffen oder sonstigen Stoffen mit ernährungsspezifischer oder physiologischer Wirkung allein oder in Zusammensetzung darstellt und
3. in dosierter Form, insbesondere in Form von Kapseln, Pastillen, Tabletten, Pillen und anderen ähnlichen Darreichungsformen, Pulverbeuteln, Flüssigampullen, Flaschen mit Tropfeinsätzen und ähnlichen Darreichungsformen von Flüssigkeiten und Pulvern zur Aufnahme in abgemessenen kleinen Mengen, in den Verkehr gebracht wird.

(2) Nährstoffe im Sinne dieser Verordnung sind Vitamine und Mineralstoffe, einschließlich Spurenelemente.

5. SOZIALGESETZBUCH

§ 34 SGB V Ausgeschlossene Arznei-, Heil- und Hilfsmittel

(1) Nicht verschreibungspflichtige Arzneimittel sind von der Versorgung nach § 31 ausgeschlossen. Der Gemeinsame Bundesausschuss legt in den Richtlinien nach § 92 Abs. 1 Satz 2 Nr. 6 fest, welche nicht verschreibungspflichtigen Arzneimittel, die bei der Behandlung schwerwiegender Erkrankungen als Therapiestandard gelten, zur Anwendung bei diesen Erkrankungen mit Begründung vom Vertragsarzt ausnahmsweise verordnet werden können. Dabei ist der therapeutischen Vielfalt Rechnung zu tragen. Der Gemeinsame Bundesausschuss hat auf der Grundlage der Richtlinie nach Satz 2 dafür Sorge zu tragen, dass eine Zusammenstellung der verordnungsfähigen Fertigarzneimittel erstellt, regelmäßig aktualisiert wird und im Internet abruffähig sowie in elektronisch weiterverarbeitbarer Form zur Verfügung steht. Satz 1 gilt nicht für:

1. versicherte Kinder bis zum vollendeten 12. Lebensjahr,
2. versicherte Jugendliche bis zum vollendeten 18. Lebensjahr mit Entwicklungsstörungen.

Für Versicherte, die das achtzehnte Lebensjahr vollendet haben, sind von der Versorgung nach § 31 folgende verschreibungspflichtige Arzneimittel bei Verordnung in den genannten Anwendungsgebieten ausgeschlossen:

1. Arzneimittel zur Anwendung bei Erkältungskrankheiten und grippalen Infekten einschließlich der bei diesen Krankheiten anzuwendenden Schnupfenmittel, Schmerzmittel, hustendämpfenden und hustenlösenden Mittel,
2. Mund- und Rachentherapeutika, ausgenommen bei Pilzinfektionen,
3. Abführmittel,
4. Arzneimittel gegen Reisekrankheit.

Von der Versorgung sind außerdem Arzneimittel ausgeschlossen, bei deren Anwendung eine Erhöhung der Lebensqualität im Vordergrund steht. Ausgeschlossen sind insbesondere Arzneimittel, die überwiegend zur Behandlung der erektilen Dysfunktion, der Anreizung sowie Steigerung der sexuellen Potenz, zur Raucherentwöhnung, zur Abmagerung oder zur Zügelung des Appetits, zur Regulierung des Körpergewichts oder zur Verbesserung des Haarwuchses dienen. Das Nähere regeln die Richtlinien nach § 92 Abs. 1 Satz 2 Nr. 6.

(2) (weggefallen)

(3) Der Ausschluss der Arzneimittel, die in Anlage 2 Nummer 2 bis 6 der Verordnung über unwirtschaftliche Arzneimittel in der gesetzlichen Krankenversicherung vom 21. Februar 1990 (BGBl. I S. 301), die zuletzt durch die Verordnung vom 9. Dezember 2002 (BGBl. I S. 4554) geändert worden ist, aufgeführt sind, gilt als Verordnungsausschluss des Gemeinsamen Bundesausschusses und ist Teil der Richtlinien nach § 92 Absatz 1 Satz 2 Nummer 6. Bei der Beurteilung von Arzneimitteln der besonderen Therapierichtungen wie homöopathischen, phytotherapeutischen und anthroposophischen Arzneimitteln ist der besonderen Wirkungsweise dieser Arzneimittel Rechnung zu tragen.

(4) Das Bundesministerium für Gesundheit kann durch Rechtsverordnung mit Zustimmung des Bundesrates Hilfsmittel von geringem oder umstrittenem therapeutischen Nutzen oder geringem Abgabepreis bestimmen, deren Kosten die Krankenkasse nicht übernimmt. Die Rechtsverordnung kann auch bestimmen, inwieweit geringfügige Kosten der notwendigen Änderung, Instandsetzung und Ersatzbeschaffung sowie der Ausbildung im Gebrauch der Hilfsmittel von der Krankenkasse nicht übernommen werden. Die Sätze 1 und 2 gelten nicht für die Instandsetzung von Hörgeräten und ihre Versorgung mit Batterien bei Versicherten, die das achtzehnte Lebensjahr noch nicht vollendet haben. Für nicht durch Rechtsverordnung nach Satz 1 ausgeschlossene Hilfsmittel bleibt § 92 unberührt.

(5) (weggefallen)

(6) Pharmazeutische Unternehmer können beim Gemeinsamen Bundesausschuss Anträge zur Aufnahme von Arzneimitteln in die Zusammenstellung nach Absatz 1 Satz 2 und 4 stellen. Die Anträge sind ausreichend zu begründen; die erforderlichen Nachweise sind dem Antrag beizufügen. Sind die Angaben zur Begründung des Antrags unzureichend, teilt der Gemeinsame Bundesausschuss dem Antragsteller unverzüglich mit, welche zusätzlichen Einzelangaben erforderlich sind. Der Gemeinsame Bundesausschuss hat über ausreichend begründete Anträge nach Satz 1 innerhalb von 90 Tagen zu bescheiden und den Antragsteller über Rechtsmittel und Rechtsmittelfristen zu belehren. Eine ablehnende Entscheidung muss eine auf objektiven und überprüfbaren Kriterien beruhende Begründung enthalten. Für das Antragsverfahren sind Gebühren zu erheben. Das Nähere insbesondere zur ausreichenden Begründung und zu den erforderlichen Nachweisen regelt der Gemeinsame Bundesausschuss

6. NOVEL FOOD VERORDNUNG

Artikel 1

(1) In dieser Verordnung ist das Inverkehrbringen neuartiger Lebensmittel und neuartiger Lebensmittelzutaten in der Gemeinschaft geregelt.

(2) Diese Verordnung findet Anwendung auf das Inverkehrbringen von Lebensmitteln und Lebensmittelzutaten in der Gemeinschaft, die in dieser bisher noch nicht in nennenswertem Umfang für den menschlichen Verzehr verwendet wurden und die unter nachstehende Gruppen von Erzeugnissen fallen:

a) Lebensmittel und Lebensmittelzutaten, die genetisch veränderte Organismen im Sinne der Richtlinie 90/220/EWG enthalten oder aus solchen bestehen;

b) Lebensmittel und Lebensmittelzutaten, die aus genetisch veränderten Organismen hergestellt wurden, solche jedoch nicht enthalten;

c) Lebensmittel und Lebensmittelzutaten mit neuer oder gezielt modifizierter primärer Molekularstruktur;

d) Lebensmittel und Lebensmittelzutaten, die aus Mikroorganismen, Pilzen oder Algen bestehen oder aus diesen isoliert worden sind;

e) Lebensmittel und Lebensmittelzutaten, die aus Pflanzen bestehen oder aus Pflanzen isoliert worden sind, und aus Tieren isolierte Lebensmittelzutaten, außer Lebensmittel oder Lebensmittelzutaten, die mit herkömmlichen Vermehrungs- oder Zuchtmethoden gewonnen wurden und die erfahrungsgemäß als unbedenkliche Lebensmittel gelten können;

f) Lebensmittel und Lebensmittelzutaten, bei deren Herstellung ein nicht übliches Verfahren angewandt worden ist und bei denen dieses Verfahren eine bedeutende Veränderung ihrer Zusammensetzung oder der Struktur der Lebensmittel oder der Lebensmittelzutaten bewirkt hat, was sich auf ihren Nährwert, ihren Stoffwechsel oder auf die Menge unerwünschter Stoffe im Lebensmittel auswirkt.

(3) Gegebenenfalls kann nach dem Verfahren des Artikels 13 festgelegt werden, ob ein Lebensmittel oder eine Lebensmittelzutat unter Absatz 2 dieses Artikels fällt.

7. DIÄTVERORDNUNG

(1) Diätetische Lebensmittel sind Lebensmittel, die für eine besondere Ernährung bestimmt sind.

(2) Lebensmittel sind für eine besondere Ernährung bestimmt, wenn sie

1. den besonderen Ernährungserfordernissen folgender Verbrauchergruppen entsprechen:
   a) bestimmter Gruppen von Personen, deren Verdauungs- oder Resorptionsprozess oder Stoffwechsel gestört ist oder
   b) bestimmter Gruppen von Personen, die sich in besonderen physiologischen Umständen befinden und deshalb einen besonderen Nutzen aus der kontrollierten Aufnahme bestimmter in der Nahrung enthaltener Stoffe ziehen können, oder
   c) gesunder Säuglinge oder Kleinkinder,
2. sich für den angegebenen Ernährungszweck eignen und mit dem Hinweis darauf in den Verkehr gebracht werden, dass sie für diesen Zweck geeignet sind, und
3. sich auf Grund ihrer besonderen Zusammensetzung oder des besonderen Verfahrens ihrer Herstellung deutlich von den Lebensmitteln des allgemeinen Verzehrs unterscheiden.

8. LEBENSMITTEL-, BEDARFSGEGENSTÄNDE- UND FUTTERMITTELGESETZBUCH

§ 2 Begriffsbestimmungen

(5) Kosmetische Mittel sind Stoffe oder Gemische aus Stoffen, die ausschließlich oder überwiegend dazu bestimmt sind, äußerlich am Körper des Menschen oder in seiner Mundhöhle zur Reinigung, zum Schutz, zur Erhaltung eines guten Zustandes, zur Parfümierung, zur Veränderung des Aussehens oder dazu angewendet zu werden, den Körpergeruch zu beeinflussen. Als kosmetische Mittel gelten nicht Stoffe oder Gemische aus Stoffen, die zur Beeinflussung der Körperformen bestimmt sind.

§ 11 Vorschriften zum Schutz vor Täuschung

(1) Es ist verboten, Lebensmittel unter irreführender Bezeichnung, Angabe oder Aufmachung in den Verkehr zu bringen oder für Lebensmittel allgemein oder im Einzelfall mit irreführenden Darstellungen oder sonstigen Aussagen zu werben. Eine Irreführung liegt insbesondere dann vor, wenn

1. bei einem Lebensmittel zur Täuschung geeignete Bezeichnungen, Angaben, Aufmachungen, Darstellungen oder sonstige Aussagen über Eigenschaften, insbesondere über Art, Beschaffenheit, Zusammensetzung, Menge, Haltbarkeit, Ursprung, Herkunft oder Art der Herstellung oder Gewinnung verwendet werden,
2. einem Lebensmittel Wirkungen beigelegt werden, die ihm nach den Erkenntnissen der Wissenschaft nicht zukommen oder die wissenschaftlich nicht hinreichend gesichert sind,
3. zu verstehen gegeben wird, dass ein Lebensmittel besondere Eigenschaften hat, obwohl alle vergleichbaren Lebensmittel dieselben Eigenschaften haben,
4. einem Lebensmittel der Anschein eines Arzneimittels gegeben wird.

(2) Es ist ferner verboten,

1. andere als dem Verbot des Artikels 14 Absatz 1 in Verbindung mit Absatz 2 Buchstabe b der Verordnung (EG) Nr. 178/2002 unterliegende Lebensmittel, die für den Verzehr durch den Menschen ungeeignet sind, in den Verkehr zu bringen,
2. a) nachgemachte Lebensmittel,
   b) Lebensmittel, die hinsichtlich ihrer Beschaffenheit von der Verkehrsauffassung abweichen und dadurch in ihrem Wert, insbesondere in ihrem Nähr- oder Genusswert oder in ihrer Brauchbarkeit nicht unerheblich gemindert sind oder
   c) Lebensmittel, die geeignet sind, den Anschein einer besseren als der tatsächlichen Beschaffenheit zu erwecken,

   ohne ausreichende Kenntlichmachung in den Verkehr zu bringen.

§ 12 Verbot der krankheitsbezogenen Werbung

(1) Es ist verboten, beim Verkehr mit Lebensmitteln oder in der Werbung für Lebensmittel allgemein oder im Einzelfall

1. Aussagen, die sich auf die Beseitigung, Linderung oder Verhütung von Krankheiten beziehen,
2. Hinweise auf ärztliche Empfehlungen oder ärztliche Gutachten,
3. Krankengeschichten oder Hinweise auf solche,
4. Äußerungen Dritter, insbesondere Dank-, Anerkennungs- oder Empfehlungsschreiben, soweit sie sich auf die Beseitigung oder Linderung von Krankheiten beziehen, sowie Hinweise auf solche Äußerungen,
5. bildliche Darstellungen von Personen in der Berufskleidung oder bei der Ausübung der Tätigkeit von Angehörigen der Heilberufe, des Heilgewerbes oder des Arzneimittelhandels,
6. Aussagen, die geeignet sind, Angstgefühle hervorzurufen oder auszunutzen,
7. Schriften oder schriftliche Angaben, die dazu anleiten, Krankheiten mit Lebensmitteln zu behandeln,

zu verwenden.

(2) Die Verbote des Absatzes 1 gelten nicht für die Werbung gegenüber Angehörigen der Heilberufe, des Heilgewerbes oder der Heilhilfsberufe. Die Verbote des Absatzes 1 Nummer 1 und 7 gelten nicht für diätetische Lebensmittel, soweit nicht das Bundesministerium durch Rechtsverordnung mit Zustimmung des Bundesrates etwas anderes bestimmt.

(3) Artikel 14 Absatz 1 der Verordnung (EG) Nr. 1924/2006 des Europäischen Parlaments und des Rates vom 20. Dezember 2006 über nährwert- und gesundheitsbezogene Angaben über Lebensmittel (ABl. L 404 vom 30.12.2006, S. 9, L 12 vom 18.1.2007, S. 3, L 86 vom 28.3.2008, S. 34), die zuletzt durch die Verordnung (EU) Nr. 116/2010 (ABl. L 37 vom 10.2.2010, S. 16)

geändert worden ist, über die Verwendung von Angaben über die Verringerung eines Krankheitsrisikos bleibt unberührt.

9. MEDIZINPRODUKTEGESETZ

§ 3 Begriffsbestimmungen

1. Medizinprodukte sind alle einzeln oder miteinander verbunden verwendeten Instrumente, Apparate, Vorrichtungen, Software, Stoffe und Zubereitungen aus Stoffen oder andere Gegenstände einschließlich der vom Hersteller speziell zur Anwendung für diagnostische oder therapeutische Zwecke bestimmten und für ein einwandfreies Funktionieren des Medizinproduktes eingesetzten Software, die vom Hersteller zur Anwendung für Menschen mittels ihrer Funktionen zum Zwecke
   a) der Erkennung, Verhütung, Überwachung, Behandlung oder Linderung von Krankheiten,
   b) der Erkennung, Überwachung, Behandlung, Linderung oder Kompensierung von Verletzungen oder Behinderungen,
   c) der Untersuchung, der Ersetzung oder der Veränderung des anatomischen Aufbaus oder eines physiologischen Vorgangs oder
   d) der Empfängnisregelung

zu dienen bestimmt sind und deren bestimmungsgemäße Hauptwirkung im oder am menschlichen Körper weder durch pharmakologisch oder immunologisch wirkende Mittel noch durch Metabolismus erreicht wird, deren Wirkungsweise aber durch solche Mittel unterstützt werden kann.

§ 19 Klinische Bewertung, Leistungsbewertung

(1) Die Eignung von Medizinprodukten für den vorgesehenen Verwendungszweck ist durch eine klinische Bewertung anhand von klinischen Daten nach § 3 Nummer 25 zu belegen, soweit nicht in begründeten Ausnahmefällen andere Daten ausreichend sind. Die klinische Bewertung schließt die Beurteilung von unerwünschten Wirkungen sowie die Annehmbarkeit des in den Grundlegenden Anforderungen der Richtlinien 90/385/EWG und 93/42/EWG genannten Nutzen-/Risiko-Verhältnisses ein. Die klinische Bewertung muss gemäß einem definierten und methodisch einwandfreien Verfahren erfolgen und gegebenenfalls einschlägige harmonisierte Normen berücksichtigen

8.4. Interview guideline

Block I - Suchroutinen

Zuerst möchte ich Sie fragen, in wie weit die Innovationsaktivitäten Ihres Unternehmens von Marktentwicklungen abhängig sind und wie ausgeprägt Ihr Interesse an Veränderungen außerhalb Ihres bestehenden Aktionsradius ist.

Lassen Sie mich ganz grundsätzlich beginnen:

(1) Fördern Sie ein fundiertes Wissen über Ihre aktuellen Wettbewerber? Geschieht dies systematisch, in Form von Scanning-Aktivitäten?

- (1)a. Wettbewerber im Pharmamarkt
- (1)b. Wettbewerber außerhalb des Pharmamarktes - *falls es sie gibt*

(2) Beschäftigen Sie sich auch mit zukünftigen Wettbewerbern in Form von Scanning-Aktivitäten?

- (2)a. Wenn ja: Auch über solche außerhalb der Pharmaindustrie?
- (2)b. Wenn nein: Ist das also nicht nötig?

(3) Pflegen Sie systematisch Kanäle für einen Wissensaustausch mit externen Partnern, um für die strategische Planung von Produktinnovationen immer up to date zu sein?

- (3)a. Welche Art von Input? Sind alle gleichermaßen wichtig?
  - Bspw. externe Allianzen
  - Bspw. externe Netzwerke
  - Bspw. Marktforschung

(4) Der Arzneimittelmarkt ist bis heute das wichtigste Standbein der Pharmaindustrie. Wenn ich das richtig sehe, ist aber auch die Entwicklung des Gesundheitsmittelmarktes wichtig *(sonst gäbe es Ihre Abteilung ja nicht)*. Warum ist dieser Markt wichtig für Sie?

- (4)a. Wenn ja: beobachten Sie ihn also systematisch? Sind Ihre Gesundheitsmittelinnovationen also das Ergebnis strategisch betriebenen Business Developments, oder eher 'Abfallprodukt' des klassischen Unternehmensgeschäfts?
- (4)b. Wenn nein: warum nicht? Welche Märkte sind dann wichtig?

Block II - Ausrichtung und Flexibilität der F&E

Lassen Sie uns kurz über die Forschungsarbeit Ihres Unternehmens außerhalb der klassischen Pharmaforschung und über die Anpassung Ihrer wissenschaftlichen Arbeit sprechen:

(5) Die regulatorischen Bedingungen der Gesundheitsmittel erlauben andere (niedrigere?) Standards bei Forschung und Entwicklung, als im Falle der Arzneimittel. Schöpfen Sie dies aus, indem Sie unterschiedliche 'Qualitätsstandards' für die Arzneimittel- und Gesundheitsmittelforschung gelten lassen?

(6) Beobachten Sie systematisch die Entwicklungen technologischer und wissenschaftlicher Trends auf dem Gebiet der Gesundheitsmittel?

- (6)a. Wenn ja:
  Welche Entwicklungen genau?
  Welche Tools sind dabei besonders wichtig?
- (6)b. Wenn nein: Findet also keine systematische Ausweitung des Wissens in diese Richtung statt?

(7) Passt sich Ihre Gesundheitsmittelforschung flexibel an neue Markttrends an? *(==> heiligt der Zweck die Mittel? - Passt sich die F&E an die Nachfrage im Markt an?)*

Block III - Interaktions- und Kommunikationsroutinen

Es ist mir wichtig, einen Eindruck davon zu bekommen, wie durchlässig Ihr Unternehmen für Ideen/Innovationsanreize ist und wie stark die Unternehmensstruktur die Kommunikation zwischen den einzelnen Bereichen und Geschäftsfeldern beeinträchtigt. Kurz: wie leicht es eine externe Neuerung hat, im Unternehmen kommuniziert und wahrgenommen zu werden.

(8) Wie wird in Ihrem Unternehmen die Zusammenarbeit zwischen unterschiedlichen Funktionsbereichen (Marketing, Design, F&E etc.) gefördert?

(9) Die Geschäftsbereiche Ihres Unternehmens unterscheiden sich stark in ihrer Größe *(Rx vs OTC vs GM, bzw. OTC vs GM)*. - Beeinflusst das die Kommunikation und Freigabe von Innovationsvorhaben? (Wird die Kommunikation gefördert?)

(9)a. Wenn ja: Gibt es erkennbare Regelmäßigkeiten?

(9)b. Wenn nein (unterschiedl. Größe): Wie kommt das?

(9)c. Wenn nein (Beeinflussung der Kommunikation): Weiter zu F10

(10) Sind alle Geschäftsbereiche des Unternehmens in den Gremien, die über die strategische Ausrichtung des Unternehmens entscheiden, gleichberechtigt vertreten?

(10)a. Gibt es Abhängigkeiten? Wer überwiegt?

Block IV - Entscheidungsprozesse, Organisatorischer Aufbau

Ich möchte mit Ihnen nun gerne über die Entscheidungsprozesse und den Aufbau Ihres Unternehmens sprechen, um zu ermitteln, wie die Gesundheitsmittelsparte in das Unternehmen eingebunden ist.

(11) Die Arzneimittelindustrie konzentriert sich in Deutschland stark auf den Apothekenmarkt für den Vertrieb von Gesundheitsmitteln. Wovon hängt die Entscheidung für den Vertriebskanal Ihrer Meinung nach ab?

(11)a. Welche Vorteile hat der Apothekenmarkt? - *Beispiel* -

(11)b. Welche Nachteile hat der Mass Market außerhalb der Apotheke? - *Beispiel* -

(12) Warum werden Gesundheitsmittel (fast) nie gleichzeitig über beide Kanäle vertrieben?

(13) Verfügt die Gesundheitsmittelsparte in Ihrem Unternehmen über unabhängige Vertriebsstrukturen, oder werden die Produkte zusammen mit den Arzneimitteln zentral vertrieben (eine Bündelung der Ressourcen)?

(14) Verfügt die Gesundheitsmittelsparte über ein eigenes Budget für die Produktentwicklung?

(14)a. Wenn nein: Wie wird R&D dann finanziert? Wer hat die Budgethoheit?

(15) Wovon hängt es ab, ob eine Produktinnovation angestoßen wird? (consumer pull vs. technology/knowledge push) - *Beispiel* -

(15)a. Innovation als Reaktion auf einen Stimulus von Außen (Markt, Nachfrage, etc.)?

(15)b. Oder entsteht der Stimulus für eine Innovation eher innerhalb des Unternehmens Neue Forschungsergebnisse, neue technologische Möglichkeiten, etc)?

(15)c. *Evtl. nachfassen:* Wäre eine Marktentwicklung allein für Ihr Unternehmen ein Grund, aktiv zu werden?

(16) Was würden Sie sagen, ist das 'Leitbild'/sind die Kernwerte einer guten Arzneimittelinnovation in Ihrem Unternehmen?

Ich gebe Ihnen mal ein paar Stichworte:

- Hohe wissenschaftliche Belegbarkeit der Wirkweise des Arzneimittels - Produktsicherheit
- Vertrauenswürdigkeit des Produkts
- Produktqualität
- Compliance
- Marktgröße für das Produkt/Vertriebsweg
- Marketingaspekte
- Preisgestaltung/Erstattung

(17) Können die o.g. 'Werte' einer Arzneimittelinnovation auch im Gesundheitsmittelmarkt durchgesetzt werden? Müssten sie es Ihrer Meinung nach?

(18) Passen Gesundheitsmittel zum innovatorischen Profil Ihrer Industrie? *(Unterschied international vs Deutschland?)*

(18)a. Alle GM gleichermaßen? Unterscheiden Sie zwischen den einzelnen Vertriebswegen oder Verkehrsfähigkeiten von Gesundheitsmitteln?

- Nem vs Diätetikum vs Medizinprodukt
- Apotheke
- Mass Market

(19) Schaden Gesundheitsmittel dem Image der Arzneimittel? Immer? Wann (nicht)?

- Sicherheit und Seriosität (Beratung durch Arzt, Apotheker) *versus* Marketing und leichte Verfügbarkeit

Offenere Fragen zum Abschluss:

(20) Was ist aus Ihrer Sicht in 1-2 Sätzen die zusammenfassende Antwort auf meine Forschungsfragen?

(20)a. Fehlt Ihnen eine entscheidende Frage/ein entscheidender Aspekt in meiner Betrachtung?

(21) Sind Sie zufrieden mit der Entwicklung Ihres Gesundheitsmittelgeschäfts?

(22) Könnten Sie sich vorstellen, dass der Gesundheitsmittelmarkt oder seine Akteure eines Tages zur Bedrohung für den Arzneimittelmarkt wird? (*bspw. durch stärkere Wirksamkeit von Gesundheitsmitteln und erhöhte Legitimität im Markt, oder durch ein upgrade der heutigen Gesundheitsmittelhersteller aus anderen Industrien zu Arzneimittelherstellern*)

Block VI - Person und Werdegang *[nur, wenn Situation passend]*

Lassen Sie mich zum Schluss noch ein paar kurze Fragen zu Ihrem beruflichen Hintergrund stellen, damit ich Ihre Antworten vor dessen Hintergrund auswerten kann:

(23) Können Sie Ihren beruflichen Werdegang vom Schulabschluss bis zum Eintritt bei XY skizzieren?

- Berufsausbildung/Studium
- Sonstige Qualifikationen, Fortbildungen
- Arbeitgeber und Positionen

(24) Welche Position haben Sie bei XY?

(25) Wie alt sind Sie?

Backup

(26) Ihre Konkurrenz im Gesundheitsmittelmarkt eignet sich zum Teil Kompetenzen durch Kooperationen an, wie im Fall von innéov, das aus einer Kooperation zwischen dem Lebensmittelhersteller Nestlé und dem Kosmetikkonzern L'Oréal entstanden ist. Wären solche Initiativen auch für die Pharmaindustrie denkbar?

(27) Verfügt die Gesundheitsmittelsparte über eigene Forschungs- und Produktionseinrichtungen?

(27)a. Wenn nein: Erlaubt die gemeinsame Nutzung der Pharma-Facilities eine flexible und schnelle Anpassung an die Gesundheitsmittelproduktion?

(27)b. Wie unabhängig ist die Gesundheitsmittelforschung von der Arzneimittelforschung? Wie beeinflussen sich die beiden?

8.5. Bibliography

A

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