

Business Model Innovation in the Pharmaceutical Industry

The Supporting Role of Organizational Design

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THE SUPPORTING ROLE OF ORGANIZATIONAL DESIGN**

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BUSINESS MODEL INNOVATION IN THE PHARMACEUTICAL INDUSTRY: THE SUPPORTING ROLE OF ORGANIZATIONAL DESIGN

Abstract

Based on interviews in LEO Pharma, UCB Pharma and Novo Nordisk, we document how deep-seated changes in the pharmaceutical industry related to increasing demands from payers, the strengthening of the role of patients, changing legal demands, and declining technological opportunity, drive a process of experimenting with business model. We distinguish between three ideal types, namely a traditionalist model (exemplified by Novo Nordisk), the full-blown service-oriented model (UCB Pharma) and the in-between model (LEO Pharma). We describe the changes to the organizational design and management processes that accompany the ongoing process of changing business models in these firms.

INTRODUCTION

The pharmaceutical industry assumes a major economic role in a number of countries (e.g., US, Germany, and Denmark) in terms of its share of overall value-added, R&D inputs, exports, and innovativeness. The industry also captures general interest because of its role as the key originator of medical innovation in the world, and has, partly for this reason, for a long time been heavily regulated. It has captured scholarly interest because of, for example, the highly “closed” innovation model, pricing policies, and dynamics of the boundaries of the firm that have characterized this industry (e.g., Bianchi, Cavaliere, Chiaroni, Frattini, & Chiesa, 2011; Danzon, 2006; Pisano, 1991). Thus, the last decades have witnessed major merger and acquisition activity, and a substantial alliance activity, for example, with biotechnology firms. Much of this activity may be seen as attempts to patch a business model—namely, the “blockbuster model” based on high-volume, high-margin sales of drugs for common conditions and driven by mainly internal and very substantial R&D inputs, as well as scale economies in R&D, production, marketing and sales (Gilbert, Henske, & Singh, 2003)—that, some argue, is “becoming extinct” (Mattke, Klautzer, & Mengistu, 2012, p. 1). This prediction is based on an argument that technological opportunities in the pharmaceutical industry are declining, development costs are soaring, copy products are proliferating, and regulatory pressures are building-up that threaten margins.

The strength and relative weight of these ongoing changes are subject to substantial debate. However, that changes in the industry are quite real is not open to dispute. We argue that these changes, some of which are external to the industry (e.g., regulatory pressure) and some internal (e.g., competitive dynamics involving copy products), drive the ongoing experimentation with business models that can be observed in the industry. Much of this experimentation takes the form of introducing the service dimension as an integral part of the emerging business models, a dynamic that has been building up over the last decade.

Business models are often taken to denote the firm’s core logic for creating and capturing value by specifying the firm’s fundamental value proposition(s), the markets and market segments it addresses, the structure of the value chain which is required for realizing the relevant value proposition, and the mechanisms of value capture that the firm deploys. We describe the reconfigurations of three companies, partly relying on the framework of Santos et al. (this volume). We show how these reconfigurations are embedded in, and related to changes in, organizational designs. Indeed, the managerial challenges of business model innovation are to a large extent organizational challenges that involve the redesign of organizational structure and control, as well as choices that involve the boundaries of pharmaceutical firms *vis-à-vis* other firms. We describe various changes in the organizational design of three select players in the industry, discuss how these

are related to the deep-seated changes the industry is witnessing, and discuss the managerial challenges of implementing organizational designs that fit the emerging business models in the industry, particularly those that shift the value-proposition towards a service-based one.

We begin by briefly discussing our data sources and the method of diverse cases; move on to a presentation of the industry context; then turn to the drivers that prompt the ongoing experimentation with business models in the industry; discuss the forms that the actual experimentation takes; and end by discussing the challenges of choosing organizational design that can embed the changing business models faced by pharmaceutical firms.

DATA AND DATA ANALYSIS

Small-N Research Designs

In the following we adopt a small-N research design to explore the organizational challenges that companies in the pharmaceutical industry face when seeking to innovate their business models. Such designs are often criticized on the ground that they are vulnerable to selection bias, and, hence, problems of external validity (Bryman, 1988; King, 1994). However, most scholars agree that when there are fundamental gaps in the understanding of a phenomenon concerning which variables matter and how, explorative research based on small-N samples is warranted (Eisenhardt, 1989; Westney & Van Maanen, 2011). Moreover, as Dyer and Wilkins (1991: 617) explain, “if executed well, case studies can be “extremely powerful” when “authors have described general phenomenon so well that others have little difficulty seeing the same phenomenon in their own experience and research.” Thus, “good stories” are successful in terms of identifying generative mechanisms that other researchers can recognize in the cases they investigate (Hedström, 2005). This study is basically an attempt to identify the operation of such mechanisms in the context of the pharmaceutical industry.

We specifically draw on a diverse-case method of selection with the primary objective of achieving maximum variation along relevant dimensions (while homogenizing other dimensions). In line with the diverse-case approach, the selection of specific pharmaceutical companies was based on the study’s aims, that is, seeking a balanced sample of companies in which issues and processes related to the organizational dimensions of business model innovation can be compared, while at the same time keeping variability reasonably high. We selected the following three companies for the sample, namely *Novo Nordisk A/S*, which pursues a “traditionalist” strategy; *LEO Pharma A/S*, which pursues a “simultaneous” approach, explicitly balancing different business models; and *UCB Pharma*, which is transitioning towards a service-oriented model. Our interviews and general industry knowledge indicates that these three firms can be taken to be representative of different kinds of experimentation with business models in the pharmaceutical industry.

In contrast to a purely inductive study, the present research is informed by *a priori* theory on organizational design and organization/environment relations (e.g., Thompson, 1967). We approach the pharmaceutical industry armed with theory, because this “increases requisite variety ... it takes a complicated sensing device to register a complicated set of events” (Weick, 2007, p. 16). The relevant theories help to organize data collection and interpretation, and metaphorically serve as a dialogue partner for the data.

Data Collection and Analysis

The data for this study was collected from three overlapping sources, namely in-depth, semi-structured interviews, documents, and observation studies. These sources were triangulated to maintain the integrity of the analysis (Miles & Huberman, 1994; Silverman, 2006). We relied on Lincoln and Guba's (1985) guidelines for “purposeful sampling” and initially interviewed top managers about how they change the organizational design of their firms in order to facilitate and encourage business model innovation. Next a “snowball” technique was adopted, asking each top manager for his or her recommendations as to who could best explain the processes of interests. Prior research (see e.g., Daft & Weick, 1984; Isabella, 1990) and the study's research objective, suggested that sampling should begin with top managers because they typically play a key role in ventures that represent new strategic directions and resource configurations for the firm. As active participants in championing a new business model, these managers represent key informants (Kumar, Stern, & Anderson, 1993) who have overall insight into the company's core capabilities, organizational structures, resource allocation, strategies etc., and are therefore in a unique position to recommend additional key and role informants at all levels within the organization.

In total, 30 in-depth interviews were carried out.¹ All interviews started with open questions about the company's overall strategy and recent experience. As the interviews progressed, the questions gradually became more structured, delving into organizational design issues in the relevant firms, and the specific challenges they faced on the organizational side with respect to business model innovation. In addition, non-participant observations were made by one of the authors of the chapter, who, in the interest of full-disclosure, is working as an industrial PhD researcher in one of the interviewed companies (i.e., LEO Pharma). Finally, we examined relevant documents, such as internal powerpoint presentations, annual company reports, and consulting reports. The documents not only supplied additional information, but also allowed us to control for memory bias by

¹ Specifically, the interviews were distributed as follows over the three firm: UCB Pharma: 15 interviews in total, ranging from Executive Vice President to Manager level; LEO Pharma A/S: 13 interviews in total, ranging from Executive Vice President to Manager level; Novo Nordisk A/S: 2 interviews in total, ranging from Corporate Vice President to Manager level.

comparing interview statements with the collected document data (Miller, Cardinal, & Glick, 1997). Our discussion of the drivers of business model innovation in the industry is mainly based on documents.

To analyze the data, we adopted Yin's (2003) “pattern-matching” method of analysis. In this approach the empirical patterns of the case (and the embedded cases) are compared with those of theory. To emerge at patterns interviews were transcribed. Following triangulation with documents, this procedure allowed for the derivation across the interviews of patterns relating to how the relevant firms were changing their organization to facilitate business model innovation. In order to further strengthen validity, respondent validation was also applied (Silverman, 2006).

DRIVERS OF BUSINESS MODEL INNOVATION IN THE PHARMACEUTICAL INDUSTRY

The extant literature does not point to any unique drivers of business model innovation (or, business model “learning”, “evolution”, “modification”, “reconfiguration” or “renewal”; cf. Demil & Lecocq, 2010; Doz & Kosonen, 2010; Dunford, Palmer, & Benveniste, 2010; Teece, 2010). Rather, it generically points to forces such as globalization, deregulation, technological advances, and changing preferences as drivers (idem.). Clearly, the ensemble of forces that drive business model innovation differs across industries. In the context of the pharmaceutical industry, we argue that the particularly important drivers are mounting payer pressures, regulatory changes, and, more controversially, declining technological opportunity.

The Payment Challenge

What is referred to by industry insiders as the “payment challenge” refers to a host of structural changes in the costs of health care and the willingness and ability of governments and insurance companies to pay for treatments that jointly put margins in the industry under strong pressure, a tendency that has been exacerbated by the emphasis on fiscal austerity since the onset of the financial crisis of 2008. Data from OECD (2010) suggest that health care spending per capita in OECD countries has risen by over 70% in real terms since the early 1990s. This increased spending can be partly attributed to deep-seated demographic, epidemiological, and economic changes. By 2020, there will be more than 7.6 billion people in the world, with 719 million (9.4%) being over 65—the segment of the population that consumes most medicine per capita. Furthermore, the size of this segment will double relative to its size in the year of 2000 (Hunter, 2013). In the developed countries, life expectancy has increased by, on average 2 years for every decade since the early 1990s. However, Hunter (2013:1818) noted, this “has not been matched by a concomitant increase in health, leading to an actual increase in the economic burden.”

WHO (2002) found that if chronic conditions are not adequately prevented and/or managed, they may become the most expensive problems faced by health care systems. Current health care systems are mainly designed to treat acute problems related to illnesses (i.e., diagnosing, testing, relieving symptoms, and developing cure). While these tasks are important for acute and episodic health problems, a remarkable discrepancy emerges when adopting this model for the management of chronic conditions. Substantial evidence suggests that patients with chronic conditions are usually undertreated in emerging countries due to limited access to medicine (WHO, 2003), while in developed countries the problem is that they do not comply to prescribed treatment regimens (Wagner et al., 2011). In particular, medical *non-compliance* has been identified as a major issue of public health which in turn imposes a considerable financial burden upon modern health care systems (Donovan, 1995; Weinman & Petrie, 1997). WHO studies show that 50% of people with a chronic condition are non-compliant (WHO, 2003). This has been estimated to cost \$177 billion annually in the USA (approximately a quarter of total annual pharmaceutical revenues) (IMS, 2008) and account for 78% of health care spending (Bodenheimer & Fernandez, 2005). For patients, non-compliance is directly related to poorer health outcomes (Loden & Schooler, 2000) and increased health care costs (Kane & Shaya, 2008).

Against this backdrop, pharmaceutical companies face surging demands from payers, who, in their efforts to control soaring health care costs, are increasingly requiring that pharmaceutical companies demonstrate that their products provide therapeutic or cost advantages over competitors' products and non-pharmaceutical treatment options.

Regulatory change

Changes in the regulatory environment have also led to the introduction of additional demanding hurdles that a new drug must clear prior to market launch. Following the well-publicized market withdrawals of high-profile pharmaceutical products such as rofecoxib (Vioxx, Merck), cerivastatin (Baycol, Bayer), troglitazone (Rezulin, Warner-Lambert) and cisapride (Propulsid, Janssen Pharmaceutica), the US Food and Drug Administration (FDA) and its counterparts in other major markets have put more focus on preapproval safety evaluations and increased their reliance on postapproval systems to monitor product safety and use (Munos, 2009). For example, with the ratification of the Food and Drug Administration Amendments Act of 2007² in the US, the FDA was granted new authority to require submission of risk evaluation, mitigation strategies and application for regulatory approval, to demand postmarket clinical studies on approved products if safety issues arise. Under such circumstances, they would be able to mandate changes to a drug's approved

² FDA Amendments Act. Pub. L. No. 110-85, 121 Stat. 823.

labeling, and to impose new distribution and use restrictions on marketed drugs (Kaitin, 2010). Globally, regulators also collaborate more closely, so when a product is rejected in one market it is more likely to be rejected in others. In 2010, for instance, EMA pulled the diabetes drug Avandia, while the FDA imposed severe restrictions on its use, and the two agencies exchanged notes before reaching a final decision.³

Declining Technological Opportunity in the Pharmaceutical Industry

In spite of steadily increasing levels of investments in R&D over the past two decades, the pharmaceutical industry has not been able to avoid a continuous decline in the number of new molecular entities (NMEs) that enter clinical development and subsequent market entry (Light & Lexchin, 2012). To illustrate, in 2002 the FDA only approved seventeen NMEs for sale in the US, that is, only a small fraction of the fifteen-year high of fifty-six approved NMEs in 1996 and the lowest since 1983 (Cockburn, 2004). The US is by no means alone. Thus, worldwide statistics suggest that the annual number of new active substances approved in major markets declined by fifty during the 1990s, while private-sector R&D expenditures tripled.⁴ These numbers have prompted concerns from industry leaders, observers, and policy makers, with some declaring an innovation crisis within pharmaceutical research.

Some scholars argue that these concerns are almost surely exaggerated: The so-called innovation crisis rests on the decline in NMEs, since the sharp peak in 1996 that resulted from the rapid backlog reduction of applications after the FDA deployed the augmented staff hired under the Prescription Drug User Fee Act of 1992 to reduce approval times (Scherer, 2007). This decline ended in 2006, when approvals of NMEs reverted to their long term mean of between 15 and 25 a year.⁵ On the basis of FDA records, Munos (2009) showed that pharmaceutical companies “... have delivered innovation at a constant rate for almost 60 years,” and new biologics⁶ have followed a similar pattern “in which approvals fluctuate around a constant, low level.” According to Hopkins, Martin,

³ Sten Stovall, “Europe’s Drug Regulator Says Innovation Must Pick Up”, The Wall Street Journal (15 December 2010).

⁴ EFPIA member companies spent \$47 billion in 2002. European Federation of Pharmaceutical Industries and Associations, “The pharmaceutical industry in figures, 2003 update (Brussels: EFPIA, 2003).

⁵ US Food and Drug Administration. New molecular entity approvals for 2010. Silver Spring: FDA, 2011. www.fda.gov/downloads/drugs/developmentapprovalprocess/howdrugsaredevelopedandapproved/drugandbiologicapprovalreports/UCM242695.pdf.

⁶ A “biologic” is manufactured in a living system such as a microorganism, or plant or animal cells. Most biologics are very large, complex molecules or mixtures of molecules. Many biologics are produced using recombinant DNA technology. A drug is typically manufactured through chemical synthesis, which means that it is made by combining specific chemical ingredients in an ordered process. <http://www.bio.org/articles/how-do-drugs-and-biologics-differ> accessed: 16-12-2013.

Nightingale, Kraft, and Mahdi (2007), not even the revolution of biotechnology changed the rate of approval of NMEs, though it influenced strategies for drug development.⁷

Thus, whether there is a crisis or not is a much more complex question than the absolute number of NMEs brought to market. More importantly is the number of NMEs that represent an actual therapeutic advance. Although innovation is often measured in terms of NMEs as a stand-in for therapeutically superior new medicines by the industry and its analysts, most have only provided trivial clinical advantages over existing treatments (Light & Lexchin, 2012). This is not a new phenomenon, the dominance of drugs without major therapeutic gains can be traced back to the “golden age” of pharmaceutical innovation. Covering the period from 1974 to 1994, the industry’s Barral report on all internationally marketed NMEs concluded that only 11% were therapeutically and pharmacologically innovative (Barral, 1996). Since the mid-1990s independent reviews have reached roughly the same conclusion that approximately 85-90% of NMEs provide minor or no clinical advantages for patients (see e.g., Angell, 2005; Luijn, Gribnau, & Leufkens, 2010).

Empowering End Users and Health Care Professionals

Historically, patients have played an essentially passive role in health delivery. In most cultures, the physician has been the sole decision-maker with regard to diagnosis and the most optimal treatment regimen; after all, they have had much more training and medical knowledge than patients. Further, in markets where patients have enjoyed health insurance, insurers have not only insulated patients from financial shocks but also from the prices of various treatments which are essential for creating optimal resource allocation in efficient markets. Patients have followed obligingly, while experts have made decisions that could, quite literally, have life-or-death consequences for them.

Prompted by the recent advances in internet and communication technologies (ICTs), transparency is expected to increase, in turn likely empowering patients and changing the practice of health care into a patient-centric model with patients having more “on demand” access to information. Social media networks—from PatientsLikeMe to Sermo and Medscape Physician Connect—are making data on outcomes and efficacy more transparent and freeing it from the control of corporate giants. New mobile technologies and apps enable patients to take a more active role in managing their own health care. For example, in diabetes, where effective disease management requires a coordinated and holistic approach, new apps assist patients in not only managing their

⁷ Such accounts obviously raise the issue of why there has been an escalating discussion of declining technological opportunities and a crisis to medical innovation. Adamini, Maarse, Versluis, and Light (2009) suggest that telling stories about the “innovation crisis” to politicians and the press is a rent-seeking plot: It helps to attract a range of government protections from the “generic” competition.

blood glucose but also other aspects of their health, such as diet and exercise.⁸ The range of apps is by no means limited to diabetes. For example, these include apps that aid patients in keeping track of vaccination schedules (i.e., Novartis' VaxTrak), control their hemophilia A Factor VIII infusions (i.e., Bayer's Factor Track), and map cancer clinical trials within 150 miles (i.e., GSK's Cancer Trials).

With the new ICTs, health care professionals can potentially access patient records from any given location. For example, physicians' access to patient history file, newest pharmaceutical data, laboratory results, insurance information and medical resources would be more effectively used by ICTs, and in turn, improving the quality of patient care (Istepanian, Jovanov, & Zhang, 2004). Further, the amount of data that can be mined from such systems can be used to compare efficacy between different treatments. Kaiser Healthcare and Intermountain Health, have already been doing this for a while, and new entrants in the personal health record (PHR) business such as Google Health and Microsoft HealthVault could take "value mining" to an entirely new level. These trends are likely to result in more empowered and better informed patients, which in turn means that physicians spend less time in explaining rudimentary facts about diseases, and rather set aside time to discuss more complex treatment aspects and listen to each patient.⁹

BUSINESS MODELS CHANGES IN THE PHARMACEUTICAL INDUSTRY

Dynamics of Business Models

Established pharmaceutical companies have reacted to the above drivers in terms of more or less radically changes to their basic value propositions, the organization of their value chains, internal organization, key resources, and revenue models. Santos, Spector and Van der Heyden (this volume) explain how firms can reconfigure their existing business models by either (1) "reactivating," that is, altering the set of elemental activities that the firm offers to its customers (e.g. offering a hot meal on flights); (2) "repartitioning," that is, altering the boundaries of the firm by moving activities and the organizational units that perform activities (e.g. outsourcing); (3) "relocating," that is, altering the (physical, cultural and institutional) location of units currently

⁸ Abott recently launched a German language iPhone app, DiabetesMapp, which allows patients to locate specialists nearby to manage a diverse range of diabetes-specific conditions, including diabetologists, psychotherapists, podiatrists, diabetes disease groups and more.

⁹ Kaplan, Greenfield, Gandek, Rogers, and Ware (1996) found that patients that engaged with the physician in a "participatory decision-making style" had improved health outcomes and were more satisfied. The study also showed that physicians with this kind of decision-making style were 30% less likely to have patient defection. In a different study based on patients with hypertension and breast cancer, they found that communication between patients and physicians affected the health status of patients. Notably, consultations where patients had engaged in prior information gathering, more information sharing between the patient and the physician, and more expression of emotion were all related to improved health outcomes (Kaplan et al., 1996).

performing activities (e.g. offshoring); and (4) “relinking,” that is, altering the linkages between the organizational units that perform these activities (e.g., an arms-length relation with a supplier becomes an alliance). This classification provides a highly convenient way to think about business model innovation, as such innovations may be understood as more or less radical changes in elements (1) to (4), either in only one of them (modular business model innovation) or in most or all of them (architectural business model innovation) (cf. Foss & Stieglitz, this volume). We rely on the Santos et al. classification in the following.

The pharmaceutical industry demonstrates various ongoing adjustments of or experimenting with existing business model ranging from changes that only involve one of the above reconfigurations, for example, an increase in the number of alliances with biotechnology firms (i.e., (2) above), to more radical changes that involve most of the above reconfigurations and which are clearly in the nature of distinct business model innovation. The data suggests a meaningful distinction between an incremental “traditionalist approach” (here exemplified by Novo Nordisk A/S), a full-blown “service-oriented approach” (UCB Pharma), and the in-between “simultaneous approach” (LEO Pharma A/S). We acknowledge that this taxonomy is neither fully exhaustive (there may be other business model and associated business model innovations), nor fully exclusive (the three business models may be partly overlapping for certain companies). Indeed, one of them, namely the simultaneous arguably represents a transitional form. Nevertheless, the three approaches represent useful ideal types that adequately represent many of the important players.

The Traditionalist Approach: Leveraging Extant Capabilities

Companies that pursue this model are not necessarily traditionalists in the sense that they stick to the block buster model. Rather, they are traditionalist in the sense that they seek to leverage all of the traditional capabilities of pharmaceutical companies to a more or less incremental change of the basic business proposition. Thus, some traditionalists leverage existing capabilities in the context of “targeted medicine,” that is, targeting drugs towards well-defined populations where “pharmacogenomics” suggests that the relevant drugs have maximum beneficial impact. Most traditionalists continue the classic “one size fits all” approach, that is, the target drugs to a mass market rather than a smaller target population. Many traditionalists are changing firm boundaries, both upstream and downstream. Thus, they are engage in partnerships across the entire life cycle of a drug, from precompetitive collaboration related to elucidating targets all the way to commercialization. They build more and deeper ties to universities to identify new treatments. Such a strategy may be complemented by buying smaller innovative firms and/or engaging in licensing agreements in order to get the production of the relevant drug in-house.

This incremental approach to business model innovation may be exemplified by the case of Novo Nordisk A/S (Novo Nordisk). The origins of Novo Nordisk started with the two small Danish companies Nordisk Insulinlaboratorium and Novo Terapeutisk Laboratorium, founded in 1923 and 1925, respectively. Today, Novo Nordisk is global health care company with nearly a century of innovation and leadership in diabetes care; it also has strong positions within haemophilia care, growth hormone therapy and hormone replacement therapy. The company is headquartered in Denmark, employs approximately 36,300 employees in 75 countries, and markets its products in more than 180 countries. In the following we briefly describe recent changes to the Novo Nordisk business model, relying on the Santos et al. (this volume) classification of business model changes.

Reactivating. In 2007, Novo Nordisk discontinued its small molecule business to focus on biopharmaceutical research and its protein-based pharmaceuticals. “Our core competences lie within therapeutic proteins, and it is within this area we can make the greatest difference in terms of patient outcomes and company growth,” said Mads Krogsgaard Thomsen, Chief Science Officer of Novo Nordisk. In 2011, Novo Nordisk has launched a bottom-of-the-pyramid (Prahalad, 2006) business model in Kenya, a country in which 250,000 people are in need of insulin, but where 80,000 of those in need have an annual income of only between 1,500 and 3,000 US dollars. To make insulin more affordable and accessible to this segment, the new model has lowered price-markups in the supply chain to the extent that insulin can be obtained at 20 cents daily, equivalent to a third of the previous price.¹⁰

Relinking. The DAWNTM study was initiated by Novo Nordisk in a partnership with the International Diabetes Federation and an international advisory panel of leading diabetes experts and patient advocates in 2001. The study was undertaken in response to the fact that despite the availability of effective therapies, less than half of individuals with diabetes were achieving adequate glycaemic control. The partnering organizations and experts recognized that new global as well as national knowledge was direly needed. This required taking a 360 degrees view, to explore the barriers inhibiting more effective delivery of diabetes care and continuous support to those in need. During that time there were no equivalent global studies, stressing the importance of non-medical attitudinal and psychological aspects of diabetes management in multiple countries.

Relocating. As a part of Novo Nordisk’s R&D internationalization strategy, the company established a R&D centre in Beijing as a wholly-owned subsidiary in 2001. They considered the

¹⁰ Like many other pharmaceutical companies, Novo Nordisk is offering a patient support program, though only in its US market. Their so-called Cornerstone4careTM patient assistance program is specifically targeted at patients that have household income below the federal poverty level.

centre to be a bridge between the scientific communities in Europe and China, and being located in the Chinese market solidified an important milestone for their future competitive position. Another reason was to provide support to existing activities, and to ensure the goodwill of the Chinese government in the future (Boel, 2007).

The Service Oriented Business Model

The full-blown service-based business model involves several radical reconfigurations relative to the traditional pharmaceutical business model. Companies that belong to this category aim at expanding the value proposition offered to customers by providing, notably, patient support services. To implement the new value proposition(s), new business models are developed which include the identification and development of new capabilities and/or redeployment of capabilities in new ways. In addition, these companies also look for new external partners that can help generate new ideas and facilitate access to the end-users.

Union Chimique Belge (UCB) illustrates these reconfigurations. UCB was founded in 1928 and headquartered in Brussels, Belgium, UCB is a patient-centric global biopharmaceutical leader (notably in epilepsy) focusing on severe diseases in two therapeutic areas, namely central nervous system and immunology.¹¹ Here are the main elements of the company's reconfigurations towards a patient-centric business model:

Reactivating. In recent years, UCB has added a range of different (online and offline-based) patient support programmes (e.g. Crohn's and MeTM, Parkinson's Well-being MapTM, etc.) to assist patients understand their condition better, and guide them to better cope and manage their disease. As the Head of HR in Europe explains: "Typically physicians are only looking at the physical symptoms related to a disease. For example, in epilepsy, physicians are primarily concerned with the number of seizures per week. But the patient demands more; s/he is not just seizure machine—s/he is a human being. So together with patients we developed an online multi-dimensional well-being map addressing concerns such as quality of life, stigma and sexual activity—things that physicians tend to neglect." It should also be mentioned that all the patient support programmes are provided for free with equal access to any patient.

Relinking. Over the past five years, UCB has increasingly been active in seeking new partnerships with various stakeholders in the industry, notably with health care payers. Recently, NICE reversed a previous decision and has accepted certolizumab pegol (Cimizia®) for the treatment of Rheumatoid Arthritis after UCB offered a risk-sharing agreement with the Department of Health in the UK. Specifically, UCB agreed to provide the first 12 weeks of Cimizia® (10 pre-

¹¹ The company had revenues of € 3.4 billion in 2012, operations in approximately 40 countries worldwide, 9,000 employees, and is listed on the Euronext Brussels Stock Exchange.

loaded 200-mg syringes) free of charge to all patients beginning treatment. Initially, Cimizia® did not receive a positive reimbursement because it was determined that it did not achieve a significant degree of cost-effectiveness. Even more radically, UCB has initiated partnerships with non-traditional stakeholders such as IBM and PatientsLikeMe.

Repartitioning. Traditionally, UCB's market research was primarily performed in-house. However, the ability to get access and collect information and data about patients plays an increasingly important role: First, it is instrumental to develop and deliver patient-centered solutions; and second, payers are increasingly demanding patient-reported outcomes during their reimbursement. However, as explained by the Vice President & Head of Europe HR: "While data-mining is clearly important, it is not really within our core competencies, companies such as IBM and PatientsLikeMe are better suited for that tasks which is why we have partnered with them. Rather, based on our strong disease understanding it is up to us make sense of all the data and subsequently convert it into solutions for patients."

The Simultaneous Approach: Ambidextrous Business Model Innovation

This approach constitutes a middle ground between the two extremes (i.e. the traditionalist and the full-blown service model). Companies pursuing the simultaneous approach maintain their incumbent business model, while at the same time pursuing business model innovation, a kind of "ambidextrous" approach (Markides, 2013). From a managerial perspective this involves the challenge that adding a new business model necessitates different and potentially incompatible value-chain activities and supporting organizational designs from the ones that the company has in place for its incumbent model. LEO Pharma A/S (LEO) illustrates the simultaneous approach.

LEO is a stand-alone, research-based pharmaceutical company founded in 1908 in Denmark. The firm develops, manufactures and markets pharmaceutical drugs to dermatologic and thrombotic patients in more than 100 countries globally.¹² In late 2011, LEO began development of its first truly patient support service, namely QualityCare™. In 2012, COLUMBUS was launched as a company-wide project explicitly aimed at business model experimentation; 29 pilot projects ("pilots") were set up in a number of subsidiaries.

Reactivating. In 2013, LEO became a service provider by adding QualityCare™ (an online platform) to its incumbent business model. Currently, QualityCare™ consists of two global frameworks, one for psoriasis and one for actinic keratosis. Through the combination of a customized web page, SMS's, emails and nurse calls, patients enrolling into QualityCare™ receive

¹² LEO Pharma has its own sales forces in 59 countries and employs more than 3,900 employees worldwide, with an annual turnover of approximately 1,072 billion Euro. The company headquarters are in Denmark. The company is wholly owned by the private and independent LEO Foundation.

information and support about their condition. The aim is to improve the overall treatment outcomes by improving the experience patients receive. One of the COLUMBUS pilots also intends to improve customer experience by providing a direct-to-patient delivery model. Through an alliance with the Dutch Thuis Apotheek, LEO products are delivered directly to patients' households, who, in turn experience greater convenience.

Relinking. Although LEO had an in-house Digital department, they used market transactions with respect to QualityCareTM. First, LEO lacked the technical capabilities to develop such a platform. Second, due to legal ramifications, LEO had to have a third-party vendor that could collect and store the individual patient data. For that reason, LEO initiated a long-term partnership with Vertic, a strategic digital agency specialized in advanced digital solutions, in 2011.

Repartitioning. While in the past, most strategic thinking with respect to innovation occurred in LEO's headquarter, COLUMBUS is an attempt to move innovation closer to the market. Hence, each pilot is led by a business model innovation or patient engagement manager from the respective subsidiary or region rather than someone from headquarter. Relatedly, to co-develop with patients, LEO initiated the "Psoriasis Frontiers" project in collaboration with the National Psoriasis Foundation (patient organization) in the US. In particular, a survey is distributed to the members of the patient organization and based on the survey responses LEO select participants for a full-day workshop. The aim is to identify specific lead users (i.e. creative individuals with strong needs). During the workshop, LEO provides the lead users with an opportunity to express their ideas and concerns related to their life as a psoriatic patient. These workshops have already been fruitful. Following the first three workshops, two concrete projects have started in new product development based on user-generated ideas.

ORGANIZATIONAL CHALLENGES OF BUSINESS MODEL INNOVATION IN THE PHARMACEUTICAL INDUSTRY

While there is a general understanding among business model scholars that business models need to be aligned with the firm's overall corporate strategy (Casadesus-Masanell & Ricart, 2010), little research has investigated how firms can realign their existing organizational design to facilitate business model innovation and what are the organizational design ramifications of such innovation. We argue that the changing business models in the pharmaceutical industry call for important changes in the organizational design of these firms. Traditionally, firms in the pharmaceutical industry have been organized along strict functional lines, so that each stage in the value chain from initial idea conception to eventual (and much later) marketing of a drug is associated with a distinct organizational unit. This is an organizational design that is geared to facilitate an emphasis on scale and throughput in the production of products. However, changing value propositions towards a

higher service-content and restructuring value chains towards more partnerships with external parties call for different, typically more project-based organizations with new roles, task structures, KPIs and so on. Overall, the changing business models in the industry call for organizational structures that lie closer to the matrix form than to the functional form.

Internal Organization

One of the few contributions to the literature that explicitly link business model innovation and organizational design is O'Reilly and Tushman (2004). They argue that firms tend to structure BMI in one of four basic ways, depending on how radical the BMI is: (1) In the *functional design* structure, BMI activities are completely integrated into the regular organizational and management structure; (2) the *cross-functional tea*, still operates within the established organization but outside the existing management hierarchy; (3) *the unsupported team* is a new unit set up outside the established organization and management hierarchy; and (4) in *ambidextrous organizations* efforts are organized as structurally independent units, each having its own processes, structures and cultures yet integrated into the existing top management hierarchy.

In general, all three companies have moved away from purely functionally oriented structures towards more project-based organizations. UCB's introduction of its "patient solution teams"—called so to stress that the aim is to provide solutions that go beyond the drug—provides an example. Being team-based, the new organization facilitates the speeding bringing-together and integration of different bodies of knowledge (in particular, UCB wanted to promote integration of marketing and R&D) so that complex patient needs can be addressed in potentially novel ways. The solution teams were headed by a Vice President and allowed to self-organize. As a result, twelve autonomous units were set up, each with their own processes to fulfill their new patient missions—resembling the organizational flexibility and entrepreneurial spirit embodied in the design of the ambidextrous organization

Novo Nordisk also seeks a stronger alignment of R&D with marketing. However, the internal organization differs in several respects from the ambidextrous organization of UCB. Novo Nordisk is more focused on exploiting its existing capabilities in developing and commercializing new drugs, rather than developing new services that address more diverse patient needs. This is in line with the traditional value proposition, and for that reason the functional design structure suffices for Novo Nordisk. That is, when new projects are initiated, they often go through the same sequence of stages and are assessed using existing criteria. Although employees may work cross-functionally in such projects, they do so only for a limited period and they still have to carry out their given functional tasks. Overall, Novo Nordisk's approach to its business model is one that emphasizes changing the

model in a highly incremental manner by fine-tuning existing elements of the model and the underlying activities, such as sales, market access, disease understanding and life-cycle management.

In contrast, LEO has yet to implement a formal organization that exhibits an integrated approach to drug development, but a version of Cooper's (1990) stage-gate model is currently being developed to mitigate this issue (interview with Director of Scientific Affairs, LEO). Much like UCB, LEO strives to be a solution provider with products and services co-developed and fitted individually for customers. A new department, Global Patient Engagement (GPE), supports this strategic reorientation. GPE is tasked with extending the incumbent business model to include a service dimension, and in general act as an active and credible integrator of business model innovation activities across the organization. To some extent, this resonates with the unsupported team structure in the sense that GPE performs a range of new value chain activities (e.g., the development and implementation of an Internet-based patient support service) that lie outside the scope of the established organization. In addition, because of its explorative purpose, GPE has more autonomy than existing departments. Of the three cases we studied for the research in this chapter, LEO is the only company that has a dedicated department with an explicit focus on business model innovation. A reason may be that LEO's incumbent model is less successful relative to the other companies in terms of profitability, hence the more explicit focus on business model innovation.

Changing Task Environments: Coordination Requirements and Resource Needs

Business model innovation usually involves addressing new task environments. Turbulent environments tend to force companies to make substantial changes to their internal task structures (Tushman, 1979). Nevertheless, despite the significant changes in the industry, Novo Nordisk has only made minor changes (e.g. the greater integration between R&D and marketing) to their internal task structure (relative to LEO and UCB). Indeed, because Novo Nordisk fundamentally sticks to its existing business model, its activities involve routine tasks that are managed through supervisory control, reliance on formalization, and centralized communication as opposed to UCB's autonomous patient solution teams. Rather, Novo Nordisk augments its business model by strengthening the company's already strong capabilities within their key functional areas.

LEO's decision to extend its current value proposition to also include services has resulted in a range of non-routine tasks. For example, the development and subsequent launch of QualityCareTM in the subsidiaries were not a routine task. Explains the Director of Global Patient Engagement: "Initially, we very much influenced and limited by our product-centric routines and constantly insisted on applying the same strict processes, principles and tactics that pharmaceuticals go through." In addition, initially QualityCareTM was not included in LEO's short-and mid-term business plans, which made it difficult to get the proper prioritization and resource commitments

from the subsidiaries. As a senior manager in Global Patient Engagement explained: “Basically, some [subsidiaries] did not make any kind of market preparation prior to launch, in a sense, they expected that corporate would just implement the service.” As this suggests, the simultaneous approach to BMI in LEO has given rise to substantial coordination issues.

Although UCB’s incumbent business model had been quite successful in recent years, top management felt that UCB should be more proactive to changes in the external environment; hence, the introduction of the patient solution team structure. An interesting aspect of this structure is that an explicit logic of complementarity was present in the development of the teams. As a Senior Vice President noted: “Market access will play a pivotal role due to the health transaction technology assessments. Companies need to get ready for innovation—not only from product and regulatory approval perspective but also how they get their products reimbursed.” This implied that over the course of six months a significant part of the organization was structured around twelve patient solution teams that consisted of people from the most crucial functions such as market, access, R&D, regulatory affairs etc. in an attempt—to ultimately speed the time to market and (perhaps more importantly) address emerging needs from patients, payers and physicians. Overall, even though this was a radically different way of structuring (e.g. new tasks, reporting lines, goals and relations among people)—UCB was able to limit coordination costs by “getting the complementarities right.”

Changing Human Capital Portfolios

Business model innovation often entails building new assets or combining existing one in new ways. This may involve specific investments and individual and organizational learning processes.¹³ It may also entail building new human resource portfolios by means of hiring and training.

LEO is actively looking for new employee-based competences: “To prepare for the more systemic nature of the industry, we search for individuals with hybrid profiles—preferably with knowledge in science, strategy, economics and marketing as well as experience from the fast-moving-consumer industry and services” (Senior Director in Leo). Furthermore, the establishment of GPE has created two new types of job positions, namely, the roles of business model innovation and patient engagement manager. Initially, these positions were only found in GPE, but lately there has been a steadily increase in patient engagement and business model innovation managers at the regional and subsidiary level.

¹³ As Winter (2000: 984) states: “... to create a significant new capability, an organization must typically make a set of specific and highly complementary investments in tangible assets, in process development, and in the establishment of relationships that cross the boundaries of the organizational unit in which the process is deemed to reside.”

Similarly to LEO, UCB is looking for generalists with capabilities of working cross-functionally and with a taste for the web, social media and customer relationship management, because of the importance of this to connecting to patients. Further, devices and diagnostic play an integral part in UCB's mission to become a patient solution provider; hence people with skills in these areas are also desired. Perhaps more importantly, UCB is aggressively recruiting for candidates that are savvy in the payer negotiation dimension (interview with the UCB Vice President & HR of Europe).

Novo Nordisk, (perhaps to a larger degree) has taken several steps to upgrade their human capital, including the so-called STAR and graduate programmes. The former is targeted at PhDs and PostDocs, whereas the latter is intended for master students. Both programmes are very structured and designed to provide talents with firm-specific competencies.

Market access was highlighted several times during the interviews. In contrast, to the other marketing functions, market access functions are typically staffed with several people holding PhD degrees or equivalent qualifications. As argued by Eichler et al. (2010), while getting regulatory approval is still important, it is of little use to industry and patients when a drug is not reimbursed, since access to high-priced drugs will likely be precluded for most patients.

Organizational Practices

Business model innovation usually involves bringing new tasks inside the company, raising new coordination requirements that in turn demand new organizational practices that can address these requirements. UCB has made significant changes to their underlying organizational practices. Thus, decision rights have been delegated to the Vice Presidents, allowing them to create their own teams (by pulling in people from across the organization) and pursuing projects without interference from the executive committee. This reallocation of decision rights was explicitly to address the new challenge of creating and delivering patient-centered solutions, namely to move decisions to where the relevant knowledge and information reside (interview with Senior Vice President and President of Europe region, UCB).

However, to further strengthen the new value proposition and structure, UCB introduced a set of other complementing practices. First, the ability to source and process relevant patient data and then convert it into an insight (i.e., useful and meaningful piece of digested information) that can be incorporated into new services, products and activities required that UCB increased their internal communication (particularly along the lateral dimension) by installing Lync (an instant messaging service) and recently UCB Plaza (a new intranet platform). Second, to compensate for the lack of human capital that can work with patient solutions in a cross-domain context, the HR department

conducts regular organizational reviews. Based on that, they rotate talents to other positions within the company, where they can have a more significant business impact.

In contrast, LEO has made less of an emphasis with respect to developing and diffusing organizational practices that reflect its new strategic orientation and underlying structure. Similarly, to UCB's Plaza, LEO has introduced an intranet-platform ("Pulse") with the aim of improving internal knowledge sharing that, however, has proven difficult. In particular, because LEO has yet to develop a culture that leverages intranet communication software. Rather, knowledge sharing is primarily sought by means of informal communication and meetings.. As an additional knowledge sharing practice, LEO's GPE have arranged a range of global workshops for employees involved in BMI. These have been quite useful in exploiting synergies among the business model pilots. In addition, recently GPE introduced the concept of "Elite project" to refine some of the more promising business model pilots and in general speed up the pilot phase. Such projects received their own coach from top management and were entitled to longer visits from GPE (wherein expert knowledge about BMI reside). In conjunction with the launch of QualityCare™, GPE developed a launch excellence tool for the subsidiaries—reflecting the (generic) steps and challenges associated with the implementation of an Internet-based platform.

Not surprisingly, Novo Nordisk has not introduced any new organizational practice to accommodate business model innovation, since the company refines rather than innovates its existing business model. Novo Nordisk probably has the most strongly institutionalized practices, as reflected in the codification of these practice in the so-called "Novo Nordisk Way," that is, ten statements describing the core practices of Novo Nordisk.¹⁴ To ensure the widespread use and adherence to these guiding practices, Novo Nordisk conducts so-called "value audits." Senior employees are selected as "facilitators" and they travel the organization to interview employees, managers and internal stakeholders of the units, looking into documents and local business practices. Based on that, an assessment is conducted assessing the degree to which the unit operated its business in accordance with "Novo Nordisk Way," areas for improvement are highlighted, and best practices that can potentially be shared across the organization are identified (interview with Corporate vice president, Novo Nordisk).

Performance Measurement Systems

¹⁴ The ten Novo Nordisk commandments are as follows: "1) We create value by having a patient centred business approach 2) We set ambitious goals and strive for excellence 3) We are accountable for our financial, environmental and social performance 4) We provide information to the benefit of our stakeholders 6) We treat everyone with respect 7) We focus on personal performance development 8) We have healthy and engaging working environment 9) We optimize the way we work and strive for simplicity 10) We never compromise on quality and business ethics"; see http://www.novonordisk.com/about_us/novo_nordisk_way/nnway_essentials.asp; accessed: 27-11-2013.

The implementation of a BMI requires alignment between organizational elements. Performance measurement systems play a pivotal role in this regard because they help to formulate, communicate and implement BMI across the organization. Specifically, they are used to control and influence behavior in the organization and guide the strategic reorientation process (Wouters, 2009). Overall, none of the companies seem to have completely abandoned the performance management systems traditionally associated with pharmaceutical companies. Hence, measurement related to, for example, sales, time to market and physician visits are still prevalent in each company. Since the majority of revenues still come from traditional drug sales, this is hardly surprising. Nevertheless, LEO has incorporated a few new key performance indicators (KPIs) into their existing systems. These are used to keep project leaders accountable. For example, GPE tracks the stages of all business model pilots including the number of pilots in preparation, progress, on hold/discontinued and implemented into daily business. Furthermore, the QualityCare™ platform has a number of inbuilt KPIs, such as customer satisfaction linked to the various services it provides and number of enrolled patient. In addition, the platform also tracks the quality of life through the dermatology life quality index (DLQI).¹⁵ Finally, GPE also measure the number of failed business model pilots versus successful pilots and the diffusion of successful pilots to other subsidiaries.

Novo Nordisk has recently defined new strategic company goals that stress the importance of new markets (especially developing countries). To support the emerging bottom of the pyramid strategy two new indicators measure (1) the number of least developed countries where Novo Nordisk operates, and (2) the number of least developed countries which have chosen to buy insulin under the best possible pricing scheme. Whereas the former is a proxy of access to essential medicines, the latter addresses the affordability of essential medicines. A number of indicators have also been set up to emphasize the importance of the “Novo Nordisk Way.” The first measures the average of respondents’ answers as to whether social and environmental issues are important for the future of the company. A second measure captures the average of respondents’ answers as to whether their manager’s behavior is consistent with Novo Nordisk values. A third one measures the percentage of fulfillment of action points planned arising from “Value audits” of the “Novo Nordisk Way” of management and values.

In contrast to LEO and Novo Nordisk, top management in UCB is more skeptical about furnishing their new internal organization with a range of new KPIs. As a Senior Vice President expressed: “During the inception of the patient solution teams, we discussed the appropriateness of

¹⁵ The DLQI was developed in 1994 and it was the first dermatology-specific quality of life instrument. It is a simple 10-question validated questionnaire that has been used in over 40 different skin conditions in over 80 countries and is available in over 90 languages. <http://www.dermatology.org.uk/quality/dlqi/quality-dlqi.html> accessed: 27-11-2013.

new KPIs. However, the conclusion was that KPIs tend to become a tick box exercise without adding much value.” Relatedly, it would not make sense to impose very rigid KPIs, as they would possibly interfere with the autonomous nature of the teams. Rather, teams that actually succeed in fulfilling a specific patient mission through the process of translating patient insights into a final solution are considered to be a proper indication of solid performance (Interview with Vice President and HR of Europe, UCB). Nevertheless, to ensure that resources were congruent with the new business model, subsidiaries had to submit regularly reports about their budget allocation. The target explicitly stated that at least 30% of the budget must be allocated to non-traditional marketing activities.

Drivers and Facilitators of Organizational Changes

There is general agreement among scholars and practitioners that change processes are complex and challenging for organization engaged in such initiatives. Change drivers, including culture, vision, leadership and communication have been argued to facilitate organizational change process (e.g., Whelan-Berry, Gordon, & Hinings, 2003). In all three companies, several of the key informants noted that the external environment had changed substantially in the past decade and, as such, partly explains the surge in BMI activity. Similarly, leadership and notably the appointment of a new CEO appeared to prompt organizational change in all three cases.

Novo Nordisk was one of the first companies in the industry to address patient-centricity. Following his appointment as CEO of Novo Nordisk in 2000, Lars Rebien initiated a number of important changes.¹⁶ Traditionally, the physician had been the customer, but Novo Nordisk decided that the user of their products should be the primary customer. A program was initiated that it made it mandatory for all Novo employees to meet a diabetic patient. In 2007, Novo Nordisk discontinued its small molecule business in an effort to focus on biopharmaceutical research and its protein-based pharmaceuticals. “Our core competences lie within therapeutic proteins, and it is within this area we can make the greatest difference in terms of patient outcomes and company growth,” said Mads Krogsgaard Thomsen, Chief Scientific Officer of Novo Nordisk.

In 2003, Roch Doliveux joined UCB and was appointed CEO in 2005. This initiated a period of many, far-reaching change initiatives. Like Lars Rebien, Roch Doliveux was also a strong believer in patient-centricity. As noted by the Vice President of New Patient Solutions and Alliance and Portfolio Management, UCB: “Roch was the first person to start bringing patients to our management meetings.” A new vision was conceived, making patient centricity center stage. In 2006, UCB turned into a biopharmaceutical company by acquiring Schwarz Pharma, the largest acquisition in UCB’s history. In 2009, UCB made 2,400 positions redundant—almost 20% of its

¹⁶ Prior to his appointment, he had led the divestment of Novo Nordisk’s enzyme business (today Novozymes A/S).

total workforce. This was the so-called SHAPE project, intended to focus on its core assets (notably within Central Nervous System), redeploy resources, advance R&D and simplify its organization. In 2010, UCB replaced ONE UCB with SHARED UCB, an initiative aimed at changing the identity of the company, promoting values such as diversity, connectivity and co-creation.

In 2011, senior management assembled the “New Journey board”, consisting of the eight most talented individuals from across the organization. Their role was two-fold: first, they had a year to explore the dynamics of the industry and how it may look like in 2020, and more importantly, what are the implications for UCB. Second, they served as change agents promoting the new values. These initiatives were part of a greater plan, namely to prepare the company for a fundamental structural change, which was the birth of the patient solution teams in 2012. As the Vice President and HR of Europe, UCB argued: “It is likely that sub-cultures will emerge in very autonomous units such as the patient solution teams, which in turn may stifle knowledge sharing among them. We believed that these initiatives would be able to counterbalance some of the issues derived from such a new structure.”

In 2008, Gitte Pugholm Aabo took over as CEO in LEO. A new vision was enacted to focus efforts on dermatology. This was followed by a new growth strategy, called “Going for Gold.” This implied change for the hitherto conservative company. In 2009, LEO acquired Peplin inc for 287,5 million US dollars. Although this was a small acquisition relative other acquisitions in the industry, it was the largest in company history. “Going for Gold” followed the bandwagon by stating that LEO should become a patient centric company. To implement that change, the “Growing LEO leaders program” was launched in late 2011, aimed at infusing 450 leaders with new values and concepts (e.g. agile, active learning and business models) to help reshaping the organizational culture into a truly global, patient-centric enterprise. Shortly after, GPE was created with the purpose of developing new patient support services and provide the ground for BMI.

While all three companies seem to adopt similar change drivers (e.g. leadership, vision and culture) in their efforts to prompt and facilitate changes or adjustments of their business models, the nature and number of facilitators differ widely. For example, while some of Novo Nordisk and UCB’s initiatives (e.g. “The Novo Nordisk Way” and “Shared UCB”) have been implemented across the whole organization, LEO’s leadership program was solely directed at 450 individuals. Perhaps not surprising given the subsequent changes to UCB’s internal organization, UCB has adopted more facilitating drivers relative to the other companies.

Lack of Fit in the Changing Business Models in the Pharmaceutical Industry?

As is evident from the previous sections, a number of different change facilitators (ranging from new structures to new organizational identity) have been implemented to support the various

types of BMI. However, as Zenger (2002, p. 80) notes, managers often “...overlay new measures on existing, functionally-oriented structures; they implement new structures without new performance measures and without new pay systems; they implement new pay systems, but fail to restructure or develop new performance measures.”

Although UCB made the most fundamental changes to its business model and underlying organization, they were not able to achieve perfect internal fit among choices with respect to activities, organization structure and practices. As the Vice President and HR of Europe, UCB notes: “Typically we experience an after chock after such a fundamental change; some people does not fit the new model; others are not happy with their new tasks and responsibilities; and some of the interfaces are not perfectly aligned. Nevertheless, when we change things in UCB we do it fast. The price we pay for that is that we do not achieve perfection the first time.” For example, the increased delegation in the patient solution teams was not accompanied with new incentives or performance measures to reflect the peculiarities of their new tasks.

Similarly, LEO experienced a number of internal fit inconsistencies. Although there has been a surge in the number of BMI managers, these managers has a dual role in the sense that they still have to carry out activities associated with the incumbent model; and since they are still formally held accountable for short-term sales targets, some of them tend to down-prioritize their business model pilots. This issue is further exacerbated by the fact that, while COLUMBUS is regarded as a key priority, it has yet to be incorporated into the company’s annual business plan (interview with Senior Business Model Innovation Manager, GPE). Similarly to UCB, LEO has not made any efforts to change its current incentive system. “I strongly believe incentives could play an important role in changing certain behaviors in the organization. However, it is a very delicate matter and should be used with caution”, said the Director of GPE, LEO. In contrast to UCB and Novo Nordisk, most of LEO’s BMI facilitators are not formalized or institutionalized across the organization, implying that some subsidiaries put more effort and resources into BMI than others. Not surprisingly, these are typically the ones that have most informal interaction with GPE. Relatedly, a recent survey among employees affiliated with COLUMBUS showed that BMI has not been sufficiently implemented in LEO.

Given Novo Nordisk’s more incremental approach to BMI, they have not suffered the same degree of internal inconsistencies compared to LEO and UCB. Although changes have been made to its incumbent model, these have not significantly violated the internal fit among existing activities, policies, capabilities etc. Rather, these changes aimed at creating a tighter fit to further exploit the success of its incumbent model. However, once Novo Nordisk’s incumbent model starts negating value it might be increasingly difficult to facilitate change due to the tight coupling. As Levinthal

(1997, p. 936) asserts: “Firms may have a difficulty navigating a changing environment not only because the changes in the environment negate the value of the organization’s assets, but also because a tightly coupled organization may have difficulty adapting to such changes.”

CONCLUSION

We have argued that a number of deep-seated drivers rooted mainly in internationalization, regulatory forces, payer pressure, increased competition from generics producers, and changing technological opportunities are shaking up the pharmaceutical industry, a tendency that has been visible for more than a decade (cf. Gilbert, Henske & Singh, 2003). The result is a decline in the importance of the traditional blockbuster business model, and an ongoing quest to discover the new profitable model(s).

This chapter has identified three ideal types that exhibit different degrees of business model innovation, primarily with respect to changing value propositions towards a higher service-content and restructuring value chains towards new activities and external partnerships. This was done in an attempt to examine the organizational design choices accompanied by such models as well as some of the liabilities of such choices. In particular, the focus has been on changes in the internal organization and its underlying task structure. A main finding was the move towards organizational structures that lie closer to the matrix form than to the functional form. UCB’s “patient solution teams” was the most extreme case—providing the organizational flexibility and entrepreneurial spirit embodied in the design of the ambidextrous organization. In contrast, Novo Nordisk is more concerned with exploiting existing capabilities to drive the traditional value proposition, and for that reason relies on the functional design structure. In between, we find LEO who has dedicated a new department (GPE) tasked with increasing the service-content and experiment with new business models—resembling the unsupported team structure in the sense that GPE performs a range of new value chain activities in parallel with the existing business.

The call for new structures was partly driven by the changing task environment, particularly in the cases of LEO and UCB which expanded their value propositions towards services. The development and launch of LEO’s patient support service QualityCareTM involved a number of non-routine tasks, which gave rise to coordination issues between the new value chain activities and the existing product-centric routines. UCB was able to mitigate these issues by swiftly structuring a significant part of the organization around the “patient solution teams” and thereby limiting coordination costs by “getting the complementarities right.” Unlike the other companies, Novo Nordisk did not encounter any notable coordination issues because they fundamentally stick to their incumbent business model.

Relatedly, the different types of business model innovation and their accompanying organizational structures were followed by adjustment and/or renewal in other areas. A recurring theme was need for new human capital to either augment the incumbent model or drive more radical business model experimentation. To address the new non-routine tasks a number of organizational practices were installed (such as reallocation of decision rights, lateral communication, workshops) to ease the new coordination requirements. Similarly, new performance measurement systems and KPIs were also set up to support the firms' (though to varying degrees) new strategic reorientations.

A number of drivers prompted the desire or need for change and facilitated the subsequent implementation of the firms' new business models. In particular, the appointment of a new CEO appeared to spark organizational change in all three cases. This was followed by new visions and strategies in the companies to drive the change. Perhaps more importantly, a range of different initiatives (e.g., "Shared UCB," "The Novo Nordisk Way" and "Growing LEO Leaders") were initiated in the three firms to implement change across the organization (though to a larger degree in UCB and Novo Nordisk). Of the three companies, UCB adopted more facilitating drivers than the other companies, which is not surprising given the fundamental change to its internal organization.

The three ideal types also gave rise to an increasing misfit between the traditional organization and the emerging organization dictated by the new models. Another main finding was the problem with internal fit inconsistencies, namely that managers overlay or introduce new practices and measures (in parallel with) on existing, functionally-oriented structures (cf. Zenger, 2002). This was evident in all three cases, though to a much lesser degree in Novo Nordisk. For example, while UCB made the most far-reaching changes to its business model and organization, they more or less kept the traditional incentives and performance measures intact—not reflecting the peculiarities of their new service-based model. Selecting a new business model is complex already, but when one considers all the elements of organization required to implement a new model, the problem becomes mindboggling complicated. However, if pharmaceutical companies are to succeed in innovating their incumbent models (especially in cases of radical change), the organizational context should be changed respectively in accordance with the new business model in order to realize complementarities and limit coordination costs.

Despite the smallness of our sample, we believe that the three ideal types are, at least to some extent, generalizable to other pharmaceutical companies. Companies such as Janssen Pharmaceuticals, Eli Lilly, Abbott, Pfizer and many more have expanded their value propositions to include different patient support services. GlaxoSmithKline (GSK) restructured its R&D administrative system by the introduction of Centers of Excellence in Drug Discovery (CEDD). Similarly to UCB's patient solution teams, "each CEDD had its own leader and management team,

and possessed most of the functions required to move a molecule from discovery to proof of concept” (Pisano, 2012: 6). Several companies (e.g. Sanofi, GSK and Pfizer) are also exploiting existing capabilities with respect to rare diseases. Because these so-called orphan drugs tend to enjoy premium prices, reduced marketing costs, increased reimbursement, longer exclusivity, small clinical trials and fast track approval procedures.

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