

Business Model Innovation The Role of Organizational Design

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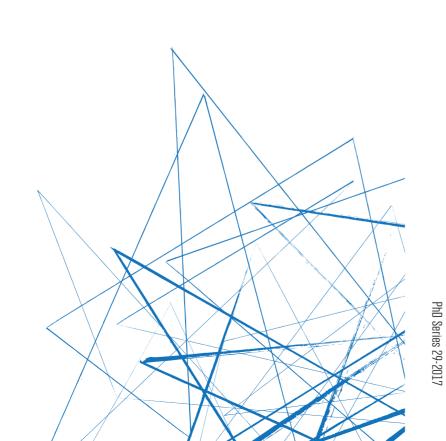
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Business Model Innovation

The Role of Organizational Design

A PhD thesis by:

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May 22, 2017

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Abstract

The topics of business model innovation (BMI) and organizational design have potentially important links. And yet, there has been little cross-fertilization of ideas between the two fields. The purpose of this thesis is to fill that gap by proposing and developing an organizational view of BMI that focuses on the missing links between business model innovation and organizational design theory. Guided by the research question—*what is the role of organizational design in the process of business model innovation?*—the thesis not only investigates how BMI activity unfolds, but also looks at the different roles of the firm's organizational design and where the activity takes place. Moreover, this research provides ample detail on how organizational complementarities emerge or vanish as a result of the fit or misfit between business model elements and design choices. To drive home these important points, I rely on insights from a multiple-case study of three pharmaceutical companies: Novo Nordisk, UCB and LEO Pharma.

Resumé

Emnerne for forretningsmodelinnovation (FMI) og organisationsdesign har potentielt vigtige forbindelser. Og dog har der kun været lidt krydsbefrugtning af ideer mellem de to felter. Formålet med denne afhandling er at udfylde dette hul ved at foreslå og udvikle et organisatorisk syn på FMI, der fokuserer på de manglende forbindelser mellem forretningsmodelinnovation og teori om organisationsdesign. Styret af forskningsspørgsmålet—*hvilken rolle har organisationsdesign i processen med innovation af forretningsmodel?*—denne afhandling undersøger ikke kun, hvordan FMI-aktiviteter udfolder sig, men ser også på de forskellige roller for virksomhedens organisatoriske komplementariteter fremkommer eller forsvinder som følge af sammenhæng eller mangel på sammenhæng mellem forretningsmodelelementer og designvalg. Til belysning af disse vigtige punkter, anvender jeg indsigter fra en multipel case-undersøgelse af tre farmaceutiske virksomheder: Novo Nordisk, UCB og LEO Pharma.

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Abbreviations

BM	Business model
BMI	Business model innovation
cMWB	Corporate Must Win Battle
EMEA	European Medicines Agency
FDA	Food and Drug Administration
GP	General practitioner
GPE	Global Patient Engagement
НСР	Health care professional
ICT	Information and communication technology
KOL	Key opinion leader
M&A	Merger and acquisition
PST	Patient Solution Team
R&D	Research and development

Acknowledgements

This thesis is the outcome of an extensive and at times grueling journey, and yet it was also immensely fascinating and rewarding, from both an intellectual and human perspective. While all of the deficiencies in this work are my own (e.g., misinterpretations, errors or omissions, lack of consistency and clarity, etc.), it would be impossible to take full credit for the strengths and valuable aspects of this thesis. Numerous people have supported me along the journey toward finishing this thesis.

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1

The Need for an Organizational Design View of Business Model

Innovation

This thesis seeks to understand business model innovation (BMI) through the lens of organizational design theory. BMI can be defined as the reconfiguration of a firm's core business model elements and/or architecture by weaving these elements together into a system that will enable the firm to create and deliver value to its target segment(s) (Foss and Saebi, 2017; Santos, Spector, and Van der Heyden, 2009). Notions such as "configuration," "system," "model," and "architecture" are at the core of the BMI construct (Foss and Saebi, 2015). However, I would argue that scholars can benefit from additionally incorporating constructs related to organizational design, such as information processing (e.g., Simon, 1945; Thompson, 1967), contingency and fit (e.g., Lawrence and Lorsch, 1967), organizational structure (e.g., Child, 1972), complementarities (e.g., Milgrom and Roberts, 1990) and interdependence (Aiken and Hage, 1968), into the BMI concept. This is because the designable parts of an organization serve as levers that managers can pull to reorient the strategic direction of the organization by, for example, defining new work roles and responsibilities, changing communication flows and channels, or introducing new rules and targets, or other elements of planning. Since the ability to change an incumbent business model (BM) usually involve changes along these dimensions, the firm's organizational design is likely to influence the quality, type, extent and degree of BMI that it achieves. In other words, the literature on BMI and the theory of organizational design should be considered in tandem. And yet, in spite of the apparent linkages between these two bodies of literature, such a connection has not received sufficient scholarly attention. This gap provides the basic motivation for this thesis.

How, then, might BMI and organizational design be related? Do managers need to redesign their organizations in order to drive and implement BMI? Or, does BMI lead to new organizational designs? And if organizational design plays a role in the process of BMI, what is that role, exactly? Where in the organization does BMI take place? How does organizational design influence which part of the BM gets innovated, and by whom? How does organizational design affect the characteristics and quality of BMI outcomes?

These questions are important to address because their answers can help elucidate the holistic nature of BMI. In contrast to more partial theoretical explanations such as the value chain (1985), the resource-based view (e.g., Barney, 1991), transaction cost economics (Williamson, 1975) and strategic network theory (Jarillo, 1995), the BMI construct not only explains the *what* (e.g., the fundamental value proposition(s) by which the firm can satisfy specific customer segments) and the *how* (e.g., the structure and processes required to realize the relevant value proposition at a profit), but also ensures integration between the two. The way in which this is achieved "can be highly firm-specific and may thus serve to differentiate the firm in the marketplace" (Foss and Saebi, 2015: 2).

An example. Through BMI, Southwest Airlines has managed to sustain company growth for three decades. Not surprisingly, several competitors (e.g., JetBlue, RyanAir, United Express) have attempted to copy Southwest's BM in whole or in part, but "none of these firms has achieved the level of success as Southwest, especially in head-to-head competition with the firm" (Morris, Schindehutte, and Allen, 2005: 732). Due to the firm specificity and underlying complexity that such innovations involve (Foss and Saebi, 2015), competitors have a hard time replicating them within their own organizational context, as opposed to, for example, copying a new product or a single process. This is the reason why the BMI phenomenon has attracted major scholarly interest in recent years. But it is also due to the holistic nature of BMI that the literature currently lacks the theoretical underpinnings and cumulative empirical base to fully explain the concept. For instance, Casadesus-Masanell and Zhu (2013: 480) note that BMI is "a slippery construct to study." Relatedly, Foss and Saebi (2017: 203) argue that the "literature does not possess clearly articulated research models that lay out the basic causal web-connecting antecedents, moderating, mediating variables with the key constructs and consequences."

However, by adopting an organizational design view, we might be able to provide the much needed theoretical basis to explain BMI. Taking the example of Southwest Airlines again, the firm's business model changes related to short haul, high frequency, point-to-point service; careful selection of airports; flights into uncongested airports; use of Boeing 737 aircraft; and differentiation are achieved by emphasizing on-time arrival, low fares, and a good passenger experience (Morris et al., 2005). To achieve this, top management made a number of organizational design choices (for a more detailed description see Gittell, 2003). First, they assigned significant decision-making authority to the frontline supervisors, enabling those supervisors to rapidly resolve day-to-day issues. Second, rather than hiring high performers or superstars, they made a deliberate effort to recruit people who excelled at working in teams. Third, so-called "boundary spanners" were brought in to improve coordination and knowledge sharing, as well as to build relationships across boundaries and provide flexibility. Fourth, new team-based performance measures were implemented to avoid "pointing the finger and blaming other departments" (Gittell, 2003: 5), and to improve learning. Finally, management introduced highly flexible job descriptions. Although "at Southwest everyone's job description [was] clear and specific, [...] there [was] an added requirement that each employee [was] expected to do whatever [was] needed to enhance the overall operation—even if that [meant] helping out with a different type of job as required (Gittell, 2003: 5). This reduced the status barriers between various job positions and helped foster stronger coworker relationships (Gittell, 2003). As this example illustrates, a firm's organizational design does play a significant role in coordinating BMI activities and supporting integration between the *what* and the how. Equally important, however, is the fact that organizational design belongs to a much more established field of research with relatively robust theoretical underpinnings and research foundations. As such, the field of organizational design offers a highly useful starting point upon which to ground research on BMI.

Practical applications of joining BMI and organizational design theory, yet with little contact made so far. An organizational design understanding can be highly valuable to practitioners and managers, because it could spell the difference between a successful and unsuccessful implementation of BMI. For example, such knowledge can help managers choose appropriate organizational design mechanisms for specific types of BMI, and understand how these mechanisms may act during different stages of the BMI process. In other words, an organizational

design view can help managers make more informed decisions about BMI. Moreover, BMI is often formulated and described in rather abstract terms. For example, Easyjet's owner Stelios Haji-Ioannou conceptualized the firm's business model (BM) as a fixed capacity, high fixed-cost service, with price-elastic demand (Doz and Kosonen, 2010). Similarly, Foss and Saebi (2015: 1) state that "business models are sometimes characterized as mental constructs—presumably mainly residing in the upper managerial echelons of a company." This level of abstraction has made increasingly difficult for managers to determine which action to take. However, by specifying new work tasks, responsibilities, budget allocations, rules and targets, BMI is made more concrete and attainable at the lower organizational levels. This is particularly important given the holistic and systemic features of such innovations-BMI does not, after all, solely occur in the upper echelons of organizations. Furthermore, as both organizational design theory and BMI deal with strategy implementation, innovation, and complementarities, one would expect an extensive crossfertilization between the two fields, simply because so many interesting and practical research possibilities emerge when we think of BMI in terms of concrete organizational design choices. And yet, aside from a few recent studies (e.g., Foss and Saebi, 2015; Foss and Saebi, 2017), there has been relatively little contact between the two fields. Although organizational design scholars have dedicated considerable attention to different innovation types (such as product, process, and organizational innovation) and dimensions (such as incremental, radical, modular and architectural innovations), they have ignored BMI. Research on BMI is still in its infancy and thus has not yet been fully integrated into the more established theories of strategic management. As a consequence, no serious theory or framework of the organizational design of BMI exists to guide academics and practitioners toward an enriched understanding of the kind of problems that intimately link the two phenomena.

What can each field learn from the other? A robust of theory BMI should attempt to specify the dimensions of the phenomenon, the (contextual) conditions under which it is more or less likely to occur, the manner in which it is manifest, and other related factors (e.g., strategy, structure and environment). In the contemporary BMI literature, BMI is usually conceptualized as an organizational change process that places heavy demands on top management's ability to lead change (e.g., Achtenhagen, Melin, and Naldi, 2013; Stieglitz and Foss, 2015) and develop new capabilities (e.g., Demil and Leccoq, 2010; Leih, Linden, and Teece, 2015) and learning processes

(e.g., Chanal and Caron-Fasan, 2010; McGrath, 2010; Cavalcante, 2014) in order to create and capture more value (e.g., Casadesus-Masanell and Zhu, 2013; Berglund and Sandström, 2013). However, as alluded to above, BMI is about much more than that. It is about designing a new architecture that specifies the functional relationships among the various BM elements and underlying organizational activities (Santos et al., 2009; Foss and Saebi, 2017) so as to promote a value-enhancing effect across a system of interdependent activities (i.e. complementarities).

A holistic view of BMI thus requires an understanding of the organizational design aspects of the BMI function. Similarly, I believe that organizational design theory can be improved by seriously considering the systemic characteristics of BMI. The concept of complementarity has become a bedrock proposition in the literature on organizational design, yet relatively little is known about the conditions under which complementarities takes place, or about the characteristics of the elements or factors among which complementarities exists (Rivkin and Siggelkow, 2003; Porter and Siggelkow, 2008; Ennen and Richter, 2009). While organizational design only deals with the designable elements of an organization, the BMI construct builds upon and extends central ideas from business strategy and its associated theoretical traditions (such as competitive strategy, value chain, the resource-based view, and network theory). Such a holistic approach may be better able to capture the systemic nature of the interrelationships between heterogeneous elements (e.g., strategy, BM, organizational structure, environment, etc.) that are likely to influence complementarities, rather than merely looking at the designable parts of organizations. In sum, the BMI literature and the theory of organizational design have much to gain from cross-fertilization. However, they must first be brought together. In the remainder of this chapter, I briefly map out the current research landscape in the BMI and organizational design fields, and further address the need for integration efforts between the two disciplines.

Research on BMI

During the last decade and a half, the BM construct has attracted substantial attention from both management scholars and practitioners (see Zott, Amit, and Massa (2011) for a comprehensive review of the literature). A BM outlines "the manner by which the enterprise delivers value to customers, entices customers to pay for value, and converts those payments to profit" (Teece, 2010: 172). In its orientation, it draws on and extends insights from the established corpus of strategic

management, including Porter's value chain, the resource-based view, and the transaction cost approach. It is presumably this ability to integrate diverse concepts and theories that has given rise to the construct's growing popularity and adoption. BM, then, is a holistic construct that not only defines "the structure of the interlocking activities associated with key strategic choices," but also the way in which the value chain is set up in order to "[realize] the relevant value proposition, and the mechanisms of value capture that the firm deploys, including its competitive strategy" (Foss and Saebi, 2015: 1).

Research on the BM construct has served a host of different purposes, providing, for example, (1) a classification scheme of firms (e.g., Timmer, 1998; Rappa; 2000; Amit and Zott, 2001; Osterwalder, Pigneur, and Tucci, 2005); (2) antecedents of heterogeneity in firm performance (e.g., Zott and Amit 2010; Weill, Malone, D'Urso, Herman, and Woerner, 2005); (3) a new vehicle *and* source of innovation (e.g., Teece, 2010; Markides, 2006), and (4) a way to integrate different theories (cf. George and Bock, 2011).

More recently, the notion of business model innovation has come into prominence as drivers such as globalization, deregulation and technological change have profoundly altered the environment of several industries and rendered more traditional types of innovation (e.g., product and process) less effective. Many scholars seem to agree on the strategic importance of BMI as a key driver of firm performance (cf. Chesbrough, 2010; Teece, 2010; Ho, Fang, and Hsieh, 2011; Zott and Amit, 2007) as well as a vehicle for organizational change and renewal (Demil and Lecocq, 2010; Ireland, Hitt, Camp, and Sexton, 2001; Johnson, Christensen, and Kagermann, 2008; Sosna, Trevinyo-Rodríguez, and Velamuri, 2010). BMI can also be used to cope with contingencies, both external (such as new entrants and changing regulations) and internal (such as organizational or managerial factors) (e.g., Casadesus-Masanell and Zhu 2013), and it "complements the traditional subjects of process, product, and organizational innovation" (Zott et al., 2011: 1032). Scholars seem to agree that the most successful firms under new circumstances seem to be the ones that can take advantage of structural changes to innovate incumbent BMs in order to compete 'differently.' An illustrative example is IBM, which successfully transformed its incumbent BM from mainly product-based to service-based in order to better meet customers' IT needs. In 2006, the majority of the company's \$90-billion revenue was generated by its IBM Global Services arm, a business that had not been in existence fifteen years prior (Chesbrough, 2007). The importance of BMI is also being recognized by other business executives. By interviewing 765 corporate and public leaders worldwide, consultants from IBM Global Business Services found that firms that were financial outperformers put twice as much focus on BMI as underperformers (Pohle and Chapman, 2006).

In spite of these efforts and increasing recognition, the BMI literature remains underdeveloped, both theoretically and empirically, "perhaps reflecting that the BMI literature is more recent than the BM literature" (Foss and Saebi, 2017: 201). As a consequence, the field of research is currently disorganized and largely a descriptive rather than a normative discipline. This is particularly evident in the heterogeneity with which scholars attempt to define and conceptualize the construct. For example, some scholars take a process view of BMI by associating it with experimentation, learning and transformation (e.g., Aspara, Lamberg, and Laukia, 2011; McGrath, 2010; Cavalcante, 2014), while others attempt to classify it according to its innovative outcomes (e.g., Velamuri, Anant, and Kumar, 2015; Sabatier, Mangematin, and Rousselle, 2010).

On the definitional issue, it has been argued that BMI occurs when a firm changes at least one of its core BM elements (e.g., Abdelkafi, Makhotin, and Posselt, 2013; Amit and Zott, 2012), or introduces a fundamentally different BM (e.g., Markides, 2006; Khanagha, Volberda, and Oshri, 2014). This lack of agreement and specificity in defining BMI reflects a deep conceptual ambiguity about the meaning, scope and relevance of the BMI construct. In a recent, and, to my knowledge, the first, systematic review of the BMI literature, Foss and Saebi (2017) raise similar concerns. They find that: (1) the different research streams regarding BMI have largely developed in parallel, with little cross-fertilization; (2) the literature in general faces problems with respect to construct clarity; (3) the basic causal web linking antecedent, moderating, and mediating variables is ill-understood; and (4) such characteristics of the field have resulted in little cumulative theorizing, and a lack of a sustained data collection analysis.

As mentioned earlier, organizational design theory may provide a theoretically and empirically grounded initial reference from which more robust theorization about the causes, processes, and consequences of BMI can emerge. While the contemporary BMI literature has given some attention to the roles of corporate strategy, cognition, learning, experimentation, resources, capabilities and leadership, surprisingly little is known about the role of organizational design in the process of BMI. That is, although BMI frequently involves reconfiguring core elements and/or the architecture/structure of the BM, the extent to which organizational design variables need to be changed to accommodate BMI and the extent to which the implementation of BMI requires a new organizational design configuration are issues that have scarcely been touched upon (Foss and Saebi, 2017).

Organizational design theory

Organizational design is a well-established and influential theory within strategic management research. In particular, much attention has been devoted to the redesign of the firm's internal organization via modification of structures, control mechanisms, information-processing mechanisms, decision-making systems, and reward and incentive systems; this has accompanied the emergence of entirely new organization types specialized to compete in dynamic, information-rich environments (Daft and Lengel, 1986; Schoonhoven and Jelinek, 1990; Damanpour, 1991; Nohria and Eccles, 1992; Mohrman, Cohen, and Mohrman, 1995; O'Reilly and Tushman, 1996; Ilinitch, D'Aveni, and Lewin, 1996; Damanpour and Gopalakrishnan, 1998; Brynjolfsson and Hitt, 2000; Zenger, 2002; Foss, 2003). More specifically, in the strategic management literature, the organizational design view of the firm has been associated with improved strategy implementation (e.g., Noble, 1999; Govindarajan, 1988), coordination (e.g., Sanchez and Mahoney, 1996; Tushman and Nadler, 1978), firm performance (e.g., Armour and Teece, 1978; Dalton, Todor, and Spendolini, 1980), and innovation (e.g., Daft, 1978).

The reason driving management scholars' attraction to organizational design probably lies in the construct's contingency approach. Essentially, contingency theory is based on the assumptions that "there is no one best way to organize, [and] any way of organizing is not equally effect" (Galbraith, 1973: 2), and that the best way to organize depends on the characteristics of the environment in which the organization is embedded (Scott, 1998). The argument that there is no one best way is supported by the work of several scholars who came to the following similar conclusions: that different environments place differing requirements on organizations (Lawrence and Lorsch, 1967); that mechanistic structures are more appropriate for stable industries, while organic structures are more suitable for industries undergoing change (Burns and Stalker, 1961); that bureaucracies, in particular, are not unitary, and take various forms depending on the setting (Pugh, Hickson, and Hinnings, 1969); and that intervention strategies vary to the extent that such

strategies need to be aligned with organizational change issues (Harrison, 1973). Thus, according to Scott (1998: 96), "contingency theory is guided by the general orienting hypothesis that organizations whose internal features best match the demands of their environments will achieve the best adaptation."

In other words, the formal parts of an organization can be designed to better "fit" one another in such a way that not only enable the firm to deal with different environmental contingencies, but allow the firm to realize complementarities. In its most general form, the notion of complementarity denotes a synergistic interaction of the design elements of a system, where doing more of one thing increases the returns from doing more of another (Milgrom and Roberts, 1995). As such, it would seem that realizing complementarities should be a key objective of the strategic organization designer; however, it should be noted that complementarities can also entail negative consequences. For example, complementarities in tightly coupled systems may raise barriers to organizational change, as change in one element both requires and impacts change in many or all other elements of that system (Gates, Milgrom, and Roberts, 1996; Matsuyama, 1995). In addition, complementarities may be complex, with multiple local equilibrium points that are by no means apparent to the decision maker, and that can only be approximated through more-or-less deliberate search processes (Foss and Stieglitz, 2015; Levinthal, 1997; Gavetti and Levinthal, 2000; Stieglitz and Heine, 2007). Nevertheless, the complexity emerging from such complementarities makes them more difficult for would-be imitators to copy than stand-alone practices (Barney, 1991; Porter and Rivkin, 1998).

Another reason for popularity of organizational design theory is that design choices can be readily implemented, in contrast to softer and more informal dimensions such as organizational culture and identity. While it can take several years to change an organization's culture or identify, top management can, within a relatively short period of time, restructure the entire organization. Thus, the designable elements of an organization "represent some of the most powerful strategic levers available to the top management of the modern corporation" (Gulati, Puranam, and Tushman, 2009: 575). Moreover, the firm's organizational design can serve to improve its durability, reliability and legitimacy. First, compared to other social structures, organizations can be designed in such a way as to persist over time by routinely and continuously supporting various efforts across a set of specified activities (Hannan and Carroll, 1995). During times of strategic and/or environmental change, such durability can offer stability to organizational members and allow for

change to better manifest. Second, organizational design provides reliability in the sense that structures, rules and routines can be designed to continuously perform the same activities. This enables managers to more easily analyze how well the company is performing, and where efficiency and effectiveness gains can be achieved. Third, legitimacy is achieved by implementing rules, job descriptions, functions, etc., that provide both guidelines and justifications to the external environment for decisions and activities (Hannan and Carroll, 1995; Meyer and Rowan, 1977).

In short, the field of organizational design is a vibrant area of research that has been used to address a number of important strategic management questions. Due to its long tradition, it has a solid theoretical foundation and a robust empirical literature. In this thesis, I define organizational design as involving "decisions about the configuration of the formal organizational arrangements, including the formal structures, processes, and systems that make up an organization" (Nadler and Tushman, 1997: 48). In important respects, as I argue below, incorporating organizational design can further the BMI literature in a fundamental way, because organizational design theory addresses important issues regarding conceptualization, coordination, implementation, systemic systems, complementarities, and organizational change, which have been largely overlooked in BMI research.

The potential for cross-fertilization

The research literatures on BMI and organizational design theory can, I believe, be fruitfully combined to form a much needed theory or research model of BMI and advance our understanding of organizational complementarities. The questions that emerge from the union of these two fields are likely to draw attention to the *locus* of BMI. While a clear definition of BMI remains elusive, there is some agreement in the literature that BMI attempts to answer three questions: *What* is the value offering (i.e., the core elements that constitute the BM)?; *Who* is the target market segment?; and (with emphasis), *How* is the offering developed and delivered to the customer? (i.e., How do the elements work together?) (cf. Santos, Spector, and Van der Heyden, 2015). The last question includes the issue of how experimentation with and exploitation of BMI is organized, planned, evaluated, and implemented within the firm. Despite the importance of this final point, scholars have mainly been preoccupied with answering the *what* and *who* questions. As such, little work has been done to move the field closer to understanding *how* and *where* BMI activity takes place. This

has been a concern for Zott and Amit (2013: 407), who note in their recent review that the extant literature has not been able to answer with precision the following:

Why and how do business models come into being? Do they emerge as part of evolutionary dynamics, or are they purposefully designed by entrepreneurial actors? And what are the implications of these various processes for the resulting business model design? What is the role of the environment and social processes in shaping business models? How much variation is there among business models, and what types and extent of variation really matters (e.g. for value creation or for value capture by the focal firm)?

There are a few notable exceptions that specifically deal with the *how* by, for example, emphasizing the importance of an organizational dimension of BMI, including the role of the firm's formal and informal (social) structures (see, e.g., Santos et al., 2009; Foss and Saebi, 2015; Foss and Saebi, 2017).

Advancing the literature on BMI. Along similar lines, I argue that organizational design theory is particularly well suited to understanding not only where BMI emerges, but also how it can be implemented, managed and even exploited. For example, high-powered incentives and decision rights can be delegated to cross-functional work teams, thereby creating a context in which new BM ideas can flourish. When an appropriate idea has been identified, BM experiment(s) can be set up within a new sub-unit or function that has its own dedicated resources and staff to demonstrate proof of concept. If the experimentation phase is successful, the proposed BM changes can be rolled out to other parts of the organization through formalized rules and procedures, which can then be used to refine and modify the new BM in order to fully exploit the opportunities presented by the changes. As noted previously, the interplay between underlying design choices and the core elements of the BM creates a complex system whose parts "interact in a nonsimple way" (Simon, 1962: 468). As a result, while competitors might be able to identify the reasons why a particular company possesses a competitive advantage, they have a harder time decomposing the complex system that constitutes the basis for this advantage. Moreover, in contrast to new strategies, product pipelines, and merger and acquisition activities that in many cases are publicly available (e.g., in annual reports), some elements of design (such as specific organizational tasks, rules, targets and

reward systems) are usually only visible to, and understood by, the people who carry them out on a daily basis (i.e., the members of the organization).

However, a firm's organizational design may also raise barriers to BMI. As explained by Sosna et al. (2010: 384), "while great and winning business models often appear to have gone straight from drawing board into implementation leading the firm to glory and success, in reality new business models rarely work the first time around, since decision makers face difficulties at both exploratory and implementation stages." In the exploratory stage, due to the durable, reliable and legitimate nature of organizational design, it might be difficult to convince top management to authorize the allocation of resources toward implementing a new BM characterized by high degree of uncertainty and unpredictability. This is especially true for organizations that have been influenced by particular sub-units over longer periods of time (Leonard-Barton, 1992; Mintzberg, 1983). During the implementation stage, due to the systemic nature of BMI, organizational realignment is required, including the need for decision makers to mobilize scarce resources, develop new capabilities and adjust organizational structures and processes to promote, learning, change and adaptation (cf. Zott et al., 2011). In other words, disregarding the systemic properties of BMI can lead to substantial coordination costs. As noted by Zenger (2002, cited in Foss 2003: 337), "changing one element in an isolated way is likely to set in motion (possibly unforeseen) processes of change in other elements because the system will grope toward an equilibrium where all elements have changed."

Advancing organizational design theory. An improved understanding of the BMI construct can also advance the theory of organizational design. Ever since the seminal work of Burns and Stalker (1961), organizational design scholars have mainly distinguished between *mechanistic* and *organic* forms of organizational design. However, cataclysmic changes (such as the proliferation of Internet and communication technologies, globalization and hyper-competition) occurring in the environment of organizations call for new forms of design. For example, scholars have begun to express avid interest in the project-based organization (Hobday, 2000; Sydow, Lindkvist, and DeFillippi, 2004), internal hybrids (Zenger, 2002; Foss, 2003), the virtual enterprise (Mowshowitz, 1997; Afsarmanesh and Camarinha-Matos, 2005), the modular organization (Sanchez and Mahoney, 1996; Schilling, 2000; Hoetker, 2006), the boundaryless organization (Ashkenas, Ulrich, Jick, and Kerr, 2002), the ambidextrous organizations (O'Reilly and Tushman, 2004), and so on. Despite these efforts, however, there is still a lack of knowledge about why and, particularly, how new organizational design forms come into being (cf. Romanelli, 1991; Lewin, Volberda, 1999). A better understanding of the dimensions of BMI may aid in this regard. Specifically, BMI varies with respect to the type, extent and degree of change. While some instances "may involve relatively minor connected changes, [others] may be massive corporate-wide processes that involve basically all employees and all processes and activities" (Stieglitz and Foss, 2015: 104). Such heterogeneity is likely to be reflected in the firm's choice of organizational design. Moreover, as mentioned earlier, I argue that the holistic nature of BMI is particularly well-suited to developing an understanding of not only how organizational complementarities are obtained, but also the challenges and difficulties that result from such a complementary logic.

Research aim and design

The overall research question guiding this thesis is What is the role of organizational design in the process of BMI? In particular, this thesis aims to further our knowledge about BMI and organizational design in two ways. First, I aim to demonstrate to scholars in both fields, although mainly to BMI scholars, the potential for gains from cross-fertilization (Chapters 2 and 3). In this regard, I introduce a new process framework that encompasses the stages through which BMI comes about and discuss the multiple roles of organizational design in this framework (Chapter 9). Second, similarly to Siggelkow (2001, 2002), this thesis adds to existing research on complementarities by providing ample detail on how organization-specific factors (such as industry, strategy, structure and BM) relate to one another and thus influence how firms go about changing, implementing and/or preserving various elements of their BMs. To drive home these insights, I adopt an inductive, multiple-case study design (Eisenhardt, 1989) (Chapter 5), in which I examine three select players in the pharmaceutical industry-namely, Novo Nordisk, LEO Pharma and UCB Pharma (Chapters 6, 7 and 8). While these firms differ markedly across a number of basic dimensions (such as disease target, firm size, and firm age), they all face the challenge of redesigning their organization to accompany an on-going process of BMI, as necessitated by environmental change (Chapter 4). These characteristics enable me to identify "uniqueness and important shared patterns that cut across cases and derive their significance from having emerged out of heterogeneity" (Patton, 2002: 235). In this way, more substantiated theory development is

possible because propositions are derived from and rooted in more varied empirical evidence, thus allowing the development of a robust integrative theory on the role of organizational design in process of BMI.

The remainder of the thesis. The thesis is organized as a monograph with ten interdependent chapters. It has considerable length and scope, which will allow me to communicate a novel understanding, as well as intricate details and nuances, of the BMI phenomenon. In particular, each chapter gradually builds upon the preceding one to uncover a more granular and complete understanding of the process of innovating a firm's incumbent BM. In the next chapters, I will elaborate on some of the ideas introduced in this chapter. More specifically, I present the current research landscape regarding BMI and show how it ties into central ideas and key constructs from the contemporary theory of organizational design. Next, I discuss the choice of research methods for this thesis and empirical context. I then move on to the three cases (Novo Nordisk, UCB and LEO Pharma), which explore different aspects of changes in the firms' organizational designs and BMs. The remaining chapters deal with cross-case findings, and the thesis concludes with a discussion of the relevant contributions, limitations and future research opportunities.

2

BMI: Literature Review and Critical Knowledge Gaps

During the last decade and a half, the BM construct has attracted substantial attention from both management scholars and practitioners (Zott et al., 2011). A BM outlines "the manner by which the enterprise delivers value to customers, entices customers to pay for value, and converts those payments to profit" (Teece, 2010: 172). Most notably, the BM builds upon and extends central ideas from business strategy and its associated traditions (such as value chain analysis, the resource-based view, strategic networks and transaction cost economics).

The growing popularity of the BM construct may be ascribed to the its holistic and systemic properties, namely, a BM is not just *what* firms do (e.g., the bundle of products and services they offer to satisfy specific market segments), but also *how* they do it (e.g., how they link factor and product markets to produce and deliver that bundle at a profit) (cf. Santos et al., 2009).

In particular, a BM is comprised of a set of interlocking activities, governed by organizational units that implement those activities both within and outside the focal firm; it is designed to create and deliver value through the production and delivery of its value proposition to a specific market segment (Santos et al., 2009; Teece, 2010). Due to the complex interactions between BM activities and organizational units, competitors find it difficult to discover and replicate those activities within their own organizational context. This helps differentiate the firm's offering and ultimately leads to a competitive advantage.

More recently, the notion of BMI has come into prominence, as drivers such as globalization, deregulation and technological change (to mention only a few) have profoundly altered the environment in several industries, rendering traditional types of innovation (e.g., product and process innovation) less effective. Scholars and practitioners agree that the most successful firms

under these new circumstances seem to be those that have taken advantage of such structural changes to innovate their incumbent BMs to gain a competitive advantage. IBM's previously mentioned transformation from a product-based to service-based focus, and the resulting revenues, is a clear example (Chesbrough, 2007).

BMI can be defined as the reconfiguration of the activities and organizational units of a firm, to create a new BM that is new to the marketplace in which the firm competes. For example the example of IBM, the company needed to develop and implement new activities and organizational units to accommodate the increasing service content of its BM. All of these changes together may add up to a massive organizational change process that places a heavy burden on the organization. It is rare that a new BM goes straight from the drawing board to full-scale implementation. Thus, BMI is difficult, inducing potentially substantial changes and interfering with the existing ways of doing things. At the same time, this complexity is coupled with the underlying specificity of the firm such that innovating a BM is likely to result in a more sustainable advantage (compared to, e.g., product innovation). This is being recognized by executives. Interviews with 765 corporate and public leaders worldwide conducted by consultants from IBM Global Business Services revealed that firms that are financial outperformers put twice as much focus on BMI as underperformers (Pohle and Chapman, 2006).

This review aims to synthesize the contemporary literature on BMI, identify key research streams, and carefully document potential knowledge gaps. The review is structured as follows: It starts with a summary of the BM construct, including the key conceptualizations, assumptions, issues, and controversies, followed by a review of the BMI literature, and ends with a discussion of the critical knowledge gaps.

What is a BM?

While BMs, as defined above, have been fundamental to business since pre-classical times (Teece, 2010), it was the advent of the Internet, the development of information and communication technologies (ICTs), and the subsequent emergence of web-based companies in the mid-1990s that prompted interest in the term. Since then, it has been widely adopted by scholars and practitioners alike, as evidenced by the growing number of publications that address the construct, including articles, books, and book chapters in the business press and academic journals.

Ghaziani and Ventresca (2005) performed a frame analysis¹ of the term "business model" by searching for use of the term in general management articles from 1975 to 2000. Searching the ABI/INFORM database provided 1,729 publications that contained the BM term. In that sample, only 166 were published in the period between 1975 and 1994, whereas the rest (1,563) belonged to the period between 1995 and 2000, indicating a substantial increase in the incidence of the term. Amit et al. (2011) found a similar pattern in a keyword-based search of the term *business model* but noted that academic research on BMs seems to trail behind practice.

During the last decade, the BM term has become important in practitioner discourse, appearing frequently in newspapers and magazines, in annual reports, in negotiations between venture capitalists and startup companies, etc. The concept's growing popularity lies in its strong communicative capacity. Foss and Saebi (2015:6) argue that "entrepreneurs stand a better chance of getting funding from [...] financiers when they can make convincing claims that they are not just pitching a value proposition, but a value proposition that is supported by value chain activities, an identification of distinct segments [...] and [...] that all this is replicable." With the emergence of web-based companies in the early 2000s, the need to demonstrate value was at its highest, largely because such companies could not be valued on the basis of past performance since there were no precedents. Therefore, investors speculated about the future value of these innovative BMs (Thornton and Marche, 2003). Pets.com, for example, received investments amounting to USD 300 million in less than two years. However, despite massive spending on marketing that generated huge brand awareness, it failed because few were willing to order pet-related products online. This is just one among many examples of a web-based company's BM being used to garner stratospheric valuations (Garfield, 2011). There were also some successful web-based startups at that time, such as Amazon (which initially reached book buyers through the Internet instead of physical stores) and eBay (which moved garage sales and neighborhood auctions into the electronic age).

Many scholars believe that awareness of the BM concept and its widespread use since the mid-1990s can be partly ascribed to the advent of the Internet as well as ICT (e.g., Amit and Zott, 2001), the growing importance of emerging markets, increased focus on social and sustainability issues (Prahalad and Hart, 2002; Seelos and Mair, 2007; Thompson and MacMillan, 2010), and an

¹ A frame analysis can be defined as "the study of the frames, or fundamental schemes of interpretation, by which people in social situations make coherent sense of what is occurring in those situations" (Chambliss, 2005: 289).

increasing number of industries and organizations reliant on post-industrial technologies (Perkmann and Spicer, 2010). Specifically, the Internet and ICT dramatically changed the way companies do business in a number of industries, and so the BM concept quickly spread to the analysis of more traditional brick-and-mortar companies. Firms from industries such as air travel and music are some of the most used BM cases.

Why BMs matter

The BM is a new unit of analysis, and thus may be useful for generating new insights into strategic management. As argued elsewhere (e.g., Amit and Zott, 2013; Foss and Saebi, 2015), the inherently systemic nature of BMs has much to offer management theory—most notably, a focus on the need for alignment of, and consistency between, strategic choices pertaining to the value proposition and mechanisms of value creation and appropriation. Similarly, Magretta (2002: 6) argues that "business models describe, as a system, how the pieces of a business fit together." The ways in which firms fit those pieces together often require highly firm-specific systems, processes, capabilities and assets. Thus, due to the level of firm-specificity and underlying complexity that a BM encompasses, advantages emerging from such differentiation may be difficult for competitors to eliminate (e.g., by replication).

BMs are usually illustrated using graphical representations, which help convey an understanding that is much simpler than the real-life situation but still resembles it in many respects. Essentially, a BM is about telling a good story about how a particular company works (Magretta, 2002). A "model" is also something that can be examined, measured, discovered, and emulated (Foss and Saebi, 2015). For instance, firms can better assess the value of a given strategy (e.g., How does our value proposition stack up against the competition?) and what it takes to implement it (e.g., Which interlocking activities and organizational units are essential to realize a given value proposition at a profit?). Intuitively, it also seems easier to change a model as opposed to an organization. A BM is malleable and therefore subject to experimentation, as its value proposition and associated mechanisms of value creation and appropriation may change in response to contingencies.

The holistic nature of the BM construct has also been useful in academic circles to: (1) classify firms according to their BMs (e.g., Timmers, 1998; Rappa, 2000; Amit and Zott, 2001;

Osterwalder et al., 2005); (2) explain variation in firm performance (e.g., Zott and Amit, 2010; Weill et al., 2005); and (3) identify new types of innovation (e.g., Teece, 2010; Markides, 2006). More recently, scholars have been delving into the relationship between BMs and the ecosystem or industry architecture (see, e.g., Adner and Kapoor, 2010; Jacobides, Knudsen, and Augier, 2006), for instance, by looking at the competition among different BMs.

Theoretical ambiguity

Despite its widespread use in both academic research and practice, the notion of a "BM" remains highly ambiguous. Zott et al. (2011: 4) note in an extensive overview of the literature (Table 2.1): "At a general level, the business model has been referred to as a statement (Stewart and Zhao, 2000), a description (Applegate, 2000; Weill and Vitale, 2001), a representation (Morris, et al., 2005; Shafer, Smith and Linder, 2005), an architecture (Dubosson-Torbay, Osterwalder and Pigneur, 2002; Timmers, 1998), a conceptual tool or model (George and Bock, 2009; Osterwalder, 2004; Osterwalder et al., 2005), a structural template (Amit and Zott, 2001), a method (Afuah and Tucci, 2001), a framework (Afuah, 2004), a pattern (Brousseau and Penard, 2007), and a set (Seelos and Mair, 2007). Surprisingly, however, the business model is often studied without an explicit definition of the concept." They found more than one third (37%) of the reviewed publications did not define the concept, instead taking its meaning more or less at face value. Less than half (44%) explicitly defined or conceptualized the BM, for example, by highlighting its main components. The remaining publications (19%) referred to the work of other scholars in defining the concept. In a more recent review, DaSilva and Trkman (2014) point to similar issues, and raise the concern that the lack of a clear distinction between the BM and other theories of management (e.g., the resourcebased view, transaction cost economics and business strategy) may turn the term into simply another management fad.

Table 2.1 Selected BM definitions

Author(s)

Definition

Papers citing the definition

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Timmers, 1998	The business model is "an architecture of the product, service and information flows, including a description of the various business actors and their roles; a description of the potential benefits for the various business actors; a description of the sources of revenues" (p. 2).	Hedman and Kalling, 2003
Amit and Zott, 2001; Zott and Amit, 2010	The business model depicts "the content, structure and governance of transactions designed so as to create value through the exploitation of business opportunities" (2001: 511). Based on the fact that transactions connect activities, the authors further developed this definition to conceptualize a firm's business model as "a system of interdependent activities that transcends the focal firm and spans its boundaries" (2010: 216).	Hedman and Kalling, 2003; Morris et al., 2005; Zott and Amit, 2007, 2008; Bock, Opsahl, and George, 2010
Chesbrough and Rosenbloom, 2002	The business model is "the heuristic logic that connects technical potential with the realization of economic value" (p. 529).	Chesbrough, Ahern, Finn, and Guerraz, 2006; Chesbrough, 2007a, 2007b; Teece, 2007, 2010
Magretta, 2002	Business models are "stories that explain how enterprises work. A good business model answers Peter Drucker's old age questions: Who is the customer? And what does the customer value? It also answers the fundamental questions every manager must ask: How do we make money in this business? What is the underlying economic logic that explains how we can deliver value to customers at an appropriate cost?" (p. 4).	Seddon, Lewis, Freeman, and Shanks, 2004; Ojala and Tyrväinene, 2006; Demil and Lecocq, 2010
Morris et al., 2005	A business model is a "concise representation of how an interrelated set of decision variables in the areas of venture strategy, architecture, and economics are addressed to create sustainable competitive advantage in defined markets" (p. 727). It has six fundamental components: the value proposition, the customer, internal processes/competencies, external positioning, the economic model, and personal/investor factors.	Calia, Guerrini, and Moura, 2007

Johnson et al., 2008	Business models "consist of four interlocking elements that, taken together, create and deliver value" (p. 52). These are the customer value proposition, the profit formula, key resources, and key processes.	Johnson and Suskewicz, 2009
Casadesus-Masanell and Ricart, 2010	"A business model is a <i>reflection</i> of the firm's <i>realized</i> strategy" (p. 195).	Hurt, 2008; Baden-Fuller and Morgan, 2010
Teece, 2010	"A business model articulates the logic, the data and other evidence that support a value proposition for the customer, and a viable structure of revenues and costs for the enterprise in delivering that value" (p. 179).	Gambardella and McGahan, 2010

Source: Adopted from Zott et al. (2011).

George and Bock (2011: 83) note that BM conceptualizations "vary widely, incorporating organizational narrative (Magretta, 2002), processes that convert innovation into value (Chesbrough and Rosenbloom, 2002), recipes for firm activities that incorporate organizational design and strategy (Slywotzky and Wise, 2003), 'flows' of information and resources (Timmers, 1998), and designed structures such as the firm's set of boundary-spanning transactions (Amit and Zott, 2001)."

This lack of definitional and construct clarity gives rise to numerous interpretations of the core construct, ultimately leading to fragmentation rather than convergence in perspectives and thus retarding cumulative research efforts on BMs. Furthermore, proponents of the BM construct often fail to define the essence of the construct in such a way that differentiates it from other strategic management constructs (such as strategy and the value chain). This is problematic, as it leads to the proliferation of different terms and labels for the same phenomena, i.e., putting "old wine in new bottle" (Suddaby, 2010).

Given this heterogeneity in terms of definition and conceptualization, it is not surprising that there is no agreed-upon framework that captures the essence of a BM. For example, Alt and Zimmermann (2001) include elements such as a mission, processes, legal issues and technology in their framework. Weill and Vitale (2001) in their framework highlight the importance of strategic objectives, a value proposition, critical success factors, core competencies, customer segments, channels and IT infrastructure. Afuah and Tucci (2003) propose a BM framework that encompasses customer value, scope, pricing, revenue sources, connected activities, implementation, capabilities and sustainability. Therefore, there is an immediate need for a clearer conceptualization and unified definition of a BM in order to coordinate research efforts and move the field forward.

The constituent parts of a BM

Despite the considerable differences in the definition and conceptualization of a BM, a consistent pattern in the meaning is becoming apparent in the literature on BMs. Scholars seem to converge on the basic idea that a BM comprises four key elements or components: value creation, value appropriation, value chain organization and the value network. Typically, these are bundles of activities that can be paired under the headings of the company's overall value proposition (*What?*), the customer segments targeted with the value proposition (*Who?*), the company's way of delivering value (*How much?*), the value chain configuration required to create and deliver the offering, the complementary resources needed to maintain a key position in this chain, and the processes and internal organization of the firm that create and reinforce linkages among the other components in the model (*How?*).

BMI: definitions, conceptualizations, and emerging research streams

As mentioned above, the extant literature on BMs is characterized by disagreement and confusion, which makes conceptualizing BMs into a common theoretical framework challenging (Zott et al., 2011). Consequently, there is no solid foundation for the study of BMI (Spieth, Schneckenberg, and Ricart, 2014). Perhaps this is also a reason for the relatively small amount of published articles on BMI in peer-reviewed management journals (such as Journal of Strategic Management, and Academy of Management Review). As argued by Foss and Saebi (2017: 201), although BM and BMI are obviously intrinsically related, "BMI introduces the additional dimension of innovation and [thereby] raises a number of crucial theoretical and empirical questions: What are the drivers, facilitators, and hindrances of the innovation of a BM? Under which circumstances can BMI give rise to sustained competitive advantage? Does BMI exclusively originate in the upper echelons, or may it originate in levels of the organization?" Due to the lack of theoretical grounding and inconsistency regarding the BM construct itself, and given the newness of BMI research, such fundamental questions remain unanswered. However, recent efforts by scholars such as Schneider

and Spieth (2013), and particularly Foss and Saebi (2017), have been made to map the current research landscape and make note of potential research gaps that need to be filled in order to move the field forward. Along similar lines, this review approaches the extant literature with the aim of improving our understanding of BMI, and especially the research question formulated in Chapter 1. I organize the extant literature on BMI according to the following themes (Table 2.2): (1) understanding and defining BMI; (2) classification of BMI; (3) drivers and barriers to BMI; and (4) a process view of BMI. Some themes have been identified by prior reviews (for a similar application, see Schneider and Spieth, 2013; Foss and Saebi, 2017), while others, such as (2) and (4), have not been covered by prior reviews. With this review, I hope to take a further step in the investigation of BMI, without claiming an exhaustive review of the literature.

Research themes	Main purpose	Author(s)	Method
Understanding and defining BMI	 The role of BMI Defining BMI 	Amit and Zott (2012); Santos et al. (2009); Sorescu, Frambach, Singh, and Rangaswamy (2011)	Conceptual, case illustrations
Classifications of BMIs	 Identify industry-specific BMs Identify so-called "iconic business models" Identify different types of BMI 	Velamuri et al. (2015); Holm, Günzel, and Ulhoi (2013); Pereira and Caetano (2015); Yunus, Moingeon, and Lehmann-Ortega (2010); Sabatier et al. (2010); Cavalcante, Kesting, and Ulhoi (2011)	Conceptual, case illustrations, and single/multiple case studies
Drivers and barriers to BMI	 Highlight key internal drivers Highlight key external drivers Highlight potential barriers and challenges 	Bock, Opsahl, George, and Gann (2012); Chesbrough (2010); Doz and Kosonen (2010); Miller, McAdam, and McAdam (2014)	Conceptual, single/multiple case studies, survey data
A process view of BMI	 Identify key stages of BMI Identify critical organizational capabilities The role of experimentation and learning Develop practitioner-oriented tools 	De Reuver, Bouwman, and Haaker (2013); Achtenhagen et al. (2013); Sosna et al. (2010); Demil and Leccoq (2010); Eppler and Hoffman (2012); McGrath (2010); Evans and Johnson (2013)	Conceptual, case illustrations, mixed method, single/multiple case studies, experimental

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Table 2.2 Themes of BMI research

Understanding and defining BMI

Many scholars have attempted to improve our understanding of BMI from a conceptual perspective, by (1) highlighting the role of BMI, (2) defining the phenomenon, and (3) addressing key conceptual problems (e.g., Santos et al., 2009; Teece, 2010; Zott and Amit, 2012). To deal with the growing challenges arising as a result of globalization, deregulation and technological change, companies are increasingly relying on BMI as an alternative or complement to product or process innovation. For example, Amit and Zott (2012:41) argue that

innovations to improve processes and products, [...] [and] are often expensive and timeconsuming, requiring considerable upfront investment in everything from research and development to specialized resources, new plants and equipment, and even entire new business units. Yet future returns on these investments are always uncertain. Hesitant to make such big bets, more companies now are turning toward BMI as an alternative or complement to product or process innovation.

Relatedly, others argue that innovative technologies or ideas alone have no economic value, but that rather it is through the design of complementary BMs that managers are able to unlock the value from those investments and market them (Massa and Tucci, 2013). In general, scholars seem to agree on the strategic importance of BMI as a key driver of firm performance (cf. Chesbrough 2010; Teece, 2010; Ho et al., 2011; Zott and Amit, 2007) as well as a vehicle for organizational change and renewal (Demil and Lecocq, 2010; Hitt, Ireland, Camp, and Sexton, 2001; Johnson et al., 2008; Sosna et al., 2010). It can also be used to cope with external contingencies (such as new entrants and changing regulations) and internal ones (such as organizational or managerial factors) (e.g., Casadesus-Masanell and Zhu 2013; Hartmann et al., 2013).

The BMI field is still in its infancy. Thus, scholars are still trying to make sense of BMI (i.e., What is it? How does it work? What are its limitations and boundary conditions?). The lack of a common understanding of BMI has resulted in several definitions (see Table 2.3), the most general of which defines BMI as "new ways to create and capture value" or the "core elements of a firm and its business logic." By contrast, few authors have explicitly defined or conceptualized BMI by, for example, specifying its main elements and processes (e.g., Amit and Zott, 2012; Santos et al.,

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2009; Sorescu et al., 2011). Moreover, existing definitions differ significantly, although they are often conflated in the sense they refer to a single phenomenon.

Author(s)	Definition	Main elements and processes
Abdelkafi et al. (2013: 13)	"A business model innovation happens when the company modifies or improves at least one of the value dimensions."	Specified according to BMs, but not BMI
Amit and Zott (2012: 44)	Business model innovation occurs when one or more of the following elements are changed: (1) content; (2) structure; and (3) governance.	 Adding new activities Linking activities in new ways Governing activities in new ways
Berglund and Sandström (2013: 276)	"A BMI can thus be thought of as the introduction of a new business model aimed to create commercial value."	Specified according to BMs, but not BMI
Casadesus-Masanell and Zhu (2013: 464)	"At root, business model innovation refers to the search for new logics of the firm and new ways to create and capture value for its stakeholders; it focuses primarily on finding new ways to generate revenues and define value propositions for customers, suppliers, and partners."	Specified according to BMs, but not BMI
Khanagha et al. (2014: 324)	"Business model innovation activities can range from incremental changes in individual components of business models, extension of existing business model, introduction of parallel business models, right through to disruption of the business model, which may potentially entail replacing the existing model with a fundamentally different one."	 Strategic intent Structural form Key roles Targeted outcomes

Table 2.3 Selected BMI definitions

Kim and Min (2015: 36)	"An incumbent firm may commit to <i>original</i> business model innovation by creating a new business model derived from its own technological breakthrough or endogenous reconfiguration of ways of doing business. Imitative BMI is an incumbent's addition of new business model already invented by other firms."	 Managerial choices Asset configuration Organizational configuration
Markides (2006: 20)	"Business model innovation is the discovery of a fundamentally different business model in an existing business."	Specified according to BMs, but not BMI
Mitchell and Coles (2003: 17)	"By business model innovation, we mean business model replacements that provide product or service offerings to customers and end users that were not previously available."	Specified according to BMs, but not BMI
Santos et al. (2009: 14)	"Business model innovation is a reconfiguration of activities in the existing business model of a firm that is new to the product service market in which the firm competes."	ReactivatingRepartitioningRelinkingRelocating
Yunus et al. (2010: 312)	"Business model innovation is about generating new sources of profit by finding novel value proposition/value constellation combinations."	Specified according to BMs, but not BMI

Because of the variations in definition, numerous interpretations of the core construct exist. Although scholars agree that BMI can be described as a process of change, there is less agreement on the magnitude of change. While some argue that BMI involves change of one or more elements of the BM, others associate it with "evolution," "adaptation," transformation," or "disruption of the business model, which may potentially entail replacing the existing model with a fundamentally different one" (Khanagha et al., 2014: 324). This general lack of definitional and construct clarity is problematic because it leads to confusion and divergence regarding the meaning of BMI. This may in turn significantly slow down research progress on BMI.

Classifications of BMI

The BMI construct has also been subject to various forms of classification. Typically, studies investigate BMI within a specific context, such as healthcare (Velamuri et al., 2015; Sabatier et al., 2010), newspapers (Santos et al., 2009; Holm et al., 2013), insurance (Desyllas and Sako, 2013), banking (Yunus et al., 2010), aviation (Schneider and Spieth, 2013; Pereira and Caetano, 2015), or entrepreneurship (Trimi and Berbegal-Mirabent, 2012). One group of scholars classifies BMI according to specific strategic purposes. For example, studies have examined BMs for general purpose technologies (Gambardella and McGahan, 2010), BMs for low-income markets (Anderson and Kupp, 2008; Sánchez and Ricart, 2010; Yunus et al., 2010), BMs for sustainable innovation (Boons and Lüdeke-Freund, 2013; Richter, 2013), service-based BMs (Kindström and Kowalkowski, 2015), and more recently, BMs for open innovation (Saebi and Foss, 2015). In a similar vein, scholars have identified a set of so-called "iconic business models" belonging to particular companies. Following Sabatier et al. (2010), an "iconic business model" is labeled with the name of the instigator company; it is also widely recognized and well established as an example of a particular way of creating and capturing value. For example, companies such as Amazon, 3M, Dell, Google, and more recently, Nestlé's Nespresso, have BMs that have become iconic (Sabatier et al., 2010; Matzler, Bailom, Von Den Eichen, and Kohler, 2013). Another group of scholars distinguishes between different types of BM change. For instance, Cavalcante et al. (2011) propose a change typology, in which they distinguish between BM creation, extension, revision, and termination. Similarly, Santos et al. (2009: 15) provide a typology for BMI, in which they specify four types of change: (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 those activities (e.g., outsourcing); (3) "relocating," that is, altering the (physical, cultural and institutional) location of units currently performing activities (e.g., offshoring); and (4) "relinking," that is, altering the linkages between organizational units that perform the activities (e.g., when an arms-length relationship with a supplier becomes an alliance). In general, this stream of research does not set forth criteria for what constitutes a BMI, and is often not clear about the unit of analysis. Moreover, it is difficult to understand the underlying differences between various types of BMI, since scholars do not always state the basic assumptions behind them. For example, what is the difference

between a sustainable BM and a service-based BM? And how is BMI different from BM change, or is it the same feature under different names? This lack of clarity is problematic because the strength of classifications or typologies lies in their ability to "describe the causal relationships of contextual, structural, and strategic factors, thus offering configurations that can be used to predict variance in an outcome of interest" (Fiss, 2011: 393).

Drivers and Barriers to BMI

Scholars have also examined the internal and external drivers of, and barriers to, BMI. With regard to external drivers, a considerable number of articles describe BMI as resulting from environmental changes, such as globalization and technological developments (De Reuver, Bouwman, and MacInnes, 2009; Lee, Olson, and Trimi, 2012; Miller et al., 2014; Sabatier, Craig-Kennard, and Mangematin, 2012; Wirtz, Schilke, and Ullrich, 2010). For example, most scholars point out that BMI is necessary to cope with "strategic discontinuities and disruptions, convergence and intense global competition" (Doz and Kosonen, 2010: 370), increasing competitive pressure or a shifting base of competition (Johnson et al., 2008), or "new communication technologies, shorter product life cycles, global markets and tougher competition" (Osterwalder, 2004: 11).

Scholars have also highlighted a number of internal strategic drivers underlying firms' BMI decisions, including structure, culture, processes, capabilities and leadership. A study of 107 multinational firms by Bock et al. (2012) revealed a number of interesting results. First, the authors found that a creative culture is associated with strategic flexibility, and is thus an important driver of BMI. Second, the reliance on external partners apparently decreases the probability achieving strategic flexibility. Third, delegation increases the probability that firms will achieve strategic flexibility, and thus BMI. Similarly, Doz and Kosonen (2010) refer to strategic agility as an important driver of BMI. They identify three meta-capabilities as being essential to strategic agility: strategic sensitivity, leadership unity, and resource fluidity. Sorescu et al. (2011) further describe interdependencies among BM elements and a customer-centric orientation as critical drivers of BMI. For example, "a sustained focus on improving the customer experience may prompt [firms] to identify innovative ways to best align their 'backstage' (back-office), 'frontstage' (physical

environment, service employees, service delivery processes), [and] 'auditorium'' (fellow customers)''' (Sorescu et al., 2011: 12).

Fewer scholars have investigated potential barriers to BMI. In a theoretical paper, Chesbrough (2010) sheds light on the barriers to BMI identified in earlier studies by Amit and Zott (2001), Christensen and Raynor (2003), Christensen (1997), and Chesbrough and Rosenbloom (2002). He identifies two type of barriers—obstruction and confusion—and suggests that organizational leadership, as well as experimentation and effectuation, can be used to overcome these barriers. In a multiple case study of the role of strategic agility during BMI, Doz and Kosonen (2010) explain that inertia can arise from various sources in defense of the status quo, thus presenting a key challenge throughout the transformation of a BM.

Although this body of research addresses a number of different drivers and antecedents of BMI, it does so mainly in conceptual or theoretical terms rather than through empirical claims. A notable exception is a study by Lee, Shin, and Park (2012). Based on a survey of 400 Korean SMEs, the authors found that globalization has forced SMEs to engage in BMI.

A process view of BMI

A number of scholars recognize BMI as a complex organizational change process, influenced by a variety of interrelated factors, such as leadership, capabilities, and learning mechanisms. At least four strands of this literature can be distinguished. The first strand describes and emphasizes critical stages of the BMI process. In a conceptual paper, De Reuver et al. (2013) coin the term "business model roadmapping" as an approach for defining the transition stages between an existing and newly designed BM. In particular, they identify four basic sequential steps: (1) identify desired changes in the BM; (2) analyze the impact of the desired BM changes on other BM domains; (3) translate BM changes into specific activities; and (4) back-casting of ideal transition path. The roadmap helps managers understand how operational actions and BM changes are interrelated. Similarly, Frankenberger, Weiblen, Csik, and Gassmann (2013) developed the so-called "4I-framework," which organizes the BMI process and sheds light on specific challenges that managers face during the initiation, ideation, integration, and implementation stages of BMI. From a slightly different perspective, Girotra and Netessine (2014: 98) describe the BMI process as "a set of key decisions that collectively determine how a business earns its revenues, incurs its costs, and

manages its risks. [The authors] view innovations to the model as changes to those decisions: *what* your offering will be, *when* decisions are made, *who* makes them, and *why*."

The second strand of literature on the process view of BMI focuses on critical organizational capabilities and processes needed to support the ongoing change process. In contrast to the first strand, this one views BMI as a non-linear process, rather than proposing a sequential ordering of actions. Demil and Lecocq (2010: 234) argue that BMI is driven by the

interactions *between* and *within* the core model components. Interactions between components will follow choices to develop a new value proposition, to create new combinations of resources or to make changes in the organizational system, and the impacts such adaptations will have on the other components and their subsidiary elements.

In other words, the process of BMI does not necessarily have to start at A and end at Z. This is further emphasized with the observation that BMI is both a planned and an emergent process. In a large case study of nine companies from different industries, Achtenhagen et al. (2013) illustrate the importance of strategizing actions (e.g., strategy development and policies and measures) and critical capabilities (e.g., recognizing business opportunities, leadership styles and characteristics of corporate culture) when conducting BMI, and suggest that not only are the two interlinked, but they are complementarities. In a longitudinal study of the Naturhouse case, Sosna et al. (2010) found that the ability to learn from unsuccessful experiments and the resilience to continue experimentation represent crucial individual and organizational capabilities for BMI.

The third strand of process-view BMI research highlights the importance of experimentation and learning in the BMI process. Yunus et al. (2010) argue that strategic experimentation is central to the process of BMI because it allows decision makers to deal with uncertainty in a controlled manner. More specifically, "launching a series of small experiments helps minimize risk and maximize the firm's rate of learning, making it possible to identify a [BM's] potential for success most efficiently" (Yunus et al., 2010: 315). Similarly, others have characterized BMI as an evolutionary process (Dunford, Palmer, and Benveniste, 2010), as ongoing processes of experimenting and learning (Chanal and Caron-Fasan, 2010; McGrath, 2010; Cavalcante, 2014) incorporating double-loop learning (Moingeon and Lahmann-Ortega, 2010), and as a discovery-

driven, trial-and-error-based process, instead of an analytical one (McGrath, 2010; Smith, Binns, and Tushman, 2010; Sosna et al., 2010).

The fourth strand offers a range of practitioner-oriented tools for managing the BMI process. For example, through an experiment, Eppler et al. (2012) showed that artifacts (such as a BM template, physical objects with sketching or PowerPoint) can have a significant influence in shaping team interactions and subsequently BM idea generation. Evans and Johnson (2013) propose the so-called "innovation readiness levels" (IRLs) framework to help managers asses "the organization's state of readiness to implement a specific BM and [as] a measure of the amount of stress an idea is likely to create for the organization" (Evans and Johnson, 2013: 52).

The common theme across these strands is that they view BMI as a dynamic process that can be shaped by both internal and external factors and their interactions. The studies are mainly anecdotal and exploratory in nature, with the primary aim of achieving a first understanding of the BMI phenomenon. This is shown by the extensive use of qualitative methods (e.g., single/multiple case study studies) rather than the testing of tightly specified hypotheses.

Critical Knowledge Gaps in the BMI Research

In the previous sections, I reviewed the extant literature on BMs and BMI. In the following, I highlight some of the more interesting knowledge gaps pertaining to BMI. Based on the review, I identify three critical gaps: (1) the nature of BMI; (2) BMI capabilities; and (3) the neglect of organizational elements in BMI research and theory.

The Nature of BMI

The extant literature on BMI has not sufficiently addressed five main issues. First, despite a flood of attention in the academic and practitioner communities, BMI remains a "slippery construct to study" (Casadesus-Masanell and Zhu, 2013). As Table 2.3 shows, there is little consistency with regard to the terminology and definitions used for BMI. In particular, the unit of analysis is often not clearly defined and explained; rather, it is often phrased in ambiguous terms such as "generating new sources of profit by finding novel value proposition" or a "novel approach to commercializing its underlying assets." In other words, an operational definition of BMI has yet to be developed. This lack of clarity stems from discrepancies in the conceptual framework of the BM construct

itself, which resides at the intersection of economics and business strategy without possessing a robust theoretical foundation in either field (Teece, 2010). According to Andersen and Kragh (2010), unspecified theoretical expectations or a lack of theoretical knowledge can lead scholars to replicate pre-existing findings, thus adding little to existing theoretical knowledge, or to produce massive amounts of data without any clarity with respect to how the data can lead to new insights.

The second issue is the question of what is being innovated. Some scholars limit BMI to an isolated change to a specific element of the BM, while others call for changes to the entire BM architecture rather than individual elements (cf. Foss and Saebi, 2017). In the first case, the nature of BMI is characterized as changes made to the "value proposition," the "value chain," the "value network," or the "revenue/cost model" (see, e.g., Giesen, Berman, Bell, and Blitz, 2007; Schneider and Spieth, 2014). Thus, as Abdelkafi et al. (2013: 13) argue, "a BMI happens when the company modifies or improves at least one of the value dimensions." By contrast, in the second case, BMI takes the form of innovations across multiple BM elements. For example, Santos et al. (2009) state that BMI happens when a firm takes steps to reconfigure its set of elementary activities by "reactivating," "repartitioning," or "relinking." Similarly, Richter (2013: 458) defines BMI "as the development of new organizational forms for the creation, delivery, and capture of value." In other words, emphasis is placed on the underlying mechanisms that link together the set of elementary activities into a coherent BM architecture (cf. Foss and Saebi, 2017; Zott and Amit, 2010). Although these contributions briefly touch on the role of organizational units, they are not particularly forthcoming about how such an architecture is formed.

The third issue regards whether BMI is something that is new to the world, to an industry, or simply to the firm that is implementing it (cf. Schumpeter, 1911; Zaltman, Duncan, and Holbeck, 1973; Damanpour, 1991; Nohria and Gulati, 1996), or as Johannessen, Olsen, and Lumpkin (2001: 22) put it, "the degree or extent of newness that constitutes an innovation" (for an application of this question in the BMI literature, see Zott and Amit, 2007).

The fourth issue regards whether innovations are "systemic" or "autonomous" (Chesbrough and Teece, 1996; Teece, 1996). Proponents of the systemic view argue that BMI benefits can mainly be obtained if a change to the firm's core BM elements is accompanied by related or complementary changes to the adjacent elements and/or architecture. For example, Zott and Amit (2012: 48) claim that BMI "encourages systemic and holistic thinking when considering innovation,

instead of isolated, individual choices." Similarly, Stieglitz and Foss (2015) argue that the main contribution of the BMI literature to macro-management theory is derived from the construct's inherently systemic character. Conversely, other scholars submit that BMI can be pursued independently, without prompting or inadvertently eliciting spontaneous changes to other parts of the incumbent BM, while still providing significant benefits. Such views emphasize the need for separation (usually in the form of spin-offs or new, autonomous units) between the "old" and "new" BM activities (see, e.g., cf. Chesbrough and Rosenbloom, 2002; Markides and Charitou, 2004; Markides, 2013). The rationale for this approach is quite obvious. As noted by Markides (2004: 23),

the existing organization and its managers will often find that the new business model is growing at their expense. They will therefore have incentives to constrain it or even kill it. Therefore, by keeping the two business models separate, you prevent the company's existing processes and culture from suffocating the new business model.

In a related fashion, drawing on the seminal work of Simon (1962) and Henderson and Clark (1990), Foss and Saebi (2017: 216) reason that "innovating a BM where the value creation, delivery, and appropriating mechanism are tightly interdependent implies architectural change; conversely, a more loosely coupled BM will entail less architectural change but potentially much modular change." In other words, innovations can either be linked into an integrated whole or partitioned into modules.

The four issues presented above give rise to a central question, namely, what the *locus* of BMI is. Is it something that takes place within the organization, and if so, where (e.g., in the upper or lower echelons, the R&D or marketing organization) and when? Or does it emerge from the firm's external value network of inter-organizational relationships (e.g., via co-creation with customers or resource integration with key suppliers)? Or is it contingent on the type of BMI or industry in which it takes place? Or is it a combination of all these things? The answers to such questions are important because they not only can help researchers set appropriate boundary conditions and differentiate the phenomenon from other similar or related concepts, but they can also help managers pinpoint where BMI activities should take place. Unfortunately, surprisingly little research has actually attempted to identify where BMI activity resides.

The BMI literature has yet to resolve the above-stated issues. Although most scholars agree that BMI constitutes new ways of doing business, there is less agreement on what constitutes newness. Some suggest that in order to distinguish itself as an innovation, a new BM should either fulfill unmet customer needs or attract new customers (Markides, 2006), while others claim that innovation status can only be achieved by creating entirely new stages within the value chain (Schweizer, 2005), without necessarily changing the product or service itself (Velamuri et al., 2015). And then there are those who argue that the innovation must be new to the industry (Santos et al., 2009). Relatedly, scholars have assessed BMI in terms of the dimensions of radicality and incrementality based on the extent to which the change departs from existing practices within the firm or industry (Abdelkafi et al., 2013; Demil and Lecocq, 2010; Enkel and Mezger, 2013; Brink and Holmén, 2009). Yet these contributions provide little guidance to the questions "What is new?" and "How new?" With regard to the extent of innovation, some argue that it is only necessary to change a single element in the BM to realize BMI (e.g., Amit and Zott 2012; Bock et al., 2012; Santos et al., 2009; Schneider and Spieth, 2013). Others allow for "one or more" elements to be changed (e.g., Frankenberger et al., 2013; Sorescu et al., 2011). And then there are those who require "simultaneous" changes to a major number of elements (Mitchell and Coles, 2003), or an entirely new bundle including all constituent elements of the BM (e.g., Velamuri, Bansemir, Neyer, and Möslein, 2013; Yunus et al., 2010). This lack of agreement about the nature of BMI makes it difficult to arrive at an operational definition of BMI.

The ambiguity with regard to the nature of BMI may be due to the conceptual discrepancies among scholars in different silos (and within the same silo). Cavalcante et al. (2011), for example, attempt to reconcile BM change with different degrees of innovation by distinguishing between BM creation, extension, revision, and termination, while Ho et al. (2011) argue that the difference between incremental and radical BMI relates both to the number of changes made to BM components, and to the degree of innovation. That is, when both are high, BMI is said to be radical, and when both are low, BMI is considered incremental. These conceptualizations seem to reconcile highly incremental and radical changes under the same BMI heading, and involve both multiple and individual changes of the BM's constituent elements. This poses a problem of synthesis for BMI theory because there exists a large middle ground in which one of the two criteria can be high and the other low. Imagine the following scenarios: (1) the degree of innovation is high, but only a single component is changed; or (2) the degree of innovation is low, but the entire component architecture is changed. Therefore, the questions of whether scenario 1 and 2, or both, qualify as BMI remain unaddressed or inadequately specified, contributing to the growing ambiguity in the literature.

BMI as an outcome-oriented activity. A large group of scholars do not seem to avoid tautology or circularity in the sense that they include outcome variables as part of their definition of BMI. For example, BMI has been defined by its ability to find "new ways to create and capture value for its stakeholders" (Casadesus-Masanell and Zhu, 2013: 464), by its ability "to create commercial value" (Berglund and Sandström, 2013: 276), "as a novel way of how to create and capture value (Frankenberger et al., 2013: 250), or as "the discovery of a fundamentally different business model (Markides, 2006: 2). In contrast, the adjacent innovation literature generally does not claim that value creation and commercial success are necessary conditions for innovation. Furthermore, incorporating outcome variables into definitions is not advisable for proper theory building, as it results in empty definitions (Suddaby, 2010).

BMI Capabilities

The BMI literature generally recognizes that organizational capabilities are instrumental to support the ongoing BMI change process. For example, Demil and Lecqoc (2010) emphasize the importance of developing "dynamic consistency," which they refer to as the capability to build and sustain firm performance while changing the BM. Gambardella and McGahan (2010) point to the importance of "commercialization capabilities," including an orientation toward marketing, and installing and selling integrated solutions based on broader customer insights. Along similar lines, Kranz, Hanelt, and Kolbe (2016) argue for the role of "balanced capabilities" to avoid misalignments with respect to the necessary timing and scope of BM change. Achtenhagen et al. (2013) identify the need for "critical capabilities," such as experimentation, a balanced utilization of resources, and coherence between leadership, organizational culture and employee commitment, in value creation processes. However, the extant literature does not shed much light on how such capabilities can be materialized. A notable exception is found in Doz and Kosonen (2010), who emphasize the importance of achieving "strategic agility" to prompt BM renewal; the authors also show how strategic agility can be achieved through the development of three-meta capabilities: strategic sensitivity, leadership unity, and resource fluidity. The scant research on capabilities is surprising, given that they may explain performance heterogeneities in BMI, since such capabilities affect the causal mechanisms (i.e., value creation and value appropriation) through which organizational, environmental, and BM-specific attributes lead to superior or inferior performance. Moreover, firms may need specific resources that cannot be acquired in strategic factor markets, and which therefore need to be developed internally through an often lengthy and complex process (Dierickx and Cool 1989; Teece, Pisano, and Shuen, 1997). For these reasons, the question of whether firms can develop or reconfigure new capabilities for BMI becomes a fundamental strategic issue. Another important issue is due to the fact that managers must usually decide which capabilities to invest in given limited resources and managerial attention. As noted by Winter (2003: 993), "deciding whether some [capability] is needed is only a small part of the total problem of making profitable capability investments; the larger part is deciding *which* among the many promising but uncertain investments should be undertaken—recognizing there are likely to be trade-offs or other interactions among them." Accordingly, more research is needed to clarify how firms create and prioritize capabilities for BMI.

The Neglect of Organization in BMI

Although notions such as design, systems, structure, architecture, configuration, and organizational elements dot the BMI literature, only a few contributions have attempted to clarify the role of organization in bringing about BMI. Bucherer, Eisert, and Gassmann (2012), for example, highlight the importance of "organizational anchoring," that is, where BMI is located at the organizational level, and which roles and responsibilities are relevant. In their multiple-case study, the authors found that companies rarely have a dedicated organizational unit for BMI. Rather, BMI is often a shared responsibility between existing units such as marketing, business development and portfolio management. Yet, these units are supportive rather than responsible for the BMI. In contrast, most companies have a dedicated organizational structure for BMI is rare. In addition, the authors found that BMI often faces significant resistance, revealing the need for resources and power to be shifted within the organization. Khanagha et al. (2014) explore the interdependence among strategy formulation, structuring, and BMI processes, and provide more clarity on the role of different

structural forms in enabling the organization to facilitate BM transformation. In a related vein, Demil and Lecocq (2010) draw on the distinction between loose and tightly-coupled organizational systems in facilitating BMI. In particular, the authors argue that tightly-coupled systems result in more positive feedback between the BM's core components, while loose coupling applies when managers do not yet completely understand the relationships between the BM's core components. Moreover, the authors conceptualize organizational structure as a part of BMI. While Schneider and Spieth (2014) similarly highlight the role of organization by exploring the impact of BMI on different dimensions of strategic flexibility (i.e., resource flexibility, coordination flexibility, and variety of managerial capabilities), it is not conceptualized as part of BMI. Bock et al. (2012) look at the effects of culture and structure on strategic flexibility in BMI and how BMI efforts moderate those relationships. Moreover, Santos et al. (2009) highlight the different roles that corporate-level strategy plays in managing BMI. More recently, ambidextrous organizational designs have been suggested to address the issue of managing conflicting BMs simultaneously (Markides, 2013). Yet, most of this work has focused primarily on the organization as a facilitator of BMI, and perhaps more worryingly, has not built on the rich body of work on organizational theory. Not surprisingly, it remains unclear which role(s) the organization plays in bringing about BMI. Is it an antecedent, moderator, mediator, or all at the same time? Or should it be considered a part of BMI? In other words, ambiguity remains about the causal link(s) between the organizational context and BMI. One of the problems might be that firms emphasize strategic fit in discussions prior to conducting BMI, while neglecting considerations of organizational fit.

A notable exception is found in Foss and Saebi (2015), who, to my knowledge, were the first ones to address the importance of and lack of attention toward the organizational dimension of BMI. Their book contains both theoretical and empirical contributions that specifically "deal with the designable parts of organizations, that is, the boundaries and internal structuring of organizations" (Foss and Saebi, 2015: 8). Nevertheless, in a recent review of the BMI literature, the authors argue that more work is still needed before we can fully understand the organizational design aspects of BMI (Foss and Saebi, 2017).

Summary

Developments in the BMI literature over the last fifteen years and diverse observations by senior scholars have consistently indicated that the literature exhibits a number of inconsistencies, competing conceptualizations and definitions with regard to the BMI construct, as well as persisting knowledge gaps. First, no agreed-upon framework or even conceptualization of BMI has emerged, and little research has been done to systematically identify the antecedents, moderators, mediators, and consequences of BMI. Thus, there is an immediate need for theoretical and conceptual clarification to pave the way for more in-depth research on BMI. In addition, the lack of clarity and consistency has made it increasingly difficult to offer practical guidance to managers and executives. Second, too little attention has been devoted to the development of capabilities for BMI purposes. Although the BMI literature highlights a range of different capabilities, empirical evidence demonstrating how such capabilities can materialize (or disappear) is rather scant. I therefore believe that more research is required to clarify how firms can develop and dynamically adapt capabilities for BMI purposes. Third, the role of the organization is still poorly understood in the BMI literature, despite its obvious importance in fostering change that may enable the organization to facilitate BMI. The limited research focusing specifically on the organization has not systematically described the process by which an organization is changed or reconfigured to allow for BMI, nor has it clearly identified whether the organization is a part of the BMI construct or whether it serves as an antecedent, moderator, mediator, or all at the same time.

Although these represent large gaps in our knowledge about BMI, it is perhaps not surprising, given that the research on BMI has yet to fully mature. According to Foss and Saebi (2017), it is to be expected that certain characteristics of an emerging research field will remain —because the field has yet to develop into a crystallized "hard core" of key theoretical constructs and assumptions regarding a new, puzzling phenomenon (Lakatos, 1970).

In the following chapter, I will demonstrate how both BMI scholars and organizational design scholars stand to gain from a productive exchange of ideas between the fields. I first introduce relevant literature on organizational design. I then discuss its application to BMI in order to provide a more solid theoretical and empirical base from which future BMI research can emerge. Following this, I briefly discuss how an improved BMI understanding can potentially further the organizational designer's knowledge about organizational complementarities. While there are other

critical areas for future BMI research, this thesis is dedicated to the organizational design of BMIs—a topic that has been almost completely neglected in academic and practitioner-oriented circles. This also constitutes an important topic in research on the strategic management of innovation, most notably because organizational design choices can be readily implemented in contrast to softer elements such as organizational culture. Organizational design, as Gulati, Puranam, and Tushman (2009: 575) note, "represent[s] some of the most powerful strategic levers available to the top management of the modern corporation."

3

Toward an Organizational Design View of BMI

As I will argue in this chapter, organizational design and BMI are inextricably linked. In Foss and Saebi's (2015) view, the designable parts of an organization can potentially act as a cause for, a barrier to, a result of, or even an embodiment of, the firm's BMI activities. Few scholars have followed Foss and Saebi's attempt to link organizational design to BMI to gain a stronger theoretical grounding for BMI research. And yet, as noted in the introductory chapter of this thesis, there are many good reasons—especially from a BMI perspective—to engage in the productive exchange of ideas and in collaborative effort. Such integration would likely inform a number of critical questions present in both fields, as well as in the mainstream strategic management literature: Can we meaningfully articulate a theory of BMI without addressing the organization in which the activity takes place? How does the organizational structure influence BMI efforts? How does the formal organization (e.g., the allocation of resources and decision-making authority) affect the type, quality, and implementation of BMI? How and why do organizational complementarities emerge or disappear?

To answer these fundamental questions, we need to combine insights from both BMI and organizational design. The present chapter deals with the potential for exchange of ideas, although primarily from the perspective of the BMI literature. I start by emphasizing the importance of organizational design and theorize about its potential roles in the BMI process. Efforts in this regard include the identification of relevant organizational design elements as well as a definition of BMI that draws on the organizational design literature. I then discuss some of the casual relationships between BMI and organizational design in an attempt to provide a much needed theoretical basis

upon which to explore the BMI construct. I end by briefly discussing what the theory of organizational design can gain through intersection with the BMI literature.

Why Organizational Design and BMI Belong Together

Organizational design matters for several reasons. Nadler and Tushman (1997: 5) propose "that the last remaining source of truly sustainable competitive advantage lies in what [are described] as organizational capabilities-the unique ways in which each organization structures its work and motivate its people to achieve clearly articulated objectives." The designable parts of an organization serve as levers that managers can pull to improve organizational efficiency and effectiveness while providing the necessary flexibility to cope with environmental change (such as changing customer needs and new technologies). Organizational design creates the infrastructure to enable strategy implementation (e.g., Gupta, 1987; Drazin and Howard, 1984). It provides accountability and motivation to employees by clearly defining roles and responsibilities. Design features have been associated with different types of innovation (Abernathy and Utterback, 1978; Aiken and Hage, 1971; Daft, 1978; Damanpour, 1991; Lakhani, Lifshitz-Assaf, and Tushman, 2012), are used as information processing mechanisms that accelerate information flow and streamline decision making (Simon, 1945; Thompson, 1967), or can be seen as ways to absorb external knowledge (Jansen, van den Bosch, and Volberda, 2005; Foss, Laursen, and Pedersen, 2011). The combined forces of competition and globalization force companies to split up their activities and search for foreign inputs, markets, and partners. This may lead to more division and the offshoring and/or outsourcing of core activities, which in turn result in added organizational complexity and a need to develop organizational design mechanisms that can accommodate such challenges (Pedersen, Venzin, Devinney, and Tihanyi, 2014).

At a more general level, organizational design has some other notable features. First, it is durable and set up in such a way to allow it to persist over time by routinely and continuously supporting a myriad of activities (Hannan and Carroll, 1995). As noted by Scott (1998: 23), "attaining stability over time in spite of shifting participants is one of the major functions of formalization." This is likely to be important for BMI, since new BMs rarely work when they are first introduced (Sosna et al., 2010). Second, organizational design provides reliability in the sense

that structures, rules and routines are set up to do the same activities over and over again (Scott, 1998)—a feature that is likely to be beneficial for more incremental types of BMI.

As shown in the previous chapter, the BMI literature often refers to notions such as design, system, structure, configuration and architecture. This directs attention to constructs that are central to organizational design, such as information processing (e.g., Simon, 1945; Thompson, 1967), contingency and fit (e.g., Lawrence and Lorsch, 1967), organizational structure (e.g., Child, 1972), complementarities (e.g., Milgrom and Roberts, 1990) and interdependence (Aiken and Hage, 1968). Thus, it seems that organizational design plays a key role in coordinating BM activities between multiple stakeholders and supporting integration across the value creating and value appropriating processes of the firm. In other words, design choices seem to be an integral part of a firm's BM so as to support the firm's core strategy. This notion is particularly apparent in Santos, Spector and Van der Heyden's (2015: 47-48) view of BMI. According to them (Table 3.1), BM changes can be characterized as

(1) *reactivating* (an alteration that either adds to or removes an activity from the incumbent business model), (2) *relinking* (an alteration that involves either changing the transaction governance among activities or the interdependence among organizational units in the incumbent model), (3) *repartitioning* (an alteration that moves the organizational units performing an activity), [and] (4) *relocating* (an alteration that maintains the existing activity set of the incumbent model while moving the organizational unit to another country).

Classification	Туре	What is Changed
Reactivating —altering the set of activities performed by the company	Adding	Adding to the activity set of a company's business model
	Removing	Removing from the activity set of a company's business model
Relinking —altering the linkages between activities	Regoverning	The governance of transactions between market, hierarchy, and hybrid
	Resequencing	The order in which organizational units perform activities

Table 3.1 Typology of BM change

Toward an Organizational Design View of BMI

		or The interdependence among organizational units between pooled, sequential, and reciprocal
Repartitioning —altering the boundaries of the focal company by moving an organizational unit across boundaries	Insourcing/outsourcing	The location of an organizational unit moves from outside to inside the company or from inside to outside the company
	Reassigning	The location of an organizational unit moves from one unit to another within the company
Relocating —altering the (physical, cultural, and/or institutional) location between organizational units performing activities	Off-shoring	The geographic location of an organizational unit moves from the company's home country to a foreign country
	On-shoring	The geographic location of an organizational unit moves from a foreign country into the home country

Source: Adopted from Santos et al. (2015).

Based on these insights, BMI can be defined as *the reconfiguration of a firm's core BM elements and/or architecture by weaving these elements together into a system that will enable the firm to create and deliver value to its target segment(s)* (Foss and Saebi, 2017; Santos, Spector, and Van der Heyden, 2009). Such changes are closely linked to changes in the firm's task environment, communication flows, roles and responsibilities, incentives and control systems—all of which are essentially changes to the various design features of the organization.

As discussed earlier, BMI is heterogeneous. Some instances may be "incremental" in nature and deviate little from the original model, while others are more "radical," involving the development of entirely new value propositions. Thus, different cases of BMI may differ with respect to the "depth" of changes (Katila and Ahuja, 2002). In a similar fashion, BMI can also be characterized in terms of "scope" or "breadth," that is, some BMI may involve numerous changes to the individual BM elements ("architectural changes"), while others cases are confined to changes made to one or few elements ("modular changes"). More specifically, architectural changes rewire complementarities across business units and departments, while modular changes do not require changes in other parts of the BM or organization (Stieglitz and Foss, 2015). Stieglitz and Foss (2015) offer a useful framework that combines the two dimensions of BMI—notably, the depth and the breadth of (intended) changes to an existing BM.

Given the above, it seems appropriate to draw on extant theorizing on organizational design to gain a more holistic understanding of BMI. The key premise of organizational design theory is that organization "solves" the problems of coordination that arise when integrating across a large number of interdependent activities (Galbraith, 1974). A considerable body of work in this domain has identified a set of key variables along which design features may be changed to solve problems of coordination. More specifically, this is achieved through means of structure, allocation of resources and work tasks (e.g., Burton and Obel, 2004; Burns and Stalker, 1961; Miller and Dröge, 1986), such as (job and unit) specialization, and coordination of communication and information flows (Tushman and Nadler, 1978; Daft 1986). Organizational design is therefore likely to influence the efficiency with which existing resources can be utilized (Zahra and Nielsen, 2002) and it forms the context for strategic choices (Lefebvre, Mason, and Lefebvre, 1997). Since BMI usually involve changes along these variables, organizational design is likely to be linked to the type, quality and quantity of BMI it produces. Moreover, organizational design constitutes an important topic within research on the strategic management of innovation, notably due to the fact that organizational design choices can be readily implemented, in contrast to softer elements such as organizational culture. Given this understanding, organizational design offers a highly useful starting point from which develop a conceptual framework that will be useful for empirical work, and it can contribute to the development of a cumulative, robust, and testable theory of BMI.

Organizational Design Drivers of BMI

While most contributions in the BMI literature focus on environmental changes (e.g., globalization and new technology) as drivers of BMI, a firm's organizational design is also likely to constitute an important driver. Given that organizational design, among other things, determines a firm's division of labor (i.e., roles and responsibilities), its boundaries, and its ability to process information, it is likely to influence which part(s) of the BM get(s) innovated. Some organizations may develop very flat structures with considerable autonomy given to employees to start and participate in new and innovative projects. For example, Oticon's adoption of this type of design restored the organization's entrepreneurial spirit and resulted in a series of breakthrough innovations that led to notable financial performance (see Foss, 2003). Dell's revolutionary *disintermediation* BM was driven by design choices, namely the alteration of the firm's boundaries by cutting out the traditional distributors of PCs. While this BMI also required new technology, especially ICT, the main motivation to change the BM was the organizational design.

A number of scholars have associated BMI with the need for learning and experimentation (cf. Sosna et al., 2010; McGrath, 2010; Doz and Kosonen, 2010; Chesbrough, 2007; Wirtz et al., 2010), with organizational change processes (Dunford et al., 2010), and with the importance of strategic sensitivity, leadership unity, and resource fluidity (Doz and Kosonen, 2010). Learning, organizational change, and the like may in turn be determined by the firm's organizational design. For example, IKEA's direct delivery and self-assembly model within the furniture industry was driven by design choices. Foss and Jonsson (2011: 1079) found that "IKEA has developed organizational mechanisms that support an ongoing learning process aimed at frequent modification of the format for replication. Another finding [was] that IKEA treats replication as hierarchical: lower-level features (marketing efforts, pricing, etc.) are allowed to vary across IKEA stores in response to market-based learning, while higher level features (fundamental values, vision, etc.) are replicated in a uniform manner across stores." Likewise, strategic sensitivity and sensing are also likely to be driven by organizational design considerations. In particular, the size and composition of the top management team might influence the company's ability to interpret signals in the environment that may call for BM changes. A large top management team composed of diverse specialists who interact with the operational levels is in a good position to detect such signals (Foss and Saebi, 2015). The level of delegation of nontrivial tasks in an organization also matters. If employees (e.g., in marketing and R&D) are given extensive decision rights that enable them to cooperate more closely with external stakeholders, they will be more likely to be in the position to sense the need for BM changes (Foss and Saebi, 2015) and drive such change.

Key Organizational Design Barriers to BMI

The BMI literature has identified several organization-based barriers to BMI, including organizational inertia, lack of capabilities, and lack of rules and regulations (e.g., Chesbrough, 2010; Richter, 2013; Hwang and Christensen, 2008). However, despite the potential role of organizational design in preventing or significantly slowing down BMI efforts, this topic has not

received much attention so far. Firms that attempt BMI may find that their existing design obstructs such efforts. Firms are often bound by their capacity to process information and to make sense of experience (March and Simon, 1958). Thus, information overload may be considered a barrier to BMI because learning everything about a new BM is difficult when there is so much to know and so much information to process. This challenge is compounded if firms decide to keep the valueadding activities of their existing BMs intact. Gaining access to relevant information and knowledge can present a challenge. The functional boundaries of an organization may restrict access to the relevant information and knowledge needed to undertake the cooperative and collaborative activities of BMI. For example, firms often separate innovative activities from the rest of the organization (Galbraith, 1982) by creating distinct organizational units. This is intended to shelter such activities from the existing organization, as they often involve markedly different processes, structures, and goals. While innovation is characterized by unpredictability, experimentation, and randomness, more conventional activities rely on predictability, efficiency, and reliability. The innovation units are thus "loosely-coupled" (Weick, 1982) to the rest of the organization, with the purpose of mitigating unpredictability (Blau and Scott, 1962). Although this creates a favorable context in which creativity and innovation can flourish, the choice also has some less desirable consequences. Without proper integration mechanisms, isolated units may become repositories of knowledge that are rarely accessed (Lyytinen and Robey, 1999). This represents a considerable issue, since BMI is a systemic activity that involves a variety of actions taken within the larger system of which it is a component part. In other words, by separating learning (innovation) from doing (implementation), organizational designs make the results of BMI distant and something that can be easily ignored by the rest of the organization.

The incentive systems of companies are usually designed to provide rewards on the basis of performance success rather than error or failure. Because of this, unsuccessful projects tend to be erased from the organization's memory out of fear that they will recur. Consequently, important knowledge is lost and cannot be used for learning and testing purposes. This situation is highly problematic due to the discovery-driven, trial-and-error-based, and experimental nature of BMIs (e.g., McGrath, 2010; Smith et al., 2010; Sosna et al., 2010). Relatedly, formal rules and procedures commonly attributed to organizations with a mechanistic structure may lower organizational commitment because such a design usually becomes a barrier to providing a service.

Implementing BMI through Organizational Design

Despite the relevance of the topic, no work, to my knowledge, has systematically linked organizational design to the implementation of BMI. That is not say that implementation challenges related to BMI have been neglected; actually, this is far from being the case (e.g., Chesbrough and Rosenbloom, 2002; Magretta, 2002; Casadesus-Masanell and Ricart, 2007; Chesbrough, 2007, 2010; Demil and Lecoq, 2010; Doz and Kosenen, 2010; Teece, 2010; Zott and Amit, 2010; Amit and Zott, 2012). However, the existing research tends to focus more on the impediments to BMI. such as organizational inertia and resistance-and less the on managerial actions that are likely to reduce or remove such impediments. This is unfortunate, as we are thereby denied the opportunity to develop insights into how BMI is implemented after its initial adoption. Given that BMI varies in nature between cases, may occur at different levels, and can be both internal and external to the firm, organizational design is potentially an important facilitator of BMI. First of all, the purpose of organizational design is to "solve" the coordination problems that arise with interdependent activities. Due to the highly systemic nature of BMI, such problems are likely to occur frequently. Interdependencies or complementarities among BM activities are central to BMI due to their valueenhancing effect (Amit and Zott, 2012). Moreover, complex interactions between many complementary activities are arguably more difficult for would-be imitators to copy than standalone activities (Barney, 1991; Porter and Rivkin, 1997). Such interdependencies or complementarities may be facilitated by the use of organizational design principles, that is, design choices that encourage managers and employees to actively shape and design both the organizational activities and the links (transactions) that weave BM activities together into a system.

The allocation of resources has an obvious impact on the proficiency with which BMI-related tasks will be implemented. If adequate resources (in terms of manpower, time and finances) are committed, then the BMI is more likely to progress through the initial phases of the implementation process. A cross-functional interface is a design mechanism that brings together various sources of expertise and increases lateral interaction between functional areas. It facilitates non-routine and reciprocal information processing (Egelhoff, 1991) and contributes to an organization's ability to overcome differences, interpret issues, and build understanding of new knowledge (cf. Daft and Lengel, 1986). In addition, it supports employees in rethinking the systemic nature of existing

activities and in revisiting the ways that components are integrated (Henderson and Cockburn, 1994). When armed with such architectural knowledge, it is likely to be easier for managers to identify how BM change efforts fit with the existing BM and organizational architecture. In other words, design choices may indirectly contribute to the development of BMI-specific capabilities.

Formalization may help increase the legitimacy of more radical forms of BMI. BMI that is new to the world or industry may be constrained by a lack of legitimacy, credibility, and acceptance from important external stakeholders, including customers, providers of external marketing, suppliers, and distributors (cf. Aldrich, 1999; Stinchcombe, 1965). Due to the uncertainty associated with such BMI, customers and providers may rely on symbolic signals of competence. Formal positions such as Chief BMI Officer or Vice President of BMI signals can be introduced to signal management experience and know-how. Given that access to the external value network is critical for BMI, the increased credibility and legitimacy associated with role formalization will likely ease the implementation of a new BM.

At a more general level, the organizational design can be viewed as a source of learning. Such new learning may in turn facilitate the growth of new capabilities that can serve as the foundation for new BMs. As stated by Foss, Pedersen, Pyndt, and Schultz (2012: 21), even if "resources and capabilities are *stocks* that may yield a *flow* of services, such services do not appear automatically [...] Rather, they are called forth and the diverse services from diverse resources have to be coordinated," which is the main purpose of organizational design.

Two sides of the same coin?

The organizational design itself is likely to constitute an inherent part of many BM innovations. Not only is it a powerful lever that managers can use to change elements in the existing BM, but it is also part of the BMI outcome in its own right. For example, to realize the benefits of open innovation models, firms need to deploy different design mechanisms, such as extensive delegation, intensive lateral and vertical communication, and rewards for knowledge sharing (cf. Foss, Laursen, and Pedersen, 2011). In a similar fashion, firms that aspire to considerably increase the service content of their BMs must enact changes throughout their existing organizational design (Kindström and Kowalkowski, 2015). Because service-based BMs often involve a high level of "co-creation," the underlying organization needs to be designed in such a way that external parties

are allowed to take part in the company's specific activities (Storbacka, Frow, Nenonen, and Payne, 2012).

In general, many of the challenges associated with BMI are to a large extent organizational design challenges that require new structure and control mechanisms, as well as choices regarding firm boundaries vis-á-vis other firms (Rasmussen and Foss, 2015). Different types of BMI and their supporting organizational structures are often followed by adjustments and/or renewal in other areas. For example, pharmaceutical firms deploy a number of complementary organizational practices (such as reallocation of resources and decision rights, lateral communication, and workshops) to mitigate the new coordination problems that arise from a changing task environment (Rasmussen and Foss, 2015). In a similar fashion, Birkinshaw and Ansari (2015) argue that BMI often requires changes to the firm's "management model," that is, the structuring, coordination, and motivation for work; the setting of goals; and the allocation of resources. In other words, organizational design seems to be intimately connected to the BMI construct and may be partly endogenous to it.

What can organizational designers gain from BMI?

Most of the classic organizational design research in the management literature is biased toward more traditional types of innovation (such as product and process innovation) and predominately focuses on large manufacturing firms (Damanpour and Gopalakrishan, 2001; Henderson and Clark, 1990; Chandler, 1962). And yet, academics and practitioners seem to agree that, in the present environment of globalization, intensified competition and ICTs, a sustained competitive advantage is more likely to emerge from BMI activities. In particular, the holistic nature of BMI is well-equipped to capture pieces of knowledge and bundle them together in such a manner that it becomes difficult for imitators to determine how the value is created and appropriated. This view accords with those found in the stream of organizational design literature that deals with the notion of new organizational forms. This notion "was propagated as shorthand for what was seen as a surge of firms experimenting with their [organizational designs]; that is, adopting new ways of structuring their boundaries and their internal organization" (Foss, 2005: 11). For example, "the learning organization," "shamrock firms," "the hollow corporation," "the hypertext organization,"

management vocabulary (Foss, 2005; Lewin and Volberda, 1999). The common characteristics of these new organizational forms were an emphasis on cross-functional teams, extensive delayering, empowerment, faster decision making, decentralization, widespread use of ICTs, and high-powered incentives (Child and McGrath, 2001; Zenger and Hesterly, 1997). Some scholars even "argue that 'traditional' coordination mechanisms such as price, authority, routines, standardization, etc., will diminish in relative importance" (Foss, 2005: 11).

However, empirical validation of these new organizational arrangements and their offshoots remains limited, and the results mixed. According to Foss and Klein (2012), much of the empirical evidence on delegation and decentralization is not particularly clear. Relatedly, Lewin and Volberda (1999) note that most of the work on new organizational forms is based on retrospective accounts of single case studies. Yet, there is considerable evidence for the increasing adaptation of high-performance work practices in specific industries and firms (e.g., Ichniowski, Kochan, Levine, Olson, and Strauss, 1996; Capelli and Neumark, 2001; Delaney and Goddard, 2002). These diverging accounts indicate that gaps still exist in our knowledge of new organizational forms, especially with regard to how they emerge (cf. Romanelli, 1991).

By adopting a BMI perspective, organizational design scholars may be better able to address some of these perplexing issues. As mentioned several times previously, the holistic characteristics of BMI are likely to have organization-wide implications. For example, in a multiple-case study of seven manufacturing firms, Kindström (2010) looked at the transition from product-based BMs toward service-based models. He found that a redesign of the organization (including a new reward system, new means of communication, dedicated roles for service, coordination across firm boundaries, etc.) was needed in order to incorporate the increased service content. In other words, a fundamentally different organizational form or architecture was created as a consequence of BMI activities. Moreover, the BMI perspective may also help reconcile the mixed evidence on delegation and decentralization. Although the organizational design literature frequently invokes these terms when talking about ways to increase creativity, innovation, knowledge sharing, and faster decisionmaking, they may produce less desirable outcomes during the implementation stage of BMI, especially if the intention is to completely transform the entire BM. The firm would not only incur substantial coordination costs, but would also forgo speedy implementation, as various organizational units and functions would need to haggle over budget and resource allocations, or about the design of the BM and the underlying organization. On the other hand, in the early stages of a new BM, delegation and decentralized structures might be useful for developing novel BMI ideas and carrying out BM experiments in distinct markets or units. In other words, the ability to detect or perceive organizational complementarities during various stages of the BMI process is critical. While the organizational design literature has dealt with the concept of complementarity for nearly three decades, little is known about "the conditions under which complementarities are likely to emerge, or on the nature of the elements or factors (e.g., organizational characteristics) among which complementarities exist" (Ennen and Richter, 2010: 2). This may in part be due to the narrow perspective offered by organizational design theory, which usually deals with the organizational design aspects of strategy and innovation implementation (i.e., the *how*). In contrast, the holistic approach offered by the BMI construct may be better for grasping complexities that stem from organizational complementarities, since it extends the *how* to the *what* and *who*. As such, the BMI literature offers a process view that not only can help us better understand why some of these new organizational forms fail in certain situations and succeed in others, but it can provide ample detail on complementarities.

Summary

Organizational design theory provides important conceptual and empirical bases for understanding the emerging field of BMI. Not only does it deal with similar or related terms such as systems, structure, architecture, complementarities, etc., but it also deals with coordination issues arising from interdependent activities. Since BMIs are widely regarded as holistic and systemic in nature, such coordination issues are likely to occur often. To solve these issues, managers can use the designable elements of the organization to redefine the value proposition, value chain and mechanisms of appropriation by, for example, establishing new organizational units, determining budget and resource allocations, and revising work tasks and responsibilities. Thus, the theory of organizational design and the literature on BMI seem to be intimately linked. As such, I argue that the firm's organizational design is likely to play several roles in the BMI process, including that of a driver, a facilitator, a barrier, or even a configuration that embodies both the core BM elements and the underlying architecture. Toward an Organizational Design View of BMI

The BMI literature may help further our understanding of new organizational forms and complementarities. In particular, BMI calls for organization-wide attention, which may in turn lead to the development of a fundamentally different organizational form. Moreover, while the classic organizational design literature mainly focuses on *how* strategy, innovation and change can be implemented, the BMI construct focuses on the *what*, *who* and *how* simultaneously. Such a holistic approach is probably better able to explain why organizational complementarities can be achieved/approximated (or why not) than more limited viewpoints can.

4

Methods

As noted in the previous chapters, research on BMI is still in a nascent stage, and it has yet to develop into a mature field of study with clearly distinguished constructs and articulated relationships between them. The role of organizational design in particular is poorly understood. The purpose of this study is to build theory by conceptually and empirically linking BMI to organizational design theory in answer to recent calls for a more comprehensive understanding of the organizational dimension of BMI (see Foss and Saebi, 2015). Specifically, this research aims to shed light on the context of *BMI* and how such innovations have unfolded in three select players of the pharmaceutical industry—with a particular focus on the role of organizational design in the process of BMI. In what follows, I start by discussing the appropriateness of the study's research design for answering this type of research question. I then describe the research context from which the cases were sampled. Next, the sources of data (collection procedures) are examined, and the chapter ends with a discussion of the data analysis methods.

Research design

To advance our understanding of the role of organizational design in BMI, I draw on an inductive, multiple-case study design (Eisenhardt, 1989). This qualitative research design is appropriate because it allows for a higher level of immersion, and thus learning, about which organizational design and BMI constructs are important, and how they may be causally related (Birkinshaw, Brannen, and Tung, 2011; Doz, 2011; Eisenhardt, 1989; Edmondson and McManus, 2007). Such an in-depth qualitative inquiry is also useful for capturing the systemic, complex and dynamic aspects of BMI, which require attention to immediate, local causes and temporal causal

orders (Miles and Huberman, 1994) as well as to the need for rich contextual and situational information and data. It is exactly this level of depth that makes multiple-case study research particularly useful for unpacking a complex phenomenon about which little is known (Eisenhardt, 1989; Gephart, 2004). As Dyer and Wilkins (1991: 617) explain, if performed appropriately, case studies can be

extremely powerful [when] authors have described general phenomena so well that others have little difficulty seeing the same phenomena in their own experience and research. We turn to the classics because they are good stories, not because they merely clear statements of a construct.

In large-*N* research, the distance between conceptual constructs and measureable variables is often significantly larger, which makes it harder to (1) really capture the underlying mechanisms, (2) determine whether a causal relationship between A and B actually exists, and (3) unravel the underlying dynamics of phenomena that play out over time (Siggelkow, 2007). While in this thesis the theoretical background precedes the empirical material, the study is phenomenon-driven and intended to provide inspiration rather than an illustration of theory (Siggelkow, 2007).

Specifically, this study is exploratory and designed to build theory on BMI and allow for theory development in an area where research is currently sparse (Strauss and Corbin, 1998). To do this, I draw on a multiple-case study design because it allows for more theory-driven variance and divergence in the data than single-case studies. It permits cross-case comparisons that can help clarify whether an emerging insight is simply idiosyncratic to a single case or consistently replicated in other cases (Eisenhardt, 1991). Such corroboration can help researchers more easily identify patterns of covariation and remove variables that do not show covariance with the dependent variable. For instance, if both of two firms under study change their organizational design to accompany BMI, it may indicate that the role of organizational design is not merely isolated to a single case, and could therefore point to a more widespread phenomenon. Moreover, key constructs and causal mechanisms are more precisely specified because it is easier to infer accurate definitions and obtain sufficient levels of construct abstraction from multiple cases (Eisenhardt and Graebner, 2007). For example, Ambos and Birkinshaw (2010) studied the process of evolution in new ventures, some of which focused on technology and capability development,

while others stressed market needs and alliance partners during the evolution process. Through the use of multiple cases, the authors were able to reach an appropriate level of abstraction to more accurately describe and specify the various archetypes of evolutionary change in science-based ventures.

The cases in the present study were selected with the primary objective of achieving maximum variation along relevant dimensions while keeping other dimensions fixed.² This required the selection of cases that would enable me to display the full range of heterogeneity characterizing X, Y, and some particular X/Y relationship (Seawright and Gerring, 2008). Thus, I deliberately chose both typical and atypical cases of BMI, as will be discussed further below. This level of heterogeneity will allow me to highlight complementary aspects of the phenomenon, specifically by matching up the individual case patterns in order to produce a more complete theoretical understanding of BMI. For example, Patton (2002: 235) asserts that maximum variation sampling yields "(1) high-quality, detailed descriptions of each case, which are useful for documenting uniqueness, and (2) important shared patterns that cut across cases and derive their significance from having emerged out of heterogeneity." This in turn leads to more robust theory because propositions are derived from, and rooted in, more varied empirical evidence.

Another important aspect of the research question relates to the processual nature of BMI. Process-based theorizing focuses on the temporal order and sequence by which a discrete series of events, activities or choices produces a phenomenon (Abott, 1988; Langley, 1999; Mohr, 1982). Rather than showing changes in the states of BMI or what causes BM change, process-based theorizing shows us *how* change occurs by specifying the "sequence of events in terms of some underlying generative mechanisms or laws that have the power to cause events to happen in the real world and the particular circumstances or contingencies when these mechanisms operate (Van de Ven and Huber, 1990: 213)." As such, the process-based view supports the maximum variation method. More specifically, while variance-based theorizing aims to explain the relationships between X and Y by isolating the net effects of single variables, process-based theorizing explains why the relationship exists by developing a story about how a series of events unfold that allow X

² The maximum variation method is related to J. S. Mill's joint method of agreement and difference (Mill, 1872), which is to say, a combination of the most similar and most different cases.

(independent variable) to exert its influence on Y (dependent variable) (Van de Ven and Huber, 1990).

Throughout the present multiple-case study, I adopt an inductive approach inspired by the grounded theory method (Strauss and Corbin, 1990), which is well-suited to building new theory. However, I do not enter the research context with a "blank mind," in line with what Suddaby (2006) recommends. Rather, I rely on the theoretical background introduced in the previous chapters as a practical starting point and stimulus for the study.

Research context

The pharmaceutical industry is an ideal context in which to study BMI. The sector has attracted a great deal of general interest because of its importance in the development of medical innovations, and partly due to this reason, has been subject to heavy regulation around the world (Rasmussen and Foss, 2015). The pharmaceutical industry has also stimulated long-standing scholarly interest because of the emphasis on innovation, environmental influences, persistent abnormal returns, and the dynamics of firm boundaries that have defined this industry (e.g., Henderson and Cockburn, 1994; Penner-Hahn, 1998; Pisano, 1991;). More recently, questions about whether the industry's traditional BM (the so-called "blockbuster" model) is becoming obsolete or at least insufficient, have dominated academic debate (Gilbert, Henske, and Singh, 2003; Kola and Landis, 2004; Munos, 2009; Christensen, Grossman, and Hwang, 2009; Lindgardt, Reeves, Stalk, and Deimler, 2009; Chesbrough, 2010; Gambardella and McGahan, 2010). The reason for this is that the industry, on the whole, is currently facing significant structural, technological, and regulatory change.

With regard to structural change, a number of changes related to the costs of health care along with a decreased willingness and ability of governments and insurance carriers to pay for treatments have jointly driven industry margins down. This trend has been exacerbated by a growing emphasis on fiscal austerity since the onset of the financial crisis in August 2007. Data from the Organisation for Economic Co-operation and Development (OECD) (2015) shows that per capita spending on health care across the OECD countries has slowed down in the wake of the financial crisis. From 2009 to 2013, the average annual health care spending growth in the OECD countries was 0.6%, in contrast to the 3.4% in the period between 2005 and 2009. The data also indicate that prior to 2005, spending on pharmaceuticals grew at faster rate than any other health care service, including

inpatient and outpatient care, and was a major driver of overall health care expenditures (see Figure 4.1). Over the following decade, however, the growth in pharmaceutical spending significantly slowed as patents for many blockbuster drugs expired and cost-containment policies were implemented, particularly as a consequence of financial turmoil in the economy. In addition to this, increasing life expectancies, coupled with declining fertility rates, mean that older people are making up an ever-greater proportion of the population across the OECD countries. For example, on average, within the OECD, the share of the population aged over 65 rose from less than 9% in 1960 to 15% in 2010, and is projected to double in the subsequent four decades to reach approximately 27% in 2050 (OECD, 2015). Similarly, population ageing is expected to accelerate in countries like China, India, Indonesia and Brazil. This demographic trend will put further pressure on health care payers, since people aged over 65 years consume the most medicine per capita. As a result, health care payers are taking measures to reduce drug expenditures, meaning that pharmaceutical companies can no longer expect the same favorable reimbursement levels or enjoy market exclusivity for the entire patent life of a product, and nor can they afford to continue clinical development of drug candidates with no demonstrated superiority over existing treatments.

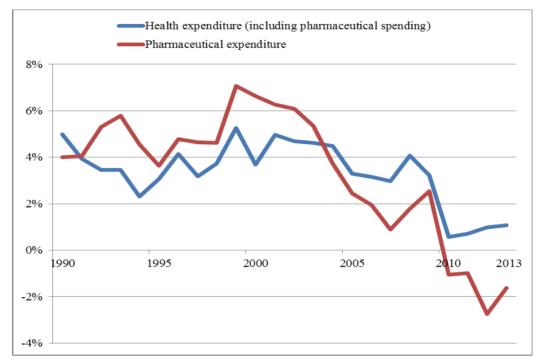


Figure 4.1 Average annual growth in pharmaceutical and total health care expenditures per capita, in real terms, averaged across OECD countries, 1990 to 2013. Source: OECD Health Statistics 2015

In terms of technological change, despite steadily increasing expenditures on R&D during the last two decades, the pharmaceutical industry is facing a continuous decline in the number of new product approvals (Light and Lexchin, 2012). This is partially due to the fact that the industry has already collected all the "low-hanging fruits" and partly due to conservative management practices (Munos and Chin, 2011). Thus, it seems that the industry's conventional BM is not well calibrated for today's environment of escalating health care costs and an emphasis on true innovation rather than marginal improvements of existing treatment regimes. On the other hand, today's environment presents a number of opportunities for the industry to reinvent and reinvigorate its BM. Recent advances in ICTs provide an opportunity for pharmaceutical companies to create new value for patients, payers, and health care professionals. Through the use of digitized health information systems, the introduction of new mobile digital devices and wearable, implanted or inserted biosensors, and the digitization of individuals' genomic sequencing data (Lupton, 2013),

pharmaceutical companies can potentially help patients improve their treatment outcomes and compliance. However, the rise of ICTs also means that patients are more empowered by "ondemand" access to information, which will, in turn, make them more critical toward treatment options.

With regard to regulatory change, regulators have become increasingly tough in the last decade and a half, giving rise to new and challenging impediments that must be cleared by any new drug candidate prior to market entry. Data offered by George Mason University's Mercatus Center and analyzed by *Regulatory Focus* shows that the number of regulatory requirements imposed by the US Food and Drug Administration (FDA) rose by 15% between 2000 and 2012.³ These requirements include safety and efficacy evaluations, pricing and reimbursement, patient reported measures, and additional clinical trial data and reporting requirements. As a consequence of this more cumbersome regulatory process, drug development costs have increased.

For these reasons, the pharmaceutical industry provides a compelling context in which to study BMI. It is an industry that is undergoing unprecedented changes caused by growing demand from payers, a strengthening of the role of patients and other stakeholders, a changing regulatory environment, and perhaps most importantly, the declining success of the industry's traditional "blockbuster" model (see the following chapter for a more detailed description of the industry context). Moreover, the industry constitutes a somewhat homogenous organizational field (Eisenhardt, 1989) in the sense that its firms have similar relationships with key stakeholders (such as patients and physicians) and deal with the same regulatory, compliance and payer environments; such homogeneity is important for minimizing external variation beyond the phenomenon of interest, thereby allowing cross-case comparisons to be made.

Sampling of cases

The unit of analysis in this study is the BMI process in the focal firm. Specifically, I seek to improve our understanding of not only the BMI activity as it unfolds, but also the various roles of organizational design, as well as where the activity resides. The research looks at three cases of BMI, and in all cases the focal firm is attempting to transition from a predominately product-

³ Retrieved January 2017 from <u>http://www.raps.org/Regulatory-Focus/News/2014/10/30/20656/Its-Not-Just-You-FDA-Regulatory-Regulato</u>

centered orientation toward more of a service orientation. The transition is driven by a host of external factors, such as cost containment measures, advancements in digital health technologies, and more stringent regulatory requirements, as well as internal motivators, such as new sources of revenue, opportunities for differentiation and stronger customer relationships (Vandermerwe and Rada, 1988; Kindstöm, 2010). The three selected case firms also share a number of other similarities that will aid with comparison and replication, yet display sufficient heterogeneity so as to produce a more complete and accurate theory of BMI. The selection method used is known as maximum variation sampling, in which the selected cases vary on one or a few dimension(s), while sharing similar characteristics on others (Flybjerg, 2006; Seawright and Gerring, 2008). Specifically, my aim was to select a range of cases that would exhibit the full range of heterogeneity to be found among the empirical occurrences of the phenomenon under study (Paton, 2002). As such, I attempted to achieve representativeness of all aspects of BMI across the case firms, meaning that I selected both typical and atypical cases of BMI.

In terms of similarities, I selected pharmaceutical companies that (1) are moving into services, (2) are predominately focused on treatment of chronic conditions, and (3) have a somewhat narrow value proposition. For the first point, transitioning into an increased service orientation is likely to cause changes to the focal firm's existing BM, as services involve a number of attributes that are fundamentally different from products. While products are tangible entities separate from the producer, services include characteristics such as intangibility, inseparability of production and consumption, heterogeneity and perishability (Parasuraman, Zeithaml and Berry, 1985). These differences present a number of managerial challenges. For example, Oliva and Kallenberg (2003: 161) argue that "services require organizational principles, structures and processes new to the product manufacturer. Not only are new capabilities, metrics and incentives needed, but also emphasis of the business model changes from transaction- to relationship-based." It should be noted that the case firms did by no means abandon their core value proposition of drug development and delivery. Rather, services are being used as add-ons to provide additional value to the core product offerings. Among other things, the new services included patient support programs, educational services, pricing schemes and various devices for more convenient drug delivery. Regarding my second criterion, I selected firms with a focus on treatment of chronic diseases such as diabetes, psoriasis and, epilepsy for two reasons. First, patients live with the disease for many years or even

for the rest of their lives, and they and their families must be educated on how to adapt and cope with the condition. These patients are often the most demanding in terms of treatment outcomes. They also tend to be more knowledgeable than other patient segments about treatment options offered by health care providers. Second, health care payers are aware of the fact that chronic diseases place a substantial economic burden on society if not managed properly and promptly. According to the World Economics Council and the Harvard School of Public Health, the cost of chronic diseases is expected to account for a staggering 48% of global gross domestic product by the end of 2030 (Dietert and Luebke, 2012). Payers must place an increased focus on chronic diseases and put pressure on drug prices as well as market access; the use of generics is also dramatically increasing (cf. Alazraki, 2011). Consequently, pharmaceutical companies serving the chronic disease segments are more likely to make frequent changes to their incumbent BMs than others. In line with the third criterion, large pharmaceutical conglomerates (such as, Merck, Pfizer and GlaxoSmithKline) were purposely omitted from the sample because they operate in so many disease or therapy areas; this would make it complicated to observe and isolate the dynamics of BMI. Instead, firms with narrower value propositions (e.g. fewer disease areas) were selected, allowing me to more easily study the phenomenon.

To gain heterogeneity, I chose firms specialized in different disease areas—diabetes, epilepsy and psoriasis—that were of various sizes in terms of annual revenues, number of employees, number of patients and number of markets. This enabled me to identify settings in which various types of BMI can emerge and develop. Table 4.1 provides an overview of the three cases: Novo Nordisk, UCB Pharma and LEO Pharma. Studying such diverse players provided a better grounding for the emerging theory than a more homogenous group would have (Harris and Sutton, 1986).

Characteristics	Novo Nordisk	LEO Pharma	UCB Pharma
Services	Drug delivery devices, pricing schemes and educational services	Patient support programs and drug delivery devices	Patient support programs and drug delivery devices

Table 4.1 Overview of case firms

Type of condition and specialization	Chronic (diabetes)	Chronic (psoriasis)	Chronic (epilepsy)
Therapy areas	Diabetes, obesity and hemostasis	Dermatology and thrombosis	Central nervous system and immunological disorders
Annual revenues (millions)	DKK 78,026	DKK 8,216	EURO 3,462
Number of employees	34,731	4,783	9,048
Number of markets (countries)	75	61	66
Year founded	1923	1908	1928

Sources: The firms' 2012 annual reports

Novo Nordisk is one of the most successful pharmaceutical companies in the world, having demonstrated double-digit growth for twelve consecutive years, the longest streak among European companies. It is also the most specialized of the three firms, with a strong and narrow focus on diabetes. For example, 78%⁴ of Novo Nordisk's total sales in 2012 were generated by the diabetes care business. Interestingly, despite many industry experts' claims that the days of the conventional BM (the "blockbuster" model) are numbered (Aspinall and Hamermesh, 2007), Novo Nordisk is leveraging existing capabilities to enact a more or less incremental change to the basic value proposition. The company's narrow focus and extensive experience in diabetes care have allowed it to perfect the model to a degree almost unmatched by any other pharmaceutical company. As such, Novo Nordisk represents an atypical case of BMI. In particular, the case illustrates that, despite claims that the conventional BM is becoming obsolete, it is still viable—although environmental pressures, such as soaring health care costs, and technological and regulatory change, pose a threat.

At the other end of the extreme is UCB Pharma. While Novo Nordisk is focused on preserving and improving the conventional BM, UCB Pharma is transforming it in radical ways by, for example, introducing a range of new patient support services, establishing partnerships with

⁴ See Novo Nordisk's annual report 2012.

non-traditional pharmaceutical stakeholders (such as kitchen appliance manufacturers and software and social media companies). Perhaps most importantly, the company has completely transformed the entire organization's structure, not only to support the increasing service content but also to capture external ideas and insights from other stakeholders (such as patients, payers and health care professionals). Recently, a number of other pharmaceutical companies (including LEO Pharma) have launched similar patient support programs or services, but to my knowledge (and that of other industry experts), no company has systematically changed its entire organization to the extent that UCB Pharma has.

Meanwhile, LEO Pharma represents a more typical case of BMI in the pharmaceutical industry. Like most other pharmaceutical companies, LEO Pharma is facing the loss of exclusivity for key products and a less promising pipeline compared to, for example, Novo Nordisk. As such, LEO Pharma's existing BM no longer seems viable. Instead, top management is attempting to shore up the deteriorating model by implementing new service offerings and experimenting with BM pilots within confined areas of the organization. In other words, this case constitutes an "inbetween" configuration, where incumbent elements (such as the overall architecture) are largely preserved (similar to Novo Nordisk), while new and more radical elements are being introduced (similar to UCB Pharma). Thus, similar to many other companies, LEO Pharma is in a situation in which new sources of revenue are needed, but the company is still reluctant to fundamentally change the incumbent BM to the extent that UCB Pharma has.

In spite of all the changes in the environment, there still seems to be a place for the conventional pharmaceutical BM, as illustrated by the case of Novo Nordisk. The company is just executing the BM much better than any other company. At the same time, other companies such as LEO Pharma and UCB Pharma face greater challenges to the traditional way of operating, and are therefore resorting to more fundamental and radical changes.

Data collection

To address the longitudinal aspects of the study, I used a combination of real-time and retrospective analyses. I started to collect data in 2012. The main fieldwork lasted from January 2013 to July 2015. Given my employment as an industrial PhD at LEO Pharma, I was able follow the company's BMI process in real-time throughout the entire period of the study (from 2012 to 2015). For the

cases of UCB Pharma and Novo Nordisk, it was only possible to follow their most recent changes over the course of two years, from 2013 to 2014 (UCB Pharma)⁵ and 2014 to 2015 (Novo Nordisk)⁶. In all three cases, the remaining years⁷ (especially the earlier ones, in which the changes to their incumbent BMs were made) were covered by means of a retrospective analysis of archival materials and the recollections of important and long-tenured individuals (cf. Leonard Barton, 1990). Semi-structured interviews represented the primary method for gathering inductive data, while archival data in the form of internal documents and publicly available information not only helped triangulate the data (Yin, 2003), but also created a rich understanding of each case context (including strategic, BM, and organizational design features), thereby providing insights to refute or reinforce interview findings (Foster, 1994).

Semi-structured interviews. Prior research has identified the BM construct as a unifying and boundary-spanning unit of analysis that captures value creation arising from multiple sources (both internal and external) (Morris et al., 2005). This warrants a holistic and ideally multi-level research strategy to unearth the process by which BMI occurs in incumbent firms. The transition toward a new BM is partly social or informal, in the sense that managers initiate the process by convincing others of the value embedded in the new model; and partly structural or formal as changes are made to the way of organizing to better accommodate the new model. As noted by Stieglitz and Foss (2015: 104), the process is "far from homogenous. Some may involve relatively minor changes … [while others] may be massive corporate-wide processes that involve basically all employees and all processes and activities." Hence, the process involves a myriad of different elements and levels of interaction among actors, both within the firm and across organizational boundaries. Consequently, I sought viewpoints from multiple informants at various levels of the organizational hierarchy and in different functions to better capture the holistic nature of BMI. This also enabled me to develop a more complete picture of how the emerging theoretical constructs are interrelated (Straus and Corbin, 1990). While the use of multiple informants limited the potential individual and

⁵ In total, I made three visits to UCB Pharma at their headquarters in Brussels (Belgium), where I stayed between one and two weeks each time. The first visit was in February 2013, the second in November 2013, and the third in October 2014.

⁶ In total, I made twelve visits to Novo Nordisk at their headquarters in Bagsværd (Denmark), where I stayed between one and five hours each time. The first wave of visits was carried out in 2014 between January and June, and the second in 2015 between April and July.

⁷ From 2000 to 2011 and 2012.

retrospective biases, it also induced richer and more elaborated models because individuals often focus on different but (sometimes) complementary aspects of major decisions (Golden, 1992; Miller, Cardinal, and Glick, 1997; Schwenk, 1985). For each case firm, I conducted semi-structured interviews with the major internal stakeholders involved in the BMI process, including employees, project leads, senior executives, directors, and key partners. Interviews lasted 51 minutes on average, with the length ranging from 30 minutes to two hours. As summarized in Table 4.2, a total of 81 semi-structured interviews with 69 different informants were audio-recorded, transcribed, and analyzed using NVivo 10.

Initially, I chose top managers who would be the most able to provide information on the main research question concerning the process of BMI. Next, a "snowball" method was adopted by asking each key informant for his or her recommendations as to who could best explain the processes of interest.

Details	Novo Nordisk	LEO Pharma	UCB Pharma
Number of internal interviews	15	20	17
Tenure	From 1 to 24 years	From 1 to 21 years	From 1 to 22 years
Function of interviewees ⁸ in managerial positions	CVP ^{9f} , VP, Global Director ^f , General Manager	CEO, EVP ^f , RVP ^{10f} , Senior Director ^f , Director ^f , Executive Director, General Manager, Unit head ^f	EVP, SVP, VP ^f , Senior Director, Director, General Manager, Unit head
	(Strategic planning, Marketing and sales, Value facilitator, R&D, HR)	(Marketing and sales, R&D, Strategic planning, HR, Market access)	(Patient solution team, HR, Marketing and sales, Finance, R&D)

Table 4.2 Overview of respondents and archival material

⁸ Interviewees marked with the subscript "f" are persons who I interviewed more than once.

⁹ Corporate Vice President.

¹⁰ Regional Vice President.

Function of interviewees in non- managerial positions	Executive Assistant, Senior Manager, Manager	Executive Assistant ^f , Senior Manager ^f , Manager ^f	Senior Manager ^f , Manager
	(Finance, R&D, Strategic planning, Market access, HR, Operations, Patient insights, Marketing and sales, Compliance and legal)	(Global patient engagement, Marketing and sales, Market access, R&D, HR, Operations, Patient insights, Compliance and legal)	(Patient solution team, Market access, HR, Patient insights, Operations, R&D, The New Journey Board, Marketing and sales, Compliance and legal)
Number of external interviews ^e	3	9	5
Background/title of external interviewees	CEO of a partner organization, management consultant, professor	Founder of a partner organization, Project director/employee of a partner organization, management consultant	Management consultant, professor, market access expert, Vice president of a partner organization
Total number of interviews ¹¹	$(15^{i}) + (3^{e}) + (2^{f})$	$(20^{i}) + (9^{e}) + (8^{f})$	$(17^{\rm i}) + (5^{\rm e}) + (2^{\rm f})$
	= 20	= 37	= 24
Public archival material	Annual reports, analyst reports, business press	Annual reports, business press	Annual reports, analyst reports, business press
Internal archival material	Memos, company newsletters	Memos, emails, strategic and tactical plans, intranet	Memos, company newsletter, intranet

Past studies on strategic management and organizational behavior have used the snowball method with success to identify relevant and influential (but not always obvious) individuals involved in the process of organizational change and entrepreneurship. This sampling technique has been used in studies on managers' interpretations of unfolding change (Isabella, 1990), the shaping of organizational boundaries (Santos and Eisenhardt, 2009), dynamic corporate forms (Galunic and Eisenhardt, 2001), and more recently, strategic adaptation in multi-business firms (Joseph and Ocasio, 2012). However, there is also an inherent danger in the snowball method. As noted by Penrod, Cain, and Starks (2003: 102), if researchers primarily rely on "participant-initiated referrals, only participants who share some social network would be researched—others 'like me."

¹¹ The following superscript letters indicate the type of informant and interview: ⁱ= Internal informant; ^e= External informant.

Yet the social networks of informants are often limited, therefore limiting the application of the findings. Thus, in addition to the snowball method, the following criteria were used to select informants. First, varying tenure length in the firm provided a temporal perspective on the case firm's BMI process, while at the same time limiting biases related to tenure. Second, the informant needed to have direct or indirect involvement in the BMI process, either as a process sponsor or decision maker, which would provide deep first-hand knowledge. Third, I interviewed individuals with different functional and hierarchical positions, which enabled me to gain a variety of perspectives. In particular, such heterogeneity in perspective allowed me to understand how the process of BMI influenced day-to-day activities in various parts of the organization. An important aim of these interviews was to fully understand the organization-wide consequences of transitioning to a new BM. The internal perspectives were complemented by five types of external informants: former employees, employees with experience in more than one case company, business partners, competitors, and industry experts. These informants offered an outsider perspective on BMI and brought a "reality check" to the internal perspectives.

The initial interview protocol was composed of two parts. The first part consisted of openended questions that allowed informants to provide a broad view of the history and evolution of the company's BM, the internal challenges, the environmental challenges and the company's responses to them. The second part focused on specific BM decisions or issues in which the informant was directly involved. At times, different probing questions were added, allowing the interviewee to react flexibly to the questions. Open-ended questions have been found to result in higher accuracy in retrospective reports (Miller et al., 1997; Graebner and Eisenhardt, 2004). Using the constant comparison method (Straus and Corbin, 1990), I adjusted the interview protocol as the data collection progressed in order to refine the emerging theoretical themes. Specifically, questions in the first wave of interviews focused on identifying the case firm's initial BM, whereas the second wave of questions focused on how coordination problems emerged as a consequence of BM changes, and how such problems could be alleviated or circumvented. In the interviews, the employees talked freely about the problems they have encountered during the BMI process. This open-ended format allowed to me delve deeper into the mechanisms underlying the innovation of an incumbent BM, as well as the associated challenges. For example, sub-themes related to coordination challenges, information flows, type of BMI, organizational structure, organizational

inertia, resources and capabilities gradually emerged. A number of individual follow-up interviews were conducted with key informants as "member checks" to ensure that the emerging themes were "sensible to, and affirmed by, those living the phenomenon of interest" (Nag, Corley, and Gioia, 2007: 829). In particular, respondents were asked to review statements and examples from prior interviews to clarify the validity of key events and the emerging constructs.

Archival data. I gathered extensive archival data from both internal and external sources that amounted to 102 documents containing 3,175 pages of data related to the case firms' BMI activities. The internal sources consisted of press releases, internal documents and presentations related to the BMI process. The external sources consisted of business press articles about each firm, located using the ABI/Inform database (from 2000 to 2015). These sources were further complemented by annual reports, analyst reports, and books about each firm, when available. I used NVivo 10 to create categories for filing, retrieving, and analyzing the archival data, separating earlier and later documents. The earlier documents for each firm described the strategies and assumptions behind the initial BM and contained clear statements about the firm's emphasis on a product- and science-based BM. Later documents described the BM differently. For instance, documents between 2007 and 2015 contained elements such as patient centricity, services, digitalization, change management, innovation, new solution- and customer-based BMs, and so on, whereas in the early 2000s, the documents mostly mentioned products and physicians.

The extensive archival data were instrumental in the development of chronological case histories for each firm. Whenever possible, the data were used as important sources of triangulation and supplementary information for use in gaining a deeper understanding of the processes, how they were presented to different constituencies, and divergence among informants, as well as means to gain a broader perspective on important issues (Miles and Huberman, 1994). Moreover, not only did the documents provide additional information, but they also allowed me to control for memory bias by comparing the interview statements with the collected documentary data (Miller et al., 1997).

Exclusive access to LEO Pharma. A number of observational studies were conducted at LEO Pharma. This included observing organizational actions, employees' routines (e.g., handling of partner calls and interactive problem solving with other functional areas), and social interactions (e.g., team and department meetings, and offsite workshops), with the aim of obtaining potentially

insightful data pertaining to individual and interpersonal issues related to BMI. In 2012, a one-day workshop was at held at Bella Sky in Copenhagen. The workshop's working title was "LEO Pharma's future BM," and it included members of the top management team, department heads or directors, and senior managers. I took detailed field notes during the 7-hour workshop and, in the process, not only captured items of potential merit for answering the research question, but also acquired useful information about LEO Pharma's history, values, and industry to aid in understanding the specific organizational context in which this company's BMI process occurs.

My attendance was only possible because I was employed by LEO Pharma as a part of the Danish Industrial PhD program. There, I was part of the Department of Global Patient Engagement, a unit within the global sales and marketing organization. The unit was largely responsible for LEO Pharma's BMI efforts, including the development and implementation of a new patient support program (QualityCareTM). My role offered a unique opportunity for observation; I occasionally shadowed organizational members as they went about their daily activities. Moreover, being one of the few BM experts in the organization, I was often invited to participate in meetings about BMI and organizational change. As a result, I gained unique insights and knowledge about the complex process of BMI that I otherwise would not have been able to obtain. I saw and experienced firsthand how various internal stakeholders resisted change by, for example, not allocating the necessary time and resources. Other barriers to change were a lack of support from top management, a reluctance to change control and incentive systems, as well as the struggle for resources and managerial attention. Obviously, my employment at LEO Pharma would be expected to give rise to biases in judgment and recall of events or issues pertaining to BMI. To mitigate this issue and enhance the validity of my findings, I relied on respondent validation (Van de Ven and Poole, 1990). Unfortunately, neither Novo Nordisk nor UCB Pharma allowed me to conduct on-site observation. Instead, I made detailed field notes regarding the setting, words, actions, and so on, that I observed prior to interviews and immediately after in order to reconstruct the experience as accurately as possible.

Validity and reliability of the data

Data validity (i.e., construct credibility, transferability, dependability, and confirmability) was checked in several ways. The use of several data collection methods (e.g., multiple informants,

semi-structured interviews, and archival data) was important given the lack of construct clarity. These methods not only enabled me to gain vast insight into various organizational levels, but they also allowed me to gain a holistic understanding of various organizational topics related to BMI, such as organizational structure, information flows, incentive systems, strategy, challenges, and resources and capabilities. This allowed triangulation of data for accuracy and authenticity, and thus paved the way for stronger substantiation of constructs (Eisenhardt, 1989). The data was meticulously managed through the development of a case study protocol which specified how the entire case study would unfold. The protocol included contact records, interview transcripts, field notes, and documents. It was structured in such a way as to offer retrieval for later investigators (Yin, 1994). Peer debriefing was used to discuss emerging patterns in the data with other researchers not involved in the study in order to "confirm interpretations and coding decisions including the development of categories" (Foster, 2004: 231). As Gioia, Corley, and Hamilton (2013) suggest, this method allows the field researcher to run his or her ideas by another researcher to obtain an outsider's perspective. In this study, the peers were department members (from the Department of Strategic Management and Globalization). Finally, to further strengthen the study's validity, respondent validation of the transcripts was applied, particularly in the case of LEO Pharma, where I was employed.

Data analysis

The focus on BMI and the organizational design that accompanies it emerged through an iterative process. Based on analyses of the comprehensive field data and existing research on BMI and organizational design, I identified a number of interrelated core concepts that described the BMI processes that unfolded during Novo Nordisk's, UCB Pharma's and LEO Pharma's transition toward a more service-based BM. Similar to prior studies on organizational change (e.g., Balogun and Johson, 2004; Barley, 1986; Siggelkow, 2002), my inductive inference was done in parallel with the data coding process so as to allow the identification of core concepts at different points in each company's history (Langley, 2007).

According to Langley (1999: 691), "no analysis strategy will produce theory without an uncodifiable creative leap, however small." In order to initiate the leap in the data, I relied on well-known and widely used techniques such as constant comparison (Glaser and Strauss, 1967; Miles

and Huberman, 1984) and content analysis (Weber, 1990). These techniques are instrumental for interpreting and making sense of data (Patton, 2015). For the content analysis, I first used NVivo 10's word frequency and text search query features to annotate sections in the transcribed interviews and documents for each case. Next, I examined all the transcripts and documents, and identified patterns and variance in descriptions of BMI using language indicators such as value proposition, patient support services, innovation, change, transformation, pipeline, products, patient insights, value chain, new partnerships, diversification, core capabilities, narrow focus, and old and new elements. I noticed that some broad organizational actions were not BMIs per se, namely, new ways of organizing, flatter structures, agility, more freedom to experiment and innovate, lack of motivation, and knowledge sharing. For instance, UCB Pharma structured its entire organization around the so-called "patient solution teams" in order to deliver more value-added and integrated solutions to patients. These actions did not represent changes to the core BM components in the same manner as the indicators listed above (e.g., value proposition and new partnerships). Nevertheless, my analysis revealed that these other broad-based forms of action, or more accurately, organizational design changes (or lack thereof) played multiple roles in the BMI process. I relied on in vivo codes (i.e., first-order concepts comprised of language used by my informants) or a short, descriptive phrase when it was impossible to obtain a meaningful code. These first-order concepts provided general insights into BMI and the accompanying organizational design, as described by informants.

I developed the second-order constructs by searching for links between and among the firstorder concepts, which allowed me to "lift [the] data to a conceptual level" (Suddaby, 2006: 636). Adhering to the inductive nature of the study, the second-order constructs emerged from my analysis. A number of the second-order constructs (including "the type of BM change," "the degree of BMI," "organizational structure," "complementarities," and "performance measures") were captured by labels already in use in the scholarly literature, while others (such as "which part of the BM is being innovated") required a new label.

Finally, I used cross-case analysis to identify similar concepts and relationships across cases, comparing the second-order constructs that I established above. Similar constructs were compiled into overarching themes that served as the basis of for my understanding of the BMI process. I

labeled these dimensions (e.g., BMI, organizational design role) by capturing the content at an even higher level of abstraction or by using similar notions from the relevant literature.

Based on these analytical procedures, I managed to create a data structure consisting of firstorder categories, second-order constructs, and overarching themes (Figure 4.2) (Corley and Gioia, 2004), which were identified through the following questions: (1) What are the external drivers that lead the focal firm to innovate its incumbent BM? (2) How did the BM and organizational design change over the period of the study? And (3) What role does the organizational design play during BMI? I used the second-order constructs and overarching dimensions depicted in Figure 4.2 to shape my account and track how each case firm's BM and organizational design changed over time. As a result, I was able to combine the literature on BMI and organizational design with my growing understanding of the BMI process and move between data and theory. In the following chapters (6-8) I present the empirical data for the individual cases, and in the subsequent findings and discussion chapters (9-10) I provide my interpretation of the data.

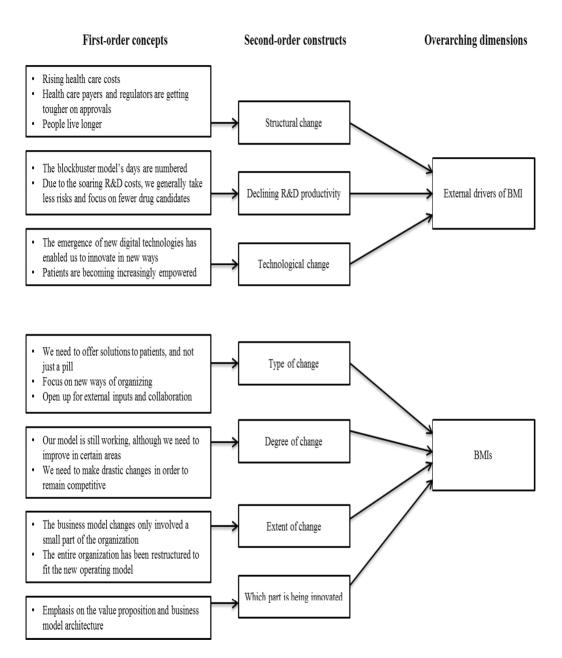
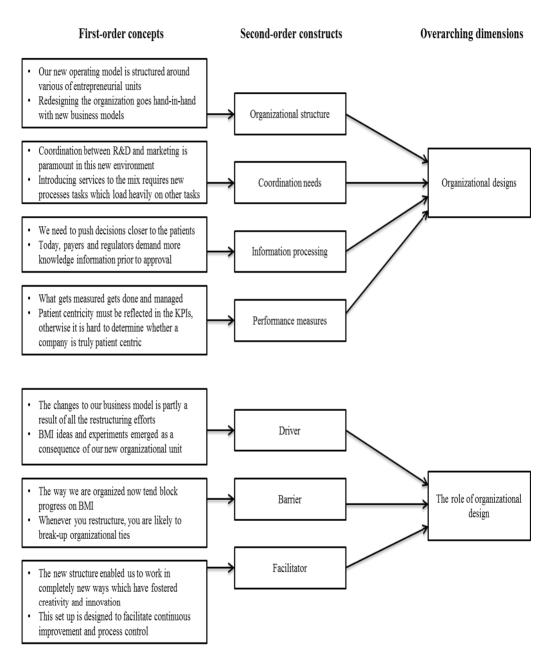


Figure 4.2 Data structure





5

The Pharmaceutical Industry: Key Characteristics and External Drivers of

BMI

The pharmaceutical industry is unique in that it is considerably more linked to science and more heavily regulated than many other industries. Since pharmaceutical innovations greatly influence people's quality of life, regulators, health care providers (e.g., physicians and pharmacists) and payers (i.e., the government and/or insurers) aim to protect the public health at reasonable cost (Ding, Eliashberg, and Stremersch, 2014).

For decades, the industry has been described by the following key characteristics: innovation, blockbuster model, finite lifespan, and marketing. Pharmaceutical companies "live or die" by their ability to develop innovative new drugs to alleviate diseases and improve public health. Without innovation, they are no longer in a position to generate new drugs with sufficiently profitable patent protection.

The so-called "blockbuster model" relies on the identification of promising new drug candidates aimed at large disease populations, that have the potential to generate at least \$1 billion dollars per year in revenue. Most pharmaceutical companies hesitate to abandon that model to focus on other types of drugs with more limited market potential (Aspinall and Hammeresh, 2007) because the cost of pharmaceutical innovation is enormous. According to many estimates, the average cost of taking a drug from discovery to market is more than \$1 billion dollars (\$0.8-1.8 billions) when adjusted for post-approval expenses and costs associated with approval in non-US markets (Munos, 2009).

With the exception of a few biological drugs, most drugs are bounded by a finite lifespan, that is, they only have a limited time to create shareholder value. The standard lifespan of a drug is

usually linked to the validity and duration of the patent. The vast majority of drugs are chemical products and have no way of extending their standard lifespan. Since the manufacturing of chemical drugs is standardized, it is generally relatively easy for competitors to produce a generic equivalent once the patent expires. The nature of biological drugs, on the other hand, is considerably more complex because they are more difficult to manufacture and have higher variable production costs.

Unlike many other products and services, pharmaceutical drugs are viewed both as a consumer product that addresses specific customer needs, and as something to which people have a fundamental right. This duality makes pharmaceutical marketing increasingly complex: On the one hand, all the basic rules of commerce should apply, but on the other hand, if the drug is something that people have a basic right to, then standard marketing practices are no longer sufficient. For example, most people will accept a neighbor being able to afford a Ferrari while they cannot. In contrast, if the neighbor gets access to an expensive but effective treatment for a disease, most people will most likely demand the same access, regardless of their financial situation. Thus, pharmaceutical companies need to consider these two conflicting roles of pharmaceutical drugs when they attempt to extract value from their innovations. In order to extract maximum value, pharmaceutical companies not only need to offer drugs that are safe and efficacious, but must also ensure careful management of their relationship with three key stakeholders-patients, health care providers (e.g., physicians and pharmacists), and payers. These stakeholders are important because a pharmaceutical drug purchase is a joint decision between the patient (user) and the health care provider (gatekeeper). Although the gatekeeper usually has the final decision-making authority on what drug a patient should use, a patient can switch to another physician or passively object by either not getting the prescription filled or not using the drug according to the physician's instructions (non-compliance). For many decades, pharmaceutical companies have specifically directed marketing efforts toward influencing physicians' prescribing behavior.

Together, the above characteristics of pharmaceuticals determine the context of pharmaceutical innovation. More recently, questions about whether these characteristics will persist or be replaced by new ones have dominated academic and practitioner debate (Gilbert et al., 2003; Kola and Landis, 2004; Munos, 2009; Ding et al., 2014; Khanna, 2012; Kessel, 2011; Mattke, Klautzer, and Mengistu, 2012). The main reason for this debate is that the pharmaceutical industry

The Pharmaceutical Industry: Key Characteristics and External Drivers of BMI

is currently facing tremendous challenges due to significant structural, technological, and regulatory change.

Structural change

Today's health care systems are under extreme pressure to control costs and justify expenditures. Estimates from the OECD show that health care spending per capita in OECD countries has risen by over 70% in real terms since the early 1990s (OECD, 2010). Similarly, since 2000, the average spending on pharmaceuticals has increased by nearly 50% in real terms (OECD, 2011), while pharmaceutical spending across OECD countries in 2013 reached approximately \$800 billion US dollars—accounting for roughly 20% of total health care spending when pharmaceutical drug consumption in hospitals was added to consumption in the retail sector (OECD, 2015). The principal driving force behind the escalating cost of health care lies in the demographic, epidemiological and economic shifts occurring across the world.

The impact of changing demographics and chronic diseases

The United Nations Department of Economic and Social Affairs has projected that the world's population will reach 8.5 billion in 2030, with 1.4 billion (16.4%) aged 60 and over (United Nations, 2015). On average, the share of the population aged over 65 years across OECD countries is projected to reach 27% in 2050 as a consequence of longer life expectancies and declining fertility rates (OECD, 2015). This specific segment of the population is also the one that consumes the most medicine per capita. In a cross-sectional study on age- and sex-specific health care costs and mortality, Alemayehu and Warner (2004) found that nearly half (48.6%) of a cohort's health care expenditures occurs during the post-65 years. Moreover, due to scientific advances, improved lifestyle and better education, life expectancy at birth continues to rise gradually across the OECD, increasing by 3 to 4 months on average each year (OECD, 2015). Although countries such as India, Indonesia, Brazil and China are nowhere near the OECD average, they have achieved significant gains in longevity over the past four decades (OECD, 2015). Although global rates of mortality from cardiovascular diseases and cancer have declined substantially in recent decades, improved life expectancy means that more and more people are living with one or more chronic conditions for longer periods. This conversion of previously terminal diseases into chronic diseases has increased

the need for long-term treatment and medications, placing new, longer-term requirements on health care systems. For example, in 2014, it was estimated that more than 380 million people had diabetes, and by 2035 this number is projected to reach almost 600 million people.¹² Chronic diseases are expected to be the primary cause of disability globally by 2020, and if not managed well, they will arguably become the most expensive problem faced by health care systems (WHO, 2002). According to the Centers for Disease Control and Prevention of the US Department of Health and Human Services, chronic diseases account for 70% of deaths and for more than 75% of direct health care costs in the US (Thrall, 2005).

The acute care model

Most current health care systems are designed to treat acute problems related to illness, such as diagnosing, testing, providing symptom relief, and developing effective treatments. Although these functions are relevant to acute and episodic health problems, a remarkable discrepancy arises when this model of care is applied to the management of chronic diseases. This is because chronic diseases differ from acute conditions in a number of important ways. While acute conditions generally have a sudden onset and last only for a short period of time without requiring ongoing treatment, chronic diseases are persistent, lasting for a considerable period of time, are not selflimiting, wax and wane in terms of symptom severity, and can usually not be cured (Priester, Kane, and Totten, 2005). In addition to these differences, chronic diseases often have multiple causes and can appear long after the causative exposure or behavior. Finally, chronic conditions tend to have a larger impact on a person's quality of life. For most acute conditions, the threat to the person's health is isolated to a single event and is relatively short-lived, but for chronic diseases, the threat is ongoing, long-lasting and affects the social, physical, psychological and economic aspects of the person's life. The current acute care model leaves little, if any, room to address the social, psychological and behavioral dimensions of chronic disease (Tinetti and Fried, 2004). In other words, it is not designed to provide the continual care needed to manage chronic diseases, nor does it deploy an integrated approach that bundles prevention and intervention strategies to effectively and equitably address the chronic disease burden. Instead, current health care systems tend to adopt a fragmented approach of care, in which subsystems (i.e., primary, secondary and tertiary care)

¹² Retrieved April 2017 from http://www.idf.org/diabetesatlas/update-2014

operate independently from one another. This has led to a misalignment of incentives and a lack of coordination that together undermine the efficient allocation of resources, and thus adversely affect the quality, cost and outcome of care (Enthoven, 2009). The fragmented nature of health care is also problematic when it comes to the needs of chronically ill patients, as they often require coordinated care from several health care entities. For example, failure to provide patients with carefully coordinated care may allow small issues to escalate into medical emergencies. Such situations can result in unnecessary hospitalization, increased mortality, and higher overall system costs. In addition, fragmentation not only frustrates patients who find it difficult to navigate the complex web of providers, but also causes delays in diagnosis and initiation of treatment, leading to late-stage disease and higher mortality rates.

The growing importance of health care payers

As a consequence of escalating health care costs and growing constraints on government budgets, there is a clear need for payers to take action to ensure better management of health care resources. Health care expenditure absorbs, on average, 15% of total government expenditure across OECD countries, with large between-country variations (OECD, 2015). Perhaps surprisingly, countries that spend the most are not necessarily those with the best health outcomes or value for the money spent. As Figure 5.1 shows, spending more for health care does not correlate directly with improvements in life expectancy.¹³ There is no straightforward answer for why this is the case. Scholars have examined the performance of modern health care systems and have found discrepancies in the setup. For example, in a systematic review of the association between health care quality and costs, Hussey, Wertheimer, and Mehrotra (2013) found that of the sixty-one studies reviewed, (1) 21 concluded that higher cost was associated with lower quality or that the relationship was mixed, and (3) 22 concluded that no significant association, or an indeterminate association, existed between cost and quality. McGlynn et al. (2003) compared the actual quality of care provided to patients and found

¹³ Efficiency of health care spending uses life expectancy as the outcome of health spending. It could be argued that this is a partial indicator, since it does not reflect the prevalence of disease, disability or quality of life, and the data constraints are significant. A study by Joumard, André, Nicq, and Chatal (2010) showed that life expectancy is highly correlated with other indicators of health status, including infant and premature mortality and better quality of life due to improved medical treatment. Life expectancy not only reflects health spending but also lifestyle choices, such as tobacco use, alcohol consumption and education level.

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significant gaps between what is known to work and the actual care provided. Specifically, the study showed that, on average, Americans only receive 55% of the care that is recommended by established medical standards. This incomplete provision of care is almost equal across the broad types of treatment, such as preventive care, acute care, and chronic care (McGlynn et al., 2003).

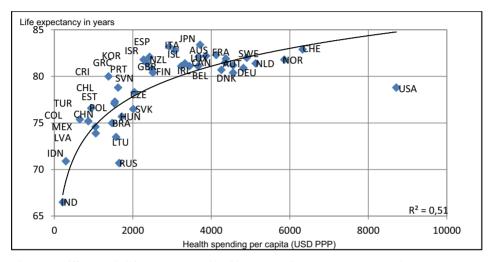


Figure 5.1 Differences in life expectancy and health care spending across OECD countries, 2013. Source: OECD Health Statistics 2015

Similar findings have been reported in countries like Australia, Canada, New Zealand, and the United Kingdom (e.g., Hussey et al., 2004). As mentioned earlier, the fragmented nature of health care gives rise to coordination problems between the various providers, which can result in an inefficient use of resources. Moreover, for several decades, health care authorities such as the Food and Drug Administration (FDA) and The European Medicines Agency (EMA) have mainly relied on comparisons between a single treatment and an extant treatment or placebo during the drug approval process (cf. Schoen et al., 2007). Requirements have been even less stringent when it comes to medical devices, where a new device only needs to be substantially equivalent to another device already on the market (Zuckerman, Brown, and Nissen, 2011). In other words, there has been little incentive for drug and device manufacturers to develop solutions that are more effective or less costly than current approved treatment regimens. As a result, expensive new therapies are

approved without good evidence that they improve patient outcomes and decrease health care costs. A recent example relates to the approval of new cancer drugs, which can cost well over \$100,000 dollars per year to purchase and are often expected to prolong the life of cancer patients for little more than a month (Kantarjian, Fojo, Mathisen, and Zwelling, 2013).

However, as a consequence of increasing costs and poor quality of care, the willingness and ability of health care payers to accept new drugs that only provide marginal improvements over existing treatment regimens (in terms of efficacy, compliance, cost-effectiveness, etc.) has vanished. Most notably, the onset of the financial crisis in August 2007 was a turning point that prompted governments to rapidly implement cost containment and quality-of-care strategies.

Across Europe, EU member states have introduced policies related to pharmaceutical pricing, reimbursement, and expenditure control (Table 5.1), as well as policies targeting specific health care stakeholders, such as physicians and pharmacists (Table 5.2). In most EU member states, price reductions and external reference pricing are some of the most frequently used policy interventions. External reference pricing refers to the practice in which a drug price is set on the basis of the lowest prices offered in other markets. This type of pricing mainly applies to reimbursable medicines, whereas non-reimbursable medicines are normally priced freely. Governments are increasingly using external reference pricing in combination with health technology assessments, where pricing is made conditional on evidence of value added (in terms of efficacy and/or cost-effectiveness) of drug innovations compared to existing treatment options (Carone, Schwierz, and Xavier, 2012).

The second most common type of intervention relates to product reimbursement and copayments. Reimbursement schemes establish the maximum price that can be reimbursed by thirdparty payers (internal reference pricing). Governments also introduce lists that specify which drugs are eligible and not eligible for public reimbursement (Aaserud, Austvoll-Dahlgren, and Sturm, 2006). Several EU member states are also increasing co-payments (by which the patient pays for part of the drug cost) by, for example, decreasing the reimbursement rate or increasing the percentage co-pay on specific treatments.

Third, governments are taking steps to directly limit pharmaceutical expenditure. This is achieved by price freezes and discounts offered by producers and distributors of pharmaceuticals to purchasers. Furthermore, payback and clawback policies are adopted to prevent budget overruns by

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demanding refunds from the pharmaceutical industry once a target budget is exceeded (Vogler, Zimmermann, Leopold, and Joncheere, 2011).

Price regulations	Examples
Price reductions: Both reimbursable and non-	UK: price cut of 1.9% on branded NHS medicines
reimbursable drug prices can be reduced	Spain: generic drug prices reduced by 30%
	Ireland: price reductions for on-patent drugs
External reference pricing: Compares drug prices in	This procedure is applied in 24 EU member states
one country against prices of the same drug in a	(except for Denmark, Sweden, and the UK)
basket of selected other countries	
Internal reference pricing: Establishes the maximum	Estonia: inclusion of 50% reimbursable drugs in the
price to be reimbursed by a third-party payer	internal reference price system
("reference price"). The patient pays the difference	Romania: change to therapeutic reference pricing (i.e.,
between the retail price and the reference price, in	broader clusters of drugs can be compared)
addition to any co-payment required. The reference	Lithuania: change in methodology of price of most
price applies to all pharmaceuticals within the	expensive drugs in a cluster (lower prices)
corresponding group of products	
VAT: Most drugs have a value-added tax below the	Finland: increase $(8 \rightarrow 9\%)$
standard VAT rate.	Greece: increase $(9 \rightarrow 10\%)$
	Latvia: increase (10 \rightarrow 12%)
Product reimbursement and co-payments	Examples
Positive/negative lists: Specify which	Iceland: changes in reimbursement status (from
pharmaceuticals are eligible for reimbursement and	general to individual) for some drugs
which are not.	Portugal: negative listings of some drugs
	Greece: re-introduction of positive list and negative list

Table 5.1 Pharmaceutical pricing, reimbursement, and expenditure policies

Co-payments: Patients are paying an increasing	Belgium: increase of percentage co-pay for some drugs
portion of the drug cost.	Denmark: increase in co-pay for fertility drugs
	France: the overall reimbursement rate is decreased

 $(35 \rightarrow 30\%)$

Examples

Italy: choice between payback and price cuts

Portugal: discount of 6% for reimbursable drugs

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Sources: Espin and Rovira (2010); Zimmermann et al. (2011)

Discounts, payback and other arrangements: policies

Expenditure controls

directly targeting cost-containment

Finally, governments are implementing policies that are an attempt to influence the behavior of wholesalers, physicians, and pharmacists. For instance, a number of the EU member states have enacted policies that obligate pharmacies to dispense the cheapest—often generic—equivalent drugs. The use of mark-ups by distributors of pharmaceuticals may also influence dispensing behavior. Meanwhile, the autonomy of physicians is constrained by closer monitoring of their prescription patterns, mandatory prescription guidelines, budget ceilings, prescription quotas, financial (dis-)incentives and educational and informational policies (Carone et al., 2012).

Table 5.2 Policies aimed at health care stakeholders

Wholesalers and pharmacists
Generic substitution: Pharmacists may be induced or mandated to dispense the cheapest bioequivalent
medicine, often called "generic substitution." It is mandatory in 8 EU member states, indicative in 14 and
disallowed in 7.
Mark-ups: Twenty-three EU member states apply wholesalers' mark-ups of the pharmaceutical prices set by
law and all EU member states apply pharmacists' mark-ups. These can be linear, regressive, a fixed-fee (NL) or
fee-for-service (UK).
Physicians
Monitoring of prescribing behavior: At least 22 EU member states monitor prescribing behavior to some extent,

for example, through looking at electronic prescriptions.

Pharmaceutical budgets: A maximum pharmaceutical budget may be established per period, region, field of specialty and physician (at least 9 EU Member States).

Prescription quotas: These may define a target percentage of generics to be prescribed by each physician or may target the average cost of prescriptions (at least 6 EU Member States).

Financial incentives: Physicians may be incentivized or punished financially by following or disregarding prescription guidelines, quotas and budgets (at least 11 EU Member States).

Source: adapted from Carone et al. (2012: 13)

Although health care payers in Europe are taking drastic steps to control pharmaceutical expenditures, the US has also introduced new reforms to manage excessive spending on health care. Most importantly, the federal Patient Protection and Affordable Care Act, signed into law in 2010, included a number of cost-containment procedures. Most of the procedures are similar to those employed by the EU member states, such as preferred drug lists, generic substitution, health technology assessment, discounts, budget ceilings, and so on. The impact of these policies is that health care payers have more power and control over pharmaceutical expenditures and the quality of care delivered to patients. As a consequence, pharmaceutical companies can no longer rely on drug innovations that only modestly improve efficacy, patient outcomes and cost-effectiveness. In fact, the FDA recently rejected a number of prescription drugs, including RLX30 (Novartis), Taltorvic (Merck), Tresiba (Novo Nordisk), Ezogabine (Valeant Pharmaceuticals and GlaxoSmithKline), on the basis of these parameters. Instead, companies need to focus on delivering real innovations that are markedly better than existing treatment options in order to receive favorable pricing and reimbursement terms. Apart from that, they also need to shift focus from physicians toward pavers and patients. The increasing use of prescription guidelines, monitoring of prescribing behavior, quotas, and so forth, means that physicians have less autonomy and control over prescription decisions, whereas payers can more directly control the accessibility to drugs. As a consequence, the pharmaceutical industry has experienced massive layoffs in recent years. According to Cegedim Strategic Data¹⁴, the size of the US pharmaceutical sales force declined by approximately 2% between 2013 and 2014, to less than 65,000—a 40% drop compared its peak level in 2006, when there were more than 100,000 US pharmaceutical sales representatives.

¹⁴ Retrieved March 2017 from <u>http://globenewswire.com/news-release/2015/03/05/712594/10123438/en/CEGEDIM-STRATEGIC-DATA-Worldwide-Pharma-Industry-Sales-Force-Levels-Flat-in-201.html</u>

Technological change

Data from the Global Health Observatory show that the average global life expectancy increased by 5 years from 2000 to 2015, the fastest increase since the 1960s.¹⁵ Much of this can be credited to significant advances in pharmacotherapy. Over the last fifteen years, however, the companies that brought us insulin, antibiotics, and a host of other "wonder drugs" seem to have lost their ability to innovate (Munos and Chin, 2011). As such, there appears to be declining technological opportunities, at least in the conventional mode of innovation within the pharmaceutical industry. However, recent advances in ICTs may facilitate the change in operating philosophy from the classical "blockbuster" model to a range of new BMs.

Innovation crisis – myth or reality?

Despite staggering R&D spending and notable advances in the basic sciences, the pharmaceutical industry has not managed to avoid a continuous decline in the number of new molecular entities (NMEs) that make it all the way through clinical development to final market approval (Light and Lexchin, 2012; Munos and Chin, 2011). To illustrate this point, in 2002, only 17 NMEs received market approval from the FDA—only a minor fraction of the fifty-six NMEs approved in 1996 and the lowest since 1983 (Cockburn, 2004). This trend is by no means isolated to the US. Between 1998 and 2008, the total output of NMEs declined by almost 50% and attrition rates have increased sharply, particularly in late-phase clinical trials (Pammolli, Magazzini, and Riccaboni, 2011). Although the number of NMEs is an imperfect measure of research outcomes, as it does not account for the quality of the R&D output, there is a growing concern about the causes and consequences of the so-called innovation crisis within pharmaceutical research. Other scholars (e.g., Hopkins, Martin, Nightingale, 2007; Munos, 2009; Schmid and Smith, 2005), however, argue that these concerns are almost surely blown out of proportion. They claim that the so-called innovation crisis rests on the drop in NME output from a sharp peak in 1996, which resulted from the rapid reduction in the backlog of applications after the FDA deployed staff hired under the Prescription Drug User Fee Act of 1992 to reduce approval times (Scherer, 2007). This drop ended in 2006, when approval

¹⁵ Retrieved March 2017 from <u>http://www.who.int/gho/mortality_burden_disease/life_tables/situation_trends_text/en/</u>

times reverted to their long-term mean of between 15 and 25 approvals per year.¹⁶ Similarly, based on FDA records, Munos (2009) showed that the R&D output of pharmaceutical companies has been more or less constant for almost 60 years, and that new biologics¹⁷ have followed a similar pattern. Whether the innovation crisis is real or a myth, it is far more interesting to look at the number of drugs that offer an actual therapeutic advance, as opposed to solely looking at the total number of approved drugs each year. Although innovation is often measured by the industry and its analysts in terms of the number of NMEs, as a stand-in for therapeutically superior new medicines, most of these NMEs have only provided modest clinical advantages over existing treatment options (Light and Lexchin, 2012). This is not a new phenomenon, but it has received more attention in recent years as a result of the increasing health care costs and aging populations. In a comprehensive study of all internationally marketed NMEs from 1974 to 1994, the industry's Barral report found that only 11% were therapeutically and pharmacologically innovative (Light and Lexchin, 2012). Since the mid-1990s, independent reviews have reached nearly the same conclusion, namely that about 85-90% of all NMEs provide trivial or no clinical advantages to patients (e.g., Angell, 2005; Luijn, Van Gribnau, and Leufkens, 2010).

Why is this the case? One reason may relate to the emergence of the "blockbuster" model in the mid-1990s. Before this, R&D units were largely independent of the company's commercial activities and were therefore free to pursue autonomous research, even if the resulting medicines targeted diseases beyond the scope of the organization's commercial capabilities (Munos and Chin, 2011). Nevertheless, to improve the commercial applications of drug research, a closer link between R&D and market demand was needed. Thus, pharmaceutical executives directed their researchers to focus mainly on the development of "blockbuster" drugs (those with peak annual single-product global sales of at least 1 billion dollars) in order to support the companies' marketing efforts. Advanced portfolio management practices (Evans, Hinds, Hammock, 2009) were adopted to systematically optimize research outcomes, limit financial risk, and bring order and predictability to

¹⁶ Retrieved March 2017 from

 $[\]label{eq:https://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/DrugandBiologicApprovalReports/UCM242695.pdf$

¹⁷ Biological products are 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. Most drugs are usually manufactured through chemical synthesis, which means that it is made by combining specific chemical ingredients in an ordered process. Retrieved March 2017 from https://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CBER/ucm133077.htm

a discovery process that was largely regarded as "chaotic" and unpredictable. Despite the good intentions of pharmaceutical executives, the new BM, with its emphasis on structure and predictability, limited the creative and autonomous characteristics of scientific discovery. Moreover, as the cost of bringing a new drug to market continued to rise sharply, many pharmaceutical companies could not justify investing in drug candidates with lower or moderate market potential (<300 million dollars) (Kessel, 2011; Khanna, 2012). This has led to an industry dominated by risk averse companies that are more inclined to pursue "safe" incremental innovations (such as "me-too" or "follow on" drugs¹⁸), rather than "breakthrough" products that offer significant therapeutic advantages over existing drugs.

At the same time, health care payers are determined to get more value for their money. Not only do they demand products that offer clinical advantages over existing treatments, but they also have requirements for cost effectiveness and patient outcomes. Clearly, this makes it increasingly difficult to sustain the blockbuster model in today's environment. This is especially reflected in the industry's withering drug pipelines and increasing generic competition (Dolgin, 2010). In addition, many mature blockbusters that once contributed to the sustenance and growth of pharmaceutical companies have lost proprietary protection. For example, well-known drugs such as Lipitor (atorvastatin), Plavix (clopidogrel), and Singulair (montelukast) came off patent in 2011. Estimates from EvaluatePharma show that 120 billion dollars in sales were lost to patent expirations between 2009 and 2014, and it is forecasted that 215 billion dollars in sales are at risk from patent expirations occurring between 2015 and 2020.¹⁹ Yet in spite of these clear issues, many companies are still attempting to patch the traditional BM by purchasing revenues through mergers and acquisitions to replace declining sales. In addition, from 2007 to 2012, the ten biggest pharmaceutical companies eliminated more than 200, 000 jobs (Khanna, 2012). Although these strategies have helped curtail expenses in the short run, they do little to address the industry's fundamental innovation challenge.

¹⁸ Hollis (2004: 1) defines 'me-too' drugs as "products which largely duplicate the action of existing drugs."

¹⁹ Retrieved April 2017 from <u>http://info.evaluategroup.com/rs/607-YGS-364/images/wp15.pdf</u>

The rise of ICT-based health care technologies

Recent advances in digital technologies such as mobile apps, social media, sensors, wearable devices, and other technologies present a wide spectrum of opportunities through which incumbent pharmaceutical companies can embrace a broader logic for value creation. These technologies can be used to promote patient adherence and can also help with lifestyle changes that are critical to therapeutic success and the patients' general quality of life, especially for the chronically ill. For example, in diabetes care, where effective disease management requires a coordinated and integrated approach, new mobile apps assist patients in not only controlling their blood glucose levels but also in managing other aspects of their lives, such as diet and exercise. The range of technologies targeting adherence is by no means limited to diabetes. Such technologies include apps, devices, sensors and patient support websites that help patients keep track of vaccination schedules (e.g., Novartis' VaxTrak), improve patient-physician communication (e.g., UCB Pharma's Parkinson's Well-Being Map), and notify caregivers of adherence and reorder drugs from the pharmacy (Vitality's GlowCap). The common denominator among these technologies is their ability to store data and report trends. In this way, deeper insights into the lives of patients can be gained. Such knowledge can inform patient-centered drug development that takes into account, for example, which adverse events lead to drug discontinuation and what causes non-compliance in different patient segments, and that combines an effective compound with a targeted engagement model (Mattke et al., 2012). In addition, the accumulated data can be used for patient outcome studies, which are becoming increasingly important for justifying higher prices and reimbursement rates in negotiations with payers.

The implementation of ICTs has also led to considerable cost savings, particularly in sales and marketing organizations. Instead of employing a massive sales force, some pharmaceutical companies are investing heavily in e-detailing, which refers to "an IT-supported sales dialogue via the internet (Heutschi, Legner, Schiesser, Barak, and Österle, 2003: 263). Rather than having pharmaceutical sales representatives visit physicians, companies can simply use digital technology to relay the latest information on the firm's prescription drugs that is relevant to the specific physician's specialty. As a result, not only are companies able to dramatically lower sales force expenses, but they are also able to offer more value to physicians. In particular, e-detailing enables physicians to retrieve information on demand rather than using valuable office time to consult with

sales representatives. When coupled with the other digital technologies, pharmaceutical companies can also add value to the physicians by providing new insights on patients' experiences with the drugs.

Historically, patients have played a relatively passive role in the medical dialogue with physicians [see Guadagnoli and Ward (1998) for a comprehensive review of patient participation in decision-making]. In most cultures, patients have always wanted to be well informed but they have preferred critical decisions to be made by their physicians. Compared to patients, physicians have accumulated medical knowledge through several years of education, training, and experience, which puts them in better position to make such decisions. Moreover, the widespread use of health insurance has, in many markets, protected patients from financial risk and out-of-pocket costs. As such, price considerations have not, until recently, changed patients' decision-making behavior. Consequently, for many years, the medical dialogue has largely been dominated by the expert authority of physicians, while patients have passively accepted that authority without much question. However, driven by the digitization of data and new modes of digital communication-for example, via social media sites such as Facebook, PatientsLikeMe, and Instagram—patients have more ready access to information. In other words, today's patients are more empowered to partner with their health care providers when making decisions about treatment options and disease management, and they expect more personal attention. Thus, the practice of health care is gradually shifting toward a patient-centric model. This means that pharmaceutical companies need to direct their attention toward the end users, rather than mainly focusing on influencing the prescribing behavior of physicians.

Regulatory change

The regulatory hurdles that a new drug must clear prior to market approval are increasing. Estimates from George Mason University's Mercatus Center and Regulatory Focus show that the number of regulatory requirements imposed by the FDA increased by 15% between 2000 and 2012.²⁰ As a consequence of the well-publicized market withdrawals of high-profile drugs such as Vioxx (Merck), Baycol (Bayer), Rezulin (Warner-Lambert) and Propulsid (Janssen Pharmaceutica),

²⁰ Retrieved March 2017 from <u>http://www.raps.org/Regulatory-Focus/News/2014/10/30/20656/Its-Not-Just-You-FDA-Regulatory-Requirements-Really-Are-Increasing/</u>

the FDA and its counterparts in other major markets have placed more emphasis on pre-approval safety evaluations and have implemented more post-approval systems to monitor drug safety and use (Kaitin, 2010). In response to the FDA Amendments Act of 2007, the FDA introduced the Sentinel Initiative in 2008. It enables the FDA to "access the capabilities of multiple, existing data systems (e.g., electronic health record systems, medical claims databases."²¹ The system is designed to both detect issues (such as higher-than-expected numbers of adverse events) and to confirm problems, including those supported by other sources (Platt et al., 2009). This system has strengthened the FDA's ability to proactively monitor the safety of medical products throughout their life cycle. The FDA not only requires pharmaceutical companies to submit an application for regulatory approval along with various risk and mitigation strategies, but can also demand postmarket clinical studies on approved products if safety issues are detected or confirmed. Depending on the outcomes of such studies, the FDA can either withdraw the product or restrict its use by, for example, mandating changes to the drug's approved labeling and distribution channels (Kaitin, 2010). European regulators have similarly implemented new rules that impose a range of different pre- and post-market requirements on drug manufacturers. In 2012, the European Medicines Agency (EMEA) established the Pharmacovigilance Risk Assessment Committee to help improve all aspects of risk management for human medicines. The committee's role is two-fold. First, it takes part in the pre-approval activities by conducting a pre-marketing pharmacovigilance inspection to assess the drug applicant's ability and capacity to meet the proposed pharmacovigilance measures (Laroche et al., 2016). The committee can also advise EMEA to impose certain conditions on a marketing authorization, such as making the approval decision conditional on, for example, specific safety measures, additional post-authorization studies, and stricter adverse event reporting requirements. Second, to keep track of unexpected complications with already approved products, the Pharmacovigilance Risk Assessment Committee, among other things, investigates safety issues identified by the EMEA or member states, conducts periodic inspections of a company's pharmacovigilance system, and verifies the drug manufacturer's corrective and preventive action submissions, as related to their pharmacovigilance measures (Borg et al., 2015).

²¹ Retrieved March 2017 (13) from https://www.fda.gov/downloads/Safety/FDAsSentinelInitiative/UCM124701.pdf

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As an outcome of these regulatory changes, the process of drug development has become increasingly complex, protracted and costly over the last decades, with the average length of clinical development being more than 7-12 years, the number of studies averaging 66, and expenditures reaching 0.802-1.8 billion dollars per approved new drug (DiMasi, Hansen, and Grabowski, 2003; Lesko, Rowland, Peck, and Blaschke, 2000; Williams and Ette, 2007; Munos, 2009). In other words, the costs and challenges associated with drug development continue to rise, while the duration of market exclusivity decreases as a consequence of the additional requirements from health care regulators.

Implications for the pharmaceutical industry

The search for the next blockbuster drugs "has served the pharmaceutical industry well, generating over 13% annual growth in market capitalization between 1992 and 2002 (Gilbert et al., 2003: 6). Thus, pharmaceutical companies have invested heavily in large infrastructure around the blockbuster model, including massive R&D and production facilities, as well as a considerable sales force. Organizations of that type are likely to exhibit considerable inertia in their strategies and structures. Even though the business environment for pharmaceutical companies has changed dramatically in the past decade and a half, the blockbuster model remains largely unchanged. However, as a consequence of the substantial structural, technological, and regulatory changes faced by the industry, the blockbuster model is gradually becoming obsolete (see Table 5.3). Based on estimates of investment levels, success rates, and projections of commercial performance, Gilbert et al. (2003: 2) "expect the blockbuster drug model to deliver just 5% return on investment—significantly lower than the industry's risk-adjusted cost of capital."

Table 5.3 Environmental changes and implications for the pharmaceutical industry

Structural change	Technological change	Regulatory change
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• Escalating health care costs	• Increasing R&D costs	• Increasing regulation		
• Changing demographics	• Lack of "true" innovation	• More challenging and		
• The rise of chronic diseases	• New digital health technologies	complex pre- and post- approval processes Shorter market exclusivity 		
Growing influence of payers		• Shorter market exclusivity		
Imp	lications for the pharmaceutical ind	ustry		
• Drug manufacturers will be paid for patient outcomes and cost-effectiveness, rather than for producing "me-too" drugs, thus demonstrating "real" value for money.				
• The ability to develop solutions that go beyond treating physical symptoms alone to also encompass the material, social, and emotional wellbeing of patients				
• The ability to collect patient data from multiple sources and turn it into insights will be key.				
Shifting focus from physicians toward payers and patients				
• Transition from a product- to a patient-centric BM				
• New partnerships and closer collaboration with payers, patients, physicians and regulators				

Rather than continuing with the traditional model, pharmaceutical companies should adopt new BMs to markedly broaden the scope of their translational research efforts in order to provide more value to their stakeholders and ultimately ensure survival. Through the use of new digital technologies such as health information systems, mobile apps, social media, sensors, data mining, wearable devices, and so on, pharmaceutical executives can design a range of new BMs that not only offer innovative solutions that more accurately reflect customer preferences, but also differentiate the offering beyond the drug.

6

Novo Nordisk: A BM Refiner

Companies that pursue BM refinement are concerned with preserving and extending the traditional pharmaceutical capability of building new, but related tasks. In a nutshell, BM changes are designed to enable the firm to capture maximum opportunities with the lowest risk of failure. Thus, rather than fundamentally changing the basic value proposition or engaging in radically new partnerships, most "refiners" modify and improve the efficiency and effectiveness of the traditional blockbuster model. For example, they vigorously search for opportunities to remove non-value-adding activities, while strategic partnerships are forged across the drug value chain to not only improve the efficacy, safety and ease of use, but also to permit access to particular groups of patients who hitherto have been denied access to a specific drug.

This incremental approach to BMI is illustrated by the case of Novo Nordisk. Novo Nordisk began with two small Danish companies, Nordisk Insulinlaboratorium and Novo Terapeutisk Laboratorium, founded in 1923 and 1925, respectively. Under modest circumstances, the companies initiated production of the groundbreaking new drug insulin, which had been recently discovered by two Canadian scientists. The two insulin manufacturers were in fierce competition with one another for several decades. Both companies had insulin manufacturing and delivery as their core area of expertise and therefore competed for the same market segments and growth limiting resources, such as researchers and scientific staff within the field of insulin and diabetes. In 1989, the two companies merged to become Novo Nordisk. Currently, Novo Nordisk is a global health care company with more than ninety years of innovation and leadership in diabetes care; it also has strong and leading positions in obesity, hemophilia and growth disorders. The company is headquartered in Denmark, employs 42,446 people in 77 countries, and markets its products in

around 170 countries. Estimates from IMS show that Novo Nordisk's diabetes portfolio accounts for approximately 27% of the global market for diabetes care products.²² In the following subsections, I will describe in detail Novo Nordisk's BM refinements and the choices that its management took with respect to organizational design during the period of 2000-2015 (Figure 6.1).

2000-2002	2003-2004	2005-2007	2008-2015
 Enzyme business (-) DAWN (+) Differential pricing policy (+) World Diabetes foundation (+) 	 New partnerships (+) Services to HCPs (+) 	 Changing Diabetes® (+) Small molecule business (-) 	No changes
 Global stakeholder engagement (+) Triple-bottom-line (+) R&D center in Beijing, China (+) 	Restructuring global marketing and stakeholder relations (+)	Revising The Novo Nordisk Way of Management	 Top management changes Resources allocated toward marketing

Figure 6.1 Novo Nordisk's BMI process

Note: The upper dark grey boxes represent BM changes while the lower light grey boxes represent organizational design changes. The (+) and (-) notations represent the addition and removal of elements, respectively.

2000-2002: Redefining the BM

Novo Nordisk reached a point where a decision was imminent as to whether the company should continue within health care and enzymes for industrial use or divest one of those activities. Prior to this, the two businesses shared a common interest related to the accumulation of knowledge in the areas of fermentation, recovery processes and related technologies. However, over the years, differences between the two increased to the extent that synergies no longer existed.

²² See Novo Nordisk's annual report (2016: 16)

Incompatible BM elements

As described above, it no longer made sense to keep the health care and enzyme activities under the same organization, as over time, the activities had come to represent quite different BMs in terms of target market segments, business cycles, economics and investment requirements. While the enzyme business was broadly structured around market segments as diverse as detergents, fuel, leather, baking, brewing, fats, and various animal feed products, the health care business was narrowly focused on diabetes care. For example, customers within food and beverages were interested in enzymes that could increase industrial efficiency by improving food production for anything from animal feed products to beer while reducing environmental impact. Meanwhile, the health care area focused on developing life-saving treatments for people with diabetes.

Novo Nordisk's core capabilities primarily resided in diabetes care, and shareholders and capital markets had historically focused on the health care, and to a lesser extent on the enzyme business. As summarized by one corporate vice president of R&D,

"Since the beginning, our strengths have been within engineering, formulating, developing and delivering protein-based treatments to people with diabetes ... A little later we also began excelling at industrial enzymes, but it was always regarded as a side activity to diabetes care."

Reactivating by removing. Due to this divergence in businesses, top management decided to divest the enzyme business into a new company called Novozymes A/S that was separate from Novo Nordisk's health care business. Also aided by other strategic considerations, the decision allowed each company to adopt its own unique BM. Put differently, the elements of value creation, appropriation, network and architecture could be designed to address the peculiarities of the health care (notably diabetes care) and enzyme businesses. This meant that each company could be more easily identified by its respective stakeholders. The path toward more value creating partnerships was also strengthened because issues such as exposure to unrelated business activities were no longer present. Most importantly, the divestment enabled Novo Nordisk to concentrate its efforts and resources on health care, and especially diabetes care.

Although the separation process was substantial and challenging due to the number of organizational functions and people involved, it merely constituted a minor change to Novo Nordisk's BM, as the core health care model remained intact. As a result, the divestment freed up not only managerial attention but also the capacity to explore new BM opportunities within health care. Thus, two new elements were added to the BM, namely what Novo Nordisk broadly referred to as "sustainable management" and "patient centricity."

Reactivating by adding. The idea behind sustainable management was to enlarge Novo Nordisk's value creating activities, as well as to add a social, bioethical and environmental dimension to the organization's value proposition. At the time, the pharmaceutical industry was going through a major public relations crisis in South Africa over the prices of HIV-AIDS drugs. Although Novo Nordisk was not involved, the situation inspired the company's new CEO, Lars Rebien Sørensen, to launch the World Diabetes Foundation (a non-profit organization) and a differential pricing policy for the least developed countries. The foundation was established in 2002 as an independent trust to support the prevention and treatment of diabetes, while the pricing policy was introduced a year earlier to improve access to the millions of people living in low-and middle-income countries. These initiatives were instrumental to forming Novo Nordisk's reputation as a responsible company committed to understanding the people it served rather than solely focusing on profit maximization. That said, there was a clear business purpose for implementing such initiatives, as the CEO explains in an interview with Harvard Business Review:²³

"Our philosophy is that corporate social responsibility is nothing but maximizing the value of the company over a long period of time, because in the long term, social and environmental issues become financial issues. There is really no hocus-pocus about this ... If we keep polluting, stricter regulations will be imposed, and energy consumption will become more costly. The same thing applies on the social side. If we don't treat employees well, if we don't behave as good corporate citizens in our local communities, and if we don't provide inexpensive products for poorer countries, governments will impose regulations on us that will end up being very costly."

²³ Retrieved January 2017 from https://hbr.org/2015/11/novo-nordisk-ceo-on-what-propelled-him-to-the-top.

At first glance, selling inexpensive insulin to developing countries does not seem like an obvious driver of revenues, but the CEO knew that tapping into the bottom-of-the-pyramid markets presents other promising opportunities. First, these markets have enormous growth potential, as they represent two-thirds of the world's population, along with the possibility of making an incalculable contribution to mankind. Second, lifting millions out of poverty by ensuring access to reliable and affordable insulin will translate into revenues in the long term. In brief, as countries get richer, they can afford better health care for their people. Unlike many other pharmaceutical companies, Novo Nordisk was owned by an independent Danish foundation (The Novo Nordisk Foundation), which allowed the company to focus on the long term. Third, Novo Nordisk's broad portfolio of insulin products made it possible to serve the world's poorer countries, while at the same time offering more advanced products to affluent countries. Finally, the new activities allowed Novo Nordisk to increase its value creation; "the more value a firm creates, the more likely it is to benefit from some of the value in the form of appropriable, if transient, rents. And what the innovator does not get in rents society gets in progress" (Moran and Ghoshal, 1996: 465).

An interesting change was made to Novo Nordisk's value network to reinforce the BM's new value creating activities. In particular, a shift in focus from the physician to the patient and other stakeholders was made in order to reflect the company's commitment to its social and environmental context. The new focus was invaluable because it not only positioned Novo Nordisk as a socially and environmentally responsible organization, but it also made sense from a BM perspective. For example, building relationships and collaborative arrangements between governments, local communities, patient associations, NGOs, and so on, helped Novo Nordisk provide the initial basis for insulin distribution in developing countries. As noted by a senior market access manager,

"A key characteristic of Novo Nordisk is our ability to enter a market early and be very patient. In this way, we are able to create a considerable amount of goodwill that can be used in different ways to provide better care for patients."

Top management, and notably, the newly established Global Stakeholder Engagement unit, utilized new partnerships to extend Novo Nordisk's capabilities well beyond its original scope. Without

them, it would have been impossible to establish the infrastructure necessary for insulin distribution.

Relocating by off-shoring. As part of Novo Nordisk's internationalization process, top management decided establish a new R&D center in Beijing in 2001 as a wholly owned subsidiary. They believed that this center could act as a bridge between the scientific communities in China and Europe. Not only did it represent an important milestone for the company's future competitiveness, but it also enabled the company to gain legitimacy and goodwill from the Chinese government.

The initial BM change characteristics. The BM changes were incremental, for example, in the form of (1) removing peripheral activities (e.g., divesting the enzyme business) from, and adding new features (e.g., a differential pricing policy) to, the existing value proposition, which improved access to markets in developing countries and positioned the company as socially and environmentally responsible, and (2) strengthening and maintaining Novo Nordisk's current path as a world leader in diabetes care. In sum, these incremental adjustments reflect processes of "innovative BM refinement" that contribute only to strengthening or improving the existing BM, and not to radically transforming it.

New organizational units, tasks, responsibilities, and performance measures

The changes made to Novo Nordisk's value creation and network components were accompanied by concomitant changes to the organizational design. The separation of the enzyme and health care businesses had significant implications for Novo Nordisk's formal organization, but for the BM, it was merely a matter of removing an activity and replacing it with a new one. Previously, although synergies still existed in some form, these did not extend beyond the discovery unit. This was a particular problem for units such as international marketing and product supply—activities between the enzyme and health care segments were simply dissimilar in terms of manufacturing processes and equipment. In terms of the nature and roles of marketing, for example, the enzyme business could use the entire marketing mix (i.e. the four P's: product, price, place, and promotion), while the health care business was limited to promotion, which was itself highly regulated. This had not posed a problem earlier, but significant growth, particularly in the health care segment, led to increasing bottlenecks in manufacturing and marketing. As the corporate vice president of marketing summarized, "Back then, we had to run really fast in marketing ... even though we had separate brand teams serving both health care and enzymes, there were simply not enough people. Moreover, our insulin portfolio was so broad, with several indications, claims, features ... that individual marketing campaigns were almost needed. I remember it was hard as a marketer, because you had a variety of quality products but you could only offer mediocre campaigns."

Relinking by resequencing. The divestment set up the organization to best use its corporate resources and factors of production to implement the chosen BM. At the same time, it also made room for new and more compatible organizational and BM changes. For example, the choice to include stakeholder relations as part of the top management team in 2002 was one of the more changes. In less than two years, stakeholder relations moved from a peripheral position within the organization to become part of Novo Nordisk's core, which already included discovery (R&D) and international operations and product supply (manufacturing). As one corporate vice president of strategy explained,

"moving stakeholder engagement into [top management] was a genius and bold move at the time ... To my knowledge, there were very few companies that had CSR represented in [top management] ... and certainly not pharma. In retrospect, I don't think many of the succeeding programs [BM changes] would have been as successful if our unit had been placed lower in the hierarchy. Novo Nordisk is run from the top down ... the higher up you are, the more resources and talent that are allocated."

Not surprisingly, the location within the organizational structure played an important role in driving BMI at Novo Nordisk. As the informant noted above, stakeholder relations' new core status enabled it to attract more resources and talent, which subsequently translated into better ideas for BM design improvements. Moreover, being part of top management also eased the implementation of such improvements. A higher position in the management hierarchy confers a bundle of advantages in this regard: easier access to information, less internal communication or bargaining needed to implement change, access to the best people, and so forth. Prior to this, ideas for

improving the BM had mainly emerged from within manufacturing or R&D due to the organization's intense focus on (1) engineering, formulating, developing and delivering proteinbased treatments, and (2) efficient large-scale production of proteins. During that period, it would be unusual if a stakeholder relations unit could drive changes in the BM.

Not only did stakeholder relations move into top management, but it became a new source of innovation for Novo Nordisk. In addition to the new differential pricing policy, the unit also launched the so-called DAWN program—a study intended to improve the understanding of the psychosocial burden of diabetes and identify critical gaps in the overall care offering. At the time, it was common to study and publish findings on disease-related symptoms, but efforts to uncover the psychosocial burden of diseases were uncommon. Not only did the DAWN study mark Novo Nordisk's commitment to patient centricity, but it opened numerous opportunities for the company to engage with a series of powerful stakeholders and build the foundation for longer-term relationships and co-operation with patients, health care professionals (HCPs), governments, researchers, and others—all of whom had complementary knowledge and assets that could form the basis for future BM improvements at Novo Nordisk.

On the surface, moving from a product-oriented BM toward a more socially and environmentally sustainable model might seem problematic due to seemingly different logics of value creation and appropriation. But for Novo Nordisk, it was almost a natural progression, as one director of marketing explained:

"You could ask, 'What does it mean to be patient centric?' Well, ultimately patients want to be cured or in some way relieved of their symptoms or signs of illness ... As a pharma company, the best way we can help is to produce high quality products that hopefully one day lead to a cure. This has always been our main priority ... to make the best products and devices available for patients so they can live a normal life. Thus, talking to patients and other stakeholders and launching pro-social and environmental programs was quite natural for us ... It was just another way to create more value for patients and society at large."

Although the new model elements represented an extension of Novo Nordisk's BM, another set of supporting practices was employed to facilitate the transition. Perhaps the most far-reaching of the various formal mechanisms for implementing BM changes was Triple Bottom Line reporting. The Triple Bottom line was seen as a reaction to the growing concerns of globalization, access to health care, human rights, bioethics, and so on, and it presumably helped differentiate Novo Nordisk's value proposition from competitors. In 2001, Novo Nordisk's stakeholder relations department outlined the approach in their report, "Reporting on the Triple Bottom Line":

"We are building the business case for sustainable development. This way, the Triple Bottom Line approach becomes integrated with the traditional definition of shareholder interest. We believe that a broader business approach modelled on the Triple Bottom Line is the right thing to do. It also makes good business sense and enables us to be a player in setting the new global agenda for pharmaceutical companies."

The Triple Bottom Line was partly a new strategic framework outlining the adoption and implementation of social and environmental responsibility, and partly new targets and performance measures reflecting those actions. A list of nineteen performance targets was compiled on the basis of the social and environmental dimensions—for example, one target included the development of sustainable BMs (e.g. the differential pricing policy) in developing countries to improve access for people with diabetes. Others included assisting governments with the development and implementation of national diabetes strategies. This set of targets linked into Novo Nordisk's balanced scorecard system to ensure proper cascading of the Triple Bottom Line approach across the organization. Specifically, the balanced scorecard was cascaded to the business unit level, and then converted into personal targets for the individual employees, which would be determined and evaluated on a biannual basis. Nearly all informants agreed that the balanced scorecard was highly effective at getting things done. One strategy manager explained:

"We try to quantify all the things we do, including softer elements such as patient centricity ... In general, it works really well at Novo Nordisk because it holds people accountable and provides a source of motivation. It ensures that all units and functions are moving in the same direction."

Moreover, the effectiveness of The Triple Bottom Line and the balanced scorecard was largely influenced by a unique organizational practice, namely the use of so-called 'Facilitators'—a small team of high profile professionals²⁴ employed by the holding company, Novo A/S. The purpose of the facilitator team is threefold: It provides (1) a systematic way to ensure that Novo Nordisk's core values are translated into action; (2) best practice sharing; and (3) problem solving. More specifically, a typical facilitation consists of a series of confidential, one-on-one interviews with the managers and employees of a specific unit. The interviews are supplemented with various written documentation and statements from external stakeholders. Interviewees are not asked to prepare in advance for their interview-rather the interviewer is interested in having an honest dialogue about successes and challenges in the interviewees' work context. The names of individual employees are never revealed in a facilitation report. However, if the facilitators find a general trend or issue that needs attention, that issue will be included in the final report, and they will also help the unit manager with finding ways to alleviate the problem and assure timely follow-up to monitor progress. Furthermore, the facilitators typically work in pairs; most departments, subsidiaries and business units are facilitated every 3-5 years, whereas strategically important areas that are under expansion will be 'facilitated' more frequently. The facilitation process was introduced in 1997, and by the early 2000s had become a well-established practice within the organization. Managers gave the following comments:

"Facilitations are taken very seriously at Novo Nordisk ... They can influence your career if you have serious findings ... a topic that people love to gossip about." (General manager)

"It's nice being able to give your opinion to someone more experienced, instead of filling out those engagement questionnaires." (Regulatory affairs manager)

"Our CEO reads all the reports ... and if you violate the Novo Nordisk Way and your employees are not doing well due to deviating leadership then you get fired." (Vice president of R&D)

²⁴ Each facilitator has experience in senior specialist or managerial positions at Novo Nordisk or Novozymes.

Novo Nordisk: A BM Refiner

The presence of facilitators, combined with the balanced scorecard and The Triple Bottom Line, produced a strong apparatus for implementing Novo Nordisk's initial BM changes. The Triple Bottom Line highlighted areas of the BM (e.g., the social and environmental aspects) that needed to be addressed, while at the same time securing employee motivation and commitment internally. This was supplemented by the balanced scorecard, which operationalized the social and environmental aspects of the BM using more quantitative measures. These practices were weaved together to create an effective implementation capability of the facilitators, who served as a control mechanism and problem-solving mechanism. Finally, the host of organizational practices also served as an important driver of BM improvements. In particular, they carried information pertaining to BM performance, change progress, implementation barriers, and so forth.

Despite the inclusion of stakeholder relations in top management, many of the organizational practices had already been in place since the mid- to late 1990s, and therefore had become stabilized as the way of doing things at Novo Nordisk. This way is similar to the *kaizen* philosophy, where "there can be no improvement where there are no standards" (Masaaki, 1986: 74). Thus, changes to Novo Nordisk's value creating activities and network were postponed until the organization had incorporated the appropriate standards and measures to ensure proper implementation.

2003-2004: BM Continuity and Global Growth

This period emerged after the initial redefinition of Novo Nordisk's BM. The first outcomes of the BM change efforts started to show, as well as the implications for the underlying organizational design. More importantly, it was a time in which Novo Nordisk experienced significant growth in sales (especially in the attractive US market), new product launches, and reorganizing activities in Europe. Meanwhile, its new BM elements also proved to be successful in positioning Novo Nordisk as a responsible organization, in contrast to the eroding reputation of the industry in general. This led to a series of new projects that were used to further test the value contribution of a more patient-centric BM.

Stability and BM Refinements

Novo Nordisk's BM remained relatively unchanged during this period—no fundamental changes were made to its core elements. Rather, it was a period best described as insightful, as it showed the effectiveness of Novo Nordisk's former BM changes. As summarized by a vice president of R&D,

"Hmm it's a difficult question ... In hindsight initiatives such as DAWN and sustainable business models played an important role in improving our reputation, but our business model was still science-based ... and ultimately that was the key value and profitability driver."

While the new elements fulfilled an important social and environmental role, they still took a backseat to Novo Nordisk's core BM elements, and to the search for better methods of diabetes treatment. With the launch of Levemir® in Europe, Novo Nordisk became the first company with a complete range of insulin analogues. This was an important achievement in several ways. An insulin analog is similar to regular human insulin, but is slightly modified to allow it to act faster (e.g. NovoRapid[®]) or slower (e.g. Levemir[®]) than regular human insulin²⁵, providing greater convenience and improved control of glucose levels. For people with diabetes, the ability to control glucose levels is crucial because it helps minimize diabetes-related complications (Hartman, 2008). Moreover, not only did Levemir® open the market for long-acting insulin and offer more predictable day-to-day control of glucose levels than conventional insulin forms and competing analogues, it was "the only insulin product in the world, that doesn't make you put on weight" (Annual report, 2004: 7). Having a broad portfolio of insulin products was another way of demonstrating commitment to patient centricity. This level of product differentiation allowed Novo Nordisk to adopt a market segmentation strategy to more clearly meet the needs of people with diabetes. In some situations, fast-acting insulin might the best choice, while in others, long-acting insulin is preferable; this choice depends on the people's individual lifestyles and personal needs. As the executive vice president and chief of science officer explained,

²⁵ Retrieved April 2017 from <u>http://type1diabetes.about.com/od/insulinandmedications/p/Insulin-Analog.htm</u>

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"that is why Novo Nordisk has developed the broadest and most comprehensive portfolio on the market [...] There is no one-size-fits-all [approach to] diabetes management" (Annual report, 2004: 7).

This broad portfolio also made it feasible for Novo Nordisk to provide inexpensive products (such as human insulin) to developing countries, while offering its more advanced and expensive products to the more affluent countries. Finally, the approval of Levemir® illustrated the variability of Novo Nordisk's core BM elements—notably, its ability to develop and deliver superior products and devices within the diabetes management sector. Relatedly, the company's diverse selection of analogues helped it to penetrate the challenging US market, especially with NovoRapid® (NovoLog® in the US) and the launch of NovoMix30® (NovoLogMix 70/30 in the US) packaged in the disposable delivery device FlexPen®.

New strategic partnerships. Although Novo Nordisk's BM remained relatively unchanged during 2003-2004, particular refinements were made to support the company's new focus on patient centricity and sustainable management. In 2003, Novo Nordisk, in collaboration with Oxford University, founded Oxford Vision 2020, whose goal was to direct attention "to the fact that three risk factors (tobacco, diet and lack of physical exercise) cause four chronic diseases (cardiovascular disease, diabetes, chronic lung disease, and some type of cancer) that are responsible for 50% of deaths globally" (Annual report, 2004: 3). The intention was threefold: (1) to put more emphasis on preventing the pandemic growth of chronic diseases rather than merely treating them; (2) and perhaps more importantly, to promote healthier lifestyles; and (3) to show that a combined effort from several stakeholders is required to tackle the leading chronic diseases. Besides its founding members, the alliance included government and public health agencies, universities, and corporations such as Johnson and Johnson, Nestlé, Unilever, the World Bank, the WHO, and the World Heart Federation. Novo Nordisk's BM was not built around prevention, given that its main value-creating activities entered the picture only after people had already developed diabetes. In fact, one could argue that a prevention-based BM would cannibalize the company's core elements (i.e., diabetes treatments). Nevertheless, top management was convinced that Novo Nordisk could potentially benefit from such involvement, as the chief executive officer explained:

"As a knowledge-based company, we know that type 2 diabetes is caused largely by factors which can be prevented. If society is moving in the direction of prevention, it makes sense for us to be involved, not only because we have knowledge about how to potentially postpone or prevent the disease, but also because we need to be alert to changes in society that could affect our long-term activities. It is about turning what could be considered a risk into an opportunity" (Annual report, 2004: 4).

Reactivating by adding a service dimension. To support the growing insulin portfolio, top management made it clear that Novo Nordisk should provide not only superior products and devices but also a range of services that would make the company the preferred partner in diabetes care. Novo Nordisk used service offerings to increase its value creation ability across the value chain. The company arranged a number of training seminars targeted at HCPs within diabetes care, particularly in developing countries. For example, a program was launched in sub-Saharan Africa to educate physicians and nurses as well as people with diabetes. Physicians and nurses often did not have the necessary training and education to properly diagnose people with diabetes. They also lacked knowledge about the latest treatments and how to manage the balance between diet, blood glucose response and daily activities. Similar programs were launched in Afghanistan, India and China, and a total of 130 initiatives were launched to support governments across the world in implementing strategies for improved diabetes care. Each program was backed by new and useful tools, such as the National Diabetes Programmes Toolbox, the Diabetes Atlas, and the Guide for Diabetes Guidelines created in collaboration with the International Diabetes Federation.

At the time, recognizing the systemic nature of diabetes care (and chronic diseases in general), top management was preoccupied with notions such as holistic care, a multi-pronged approach, and not least, the Triple Bottom Line. Services are ideal for tackling systemic issues because they can be invoked during the various stages of the disease journey. People with diabetes go through the following stages: (1) prevention (e.g. diet and exercise); (2) diagnosis (e.g., using $A1c^{26}$ tests and other tests); and (3) diabetes management (e.g., diet, exercise, medication and emotional well-being). The various stages may include interactions with a host of different HCPs,

²⁶ The A1c test is common blood test used to diagnose type 1 and type 2 diabetes.

such as an endocrinologist, psychologist, ophthalmologist, dietician, podiatrist, and cardiologist. Moreover, having diabetes is something that usually lasts for a lifetime, since it cannot be cured; it therefore requires intensive, long-term self-management. The sum of these characteristics created a context that is prone to mistakes as well as opportunities for additional value creation. Capitalizing on the latter, many of the company's programs were based on improving the training of HCPs, which translated into added value by: (1) improving HCPs' ability to diagnose, select the proper treatment and offer advice and guidance to patients; and (2) improving the satisfaction (and potentially the adherence to treatment) of patients and families. Other programs promoted diabetes awareness and healthier lifestyles through collaborative efforts with local communities and governments, thereby creating value in the stage of prevention.

Consequently, although Novo Nordisk had a narrower scope than other pharmaceutical companies in terms of the number of therapy areas targeted, they were able to expand the value proposition, and utilize the value network and architecture to a greater extent than competitors. Novo Nordisk was now present during all stages of the disease journey (i.e., from prevention to diabetes management), while competitors and the industry as a whole were more concerned with disease treatment. Many informants working at the company at that time stated that such patient-centered and prevention-based activities were unusual in the industry, but that the company's strategic focus allowed such a pursuit. A corporate vice president of marketing added:

"Our strategic focus on diabetes allowed us to put far more efforts into a narrower area ... and diabetes is actually not that narrow commercially. Therefore, it was possible for us to do things, I would argue, much better than any of our competitors. Doing the kind of things we are doing is impossible if you are in seven major therapeutic areas."

A vice president of strategy and planning explained that it was a deliberate choice for Novo Nordisk to have a presence at multiple points in the value chain:

"Adding services to the mix was part of becoming a diabetes care provider rather than being perceived as only another insulin manufacturer."

Or, as the vice president of clinical trials put it,

"At Novo, we tend to do everything related to diabetes in house [example from clinical trials]. Small things such as blood samples and some safety procedures we outsource, but monitoring and all other things we do in house because we want to collaborate with KOLs [key opinion leaders]. And when they think diabetes, they think Novo Nordisk. We can't have a monitor coming from Quintiles and asking who is conducting this study. [For] clinical trials within diabetes, we know that we are the best because we look at CMR benchmark data. Their partners say 'Novo is the best to conduct these things.' So if we come and ask for certain types of patients, they are more open to let us do it because they know Novo makes the best insulin."

This quote reflects top management's ambition to make Novo Nordisk synonymous with diabetes so that key opinion leaders²⁷ and ultimately physicians would recommend and prescribe Novo Nordisk's products and devices. Specifically, the added service dimension allowed the company to (1) lock out competitors; (2) lock in important gatekeepers and, in the end, patients; (3) unlock more value from the growing insulin portfolio (cf. Vandermerwe and Rada, 1988); (4) access important resources or capabilities; and (5) ultimately differentiate from competing insulin suppliers and other pharmaceutical companies in terms of value provided.

Even though the new alliance and added service dimension were minor changes relative to earlier BM changes (i.e., removal of elements and introduction of new elements)—in the sense that they constituted elaborations of existing elements (namely, sustainable management and patient centricity)—they offered a bundle of complementary features that reinforced prior BM choices. More specifically, training and educating HCPs could lead to: (1) higher prescribing rates and brand loyalty for Novo Nordisk products; and (2) opportunities to gain valuable insights from HCPs that could be used to further improve the BM. It was relatively easy for Novo Nordisk to legitimize the new service offering, because the company not only had the most advanced insulin products and devices, but it also possessed decades of experience dealing with research on diabetes, not to mention the recent DAWN findings, which showed the psychosocial burden of diabetes and lack of

²⁷ In the pharmaceutical industry, "key opinion leaders are physicians who influence their peers' medical practice, including but not limited to prescribing behaviour." Retrieved April 2017 from <u>http://www.pharma-mkting.com/glossary/keyopinionleader.htm</u>

reliable treatment options. As a result, Novo Nordisk was in a good position to offer these types of services related to training and education. Overall, the new service dimension, coupled with new partnerships, allowed Novo Nordisk to extend its value proposition and enter other key areas of the value chain.

Realizing complementarities and the organization of servitization

As with the BM changes, the degree of organizational design change at Novo Nordisk remained relatively low, especially in relation to the previous divestment and move of stakeholder relations into top management. During this period, not only was continuity prioritized, but important new roles were added and intra-organizational coordination and optimization activities took place. In particular, the international marketing unit came to play a prominent part in the improvement of Novo Nordisk's BM. One corporate vice president of marketing summarized it nicely:

"We had just started gaining some traction in the US market and the organization was finally settled in after the demerger."

This period could be interpreted as a post-change period—in which stability allowed for change to better manifest itself and *mesh* with the surrounding organization. Although only on a small scale, Novo Nordisk did alter some elements of its formal design to improve the meshing process. Perhaps the most critical one included the reorganization of Novo Nordisk's European activities. The combination of high growth rates and new product launches had stifled coordination within the European market, and in order to improve it, a new European headquarters was built in Zurich, Switzerland in 2002. In addition, seven business areas were consolidated into five equal-sized areas to strengthen sales and marketing activities. During the same period, sales and marketing activities were also significantly expanded in key growth markets such as the US, Brazil and China. As one general manager noted,

"You could argue it was really the rise of marketing at Novo Nordisk. It was a strange time with a lot of growth and expansion but at the same time fierce competition. Until then, our main focus had always been on R&D ... and to some degree production due to the quality issues in the late 90s ... But now there was an urgent need to improve the sales organization. This was really

frustrating for us in the affiliate companies, because demand was high and we probably had the best products ... but we lacked sales reps and sophisticated marketing methods."

While marketing had always played an integral role at Novo Nordisk, it was always secondary to the discovery and operation units. Yet the increasing growth, particularly in the US led top management to devote even more resources toward marketing. To effectively market the growing portfolio of analogues, a larger and more diverse sales force was needed, particularly in the US. As mentioned earlier, although diabetes represents a single therapeutic area, it is a very broad field due to its inherent complexity. Thus, a diverse selection of products is needed, as each has its own distinct advantages and disadvantages, depending on the patient's unique circumstances. Novo Nordisk had this diverse selection of products and devices, but physicians were not up to date with the latest treatment options. The role of marketing was to make the prescribing physician aware of those options. Thus, the US sales force was increased by 150 sales representatives who would specialize in key strategic products, including NovoLog®, NovoLogMix® 70/30 and FlexPen®.

Similarly, Novo Nordisk's move into services also required additional workers—especially at the subsidiary level. During the previous four years, Novo Nordisk had been developing a model for sustainable diabetes care in developing countries. The roll-out of the model started with the introduction of the differential pricing policy and the establishment of relationships with key stakeholders (e.g., governments, NGOs, and local communities), followed by the provision of services. In 2003, Novo Nordisk funded a network of nationwide diabetes clinics in Tanzania. The Ministry of Health in Tanzania staffed the clinics with physicians and nurses from the national regional hospitals, while Novo Nordisk was responsible for training and educating the HCPs. Similar programs were launched in India, Malaysia, Costa Rica, China, and Bangladesh. The task of setting up clinics and establishing the right relationships with relevant actors was delegated to the local subsidiary, while the international marketing unit at corporate headquarters developed the core material for the training sessions. However, even though marketing received more resources at the subsidiary level, most of the resources were allocated to traditional sales and marketing activities in the form of, for example, sales staff increases and promotional activities.

Importantly, including services as part of the value proposition indirectly led to greater integration between discovery, international marketing, stakeholder relations, international operations and product supply. The core part of the HCP training material was based on the company's considerable knowledge accumulated within its discovery unit over the years. This gave rise to increased interactions between discovery and international marketing. The People, Reputation and Relations unit (formerly, stakeholder relations) allowed Novo Nordisk to (1) secure important macro-level relationships, (2) translate and integrate Triple Bottom Line thinking into all business processes, and (3) monitor progress on the Triple Bottom Line. Before this period, there was little internal communication and knowledge sharing along the horizontal dimension of the organization. As one vice president noted,

"We have always been very science-based and functionally structured, but some of the BOP [bottom of the pyramid] projects really helped breaking down silos and reshape the company"

The stakeholder relations unit had been expanded in 2004 to include corporate communications, human resources and occupational health services. This indicated continued support of the unit from top management. The People, Reputation and Relations department was headed by Lise Kingo, executive vice president. She argued that the unit controlled two of the company's most important assets—namely, its people and its reputation (Morsing and Oswald 2009). But it was the unit's dual role as an integrator and monitor that helped the organization identify and realize complementarities. This role was further strengthened as the Triple Bottom Line got added to Novo Nordisk's Articles of Association "to specify that the company will strive to conduct its activities in a financially, environmentally and socially responsible way" (Annual report, 2004: 9).

2005-2007: Discontinuing small molecules and changing diabetes

The previous period could be described as stable, without any notable changes to the BM. Time was given for the new BM elements and organizational tasks to mesh together into a coherent whole. But during those years, it also became apparent that the BM could be even more focused on diabetes care and more compatible with Novo Nordisk's core capabilities. Therefore, top

management decided, once again, to reactivate the BM, including, most importantly, discontinuing Novo Nordisk's small molecule business. 2003-2004 was also a period in which the organization performed better than ever financially and operationally, but at the same time faced growing pressure from globalization and payers.

A more intense focus on the core

The period of 2005-2007 represented another defining moment in Novo Nordisk's BM refinement process. The initial changes made in the early 2000s involving the divestment (focusing) and expansion of the value proposition (expanding the scope) had proven to be a successful model for value creation and appropriation. As a result, top management decided to elaborate further on the element of sustainable management by introducing the Changing Diabetes® movement. Despite the company's success, however, there was an growing consensus among top managers that presence in the small molecule segment was perhaps not commercially viable.

Reactivating by adding. Novo Nordisk entered 2005 with astonishing reports of growth in sales and earnings of 16% and 17%, respectively, compared to the previous year. This provided proof of the efficiency and effectiveness with which the organization had managed to implement and refine its BM over the previous five years. Being a world leader in diabetes care, however, entailed responsibility, and there was still room for improved methods of intervention. The incidence of diabetes was escalating at an ever-faster pace in low- and middle-income countries as a result of increased urbanization and growing affluence, which led to more inactive lifestyles and the consumption Western-style nutrition containing high amounts of fat, sugar and salt. To confront the growing pandemic, Novo Nordisk launched yet another initiative, Changing Diabetes®. This was not just another initiative. In fact, it became part of the organization's mission statement. The Changing Diabetes® program represented an extension of previous activities within, for example, DAWNTM. It also reflected increasing interest from other stakeholders in fighting diabetes and other chronic diseases. Training of HCPs was improved as a consequence of Changing Diabetes® buses, which drove around in various countries and not only helped improve disease awareness, but also aided in diagnosis and disease management. This indicated another incremental improvement built upon the foundational elements laid down in previous years.

Reactivating by removing. After several years of concerted effort, top management decided in 2007 to discontinue Novo Nordisk's research and development on small molecule oral therapies for type 2 diabetes. This change seemed like a natural progression, as the organization's core focus was always on large molecules, a priority that has not changed since the formation of Novo Nordisk's parent companies in the 1920s. As the chief of science officer Mads Krogsgaard also explained:²⁸

"Our core competencies lie within therapeutic proteins [large molecules], and it is within this area that we can make the greatest difference in terms of patient outcomes and company growth. Therefore, it is a logical move to focus all our research and development efforts on this area."

The magnitude of change varied greatly from the divestment in 2000. In fact, the decision only impacted approximately 180 employees. Nevertheless, it still signified an important decision in terms of Novo Nordisk's BM design. This was addressed by several informants. The corporate vice president of marketing stated:

"Small molecules are fantastic. They are fast to develop and you can reach big populations with them. They are also promiscuous in a way—chemically promiscuous in the body biologically, and they are active in many more sites than you probably know in a typical clinical program, which is also why you see great safety concerns ... I think we took a brave decision to say even if small molecules play a role in diabetes (and they do, and there are plenty of them), we decided not to pursue them ... In those days there was no certainty that we would continue to be successful in the biologic space. Therefore, it was a bold move to say ... half of the market we are not going to address."

One R&D director also added:

²⁸ Retrieved April 2017 from <u>http://www.outsourcing-pharma.com/Preclinical-Research/Novo-Nordisk-stops-small-molecule-drug-development</u>

"We flirted a little bit with small molecules, didn't get much traction and then we took the decision to go back to basics, but small molecules were almost half of the diabetes market."

Here, making a deliberate choice or trade-off about what to do and what not to do was at the heart of the strategy. In the end, the choice was informed by Novo Nordisk's underlying BM, which was more compatible with serving the market for large molecules.

Organizational design as a preserving and implementing mechanism

Novo Nordisk's organizational design remained more or less unchanged in the 2005-2007 period. Despite the significance of removing small molecules from the value proposition, the change merely involved closing down a smaller area of discovery that had 180 people, of whom half were offered other positions within the company. While there are notable differences between small and large molecules from a scientific point of view, the characteristics underlying developing, manufacturing, and marketing products based on small and large molecules technologies are quite similar (Rozek, 2013). Thus, changes to the formal organization could be kept to a minimum.

While Novo Nordisk's formal design remained relatively intact, the small change served a secondary but still important role in explaining the effectiveness of the company's BM. Specifically, the organizational design was associated with stability—a continuation of direction with minor refinements of and extensions to existing organizational units. As one executive assistant stated,

"We are very conservative and rarely change things around here, which can be quite annoying at times. On the other hand, people know the organization very well—the direction of the company—and what is expected."

Or, as noted by one vice president of marketing:

"We are here to serve patients and the best way we can do that is by delivering optimal treatments. So let's focus on that instead of doing a lot of crazy things."

The ability to preserve the structure also made it easier for managers to suggest and/or implement BM changes, because they could with greater certainty assess: (1) what kind of changes would be in alignment with the structure; and (2) follow the existing procedures of implementation. The fundamental implementation issue with any strategic change relates to coping with uncertainty (March and Simon, 1958; Thompson, 1967). Although Novo Nordisk performed better than ever and seemed to have found the proper balance between change and stability, it could not entirely escape the consequences of globalization. One of the company's core BM elements was particularly threatened, namely that of the Novo Nordisk Way of Management. This element was unique, especially since it was partly an element of the BM and partly organizational-extending all the way from R&D through manufacturing and marketing, and then beyond firm boundaries to external stakeholders. The Novo Nordisk Way of Management was the overarching organizational and cultural framework of the organization. Not only did it encompass the demand that deliverables meet the company's vision, values, commitments, fundamentals, but it also delineated the methodology (i.e., sustainability reporting, balanced scorecard, and facilitation) upon which these factors would be measured and scrutinized. As the corporate vice president of strategy and planning explained,

"It's a robust framework for getting things done, because it's very consistent and coherent—that means even though things change slightly, the Novo Nordisk Way remains more or less constant ... And you know what is within its scope and what is not. At the same time, it enables us to systematically measure things and thereby forces people to quantify ideas and projects."

The framework was also useful for coordinating and aligning various tasks and activities between the organizational units. Equally important is that it was commonly used for (1) settling disputes; (2) reducing ambiguity; and (3) judging incommensurable things. These functions were mentioned by several informants, especially the point about settling disputes and coming into agreement. The corporate vice president of marketing provided a good example:

"I have often referred to the Novo Nordisk Way of Management when I needed to legitimize specific priorities. In marketing we serve a number of different stakeholders ... and all of them think they are important, but that is not always the case. Then they get angry if they don't get the attention that they feel they deserve ... Therefore, I always ask my team to prioritize projects that are more in accordance with the Novo Nordisk Way. Then there is not so much to discuss ... And it also makes things easier for me when I have to argue for budget allocations."

Nevertheless, with the increasing presence of globalization and continued growth of the company, the integrative properties of the Novo Nordisk Way of Management ran the risk of being spread too thinly. These integrative properties were derived from the people who worked according to the framework; without the right people, it would be impossible to execute and uphold the Novo Nordisk Way of Management, which essentially glued together organizational units and BM elements into bundles of value creation and appropriation, which underpin the implementation of BMI. The Novo Nordisk Way was fundamentally based on respect for the individual as well as social and environmental responsibility—a set of Scandinavian values that did not readily lend itself to implementation in some new markets. Consequently, top management decided to exert additional efforts to maintain and spread the framework because it was such an important component of the company's culture, organization and BM.

2008-2015: BM Success, Decline, and Refocus

The period of 2008-2015 was a particularly long and, in many ways, defining period for Novo Nordisk's BM endeavors. The period began with the unfolding financial crisis in 2008. While many companies, large and small, were severely affected, Novo Nordisk managed to report positive performance. However, even though the pharmaceutical industry was more resilient than others—due to the fact that people continue to become ill and need treatment irrespective of global economic forces—pharmaceutical companies and even Novo Nordisk were challenged. For almost a decade, Novo Nordisk's BM remained unchanged with respect to adding new (or removing active) BM elements. A lengthy process of repetition was started to build upon the firm's prior and core BM choices, ultimately leading to an extended focus on marketing, and a move away from people, reputation and relations.

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Oscillating between value creation and appropriation

During the 2008-2015 period, not a single new element was added to Novo Nordisk's BM, nor was anything removed, even in light of a more challenging environment. The top management team was firmly convinced that they had a winning BM. As summarized by a vice president of marketing,

"Many pharma companies are changing these days, because they are unable to deliver on innovation. Instead they try to deliver through increased M&A activity, new business models, or both. We, on the other hand, have a model that works ... so why change it."

Once again, the strength of Novo Nordisk's BM became apparent when top management introduced Victoza®, the first once-daily human GLP-1 analogue, approved for launch in Europe in 2009 and in the US and Japan in 2010. Victoza® represented the latest and most advanced analogue to date, and included benefits such as administration once a day at any time not related to meals, and lowered appetite, which resulted in weight loss over time. The product was approved as supplementary to diet and exercise to improve glycose control in adults suffering from type 2 diabetes. The approval allowed Victoza® to be used as a monotherapy, or as a second-line treatment in combination with other oral medications prescribed for diabetes. In addition, the US market for GLP-1 drugs was especially attractive because Eli Lilly's Byetta was the only drug on the market and Victoza® was superior in terms of safety and efficacy. A few years later, in 2011, Victoza® reached the status of a blockbuster drug, generating more than \$1 billion in sales. This success demonstrated Novo Nordisk's longstanding tradition within diabetes care and protein engineering. Several informants highlighted the excellence of Novo Nordisk's R&D organization. As the corporate vice president of strategy and planning nicely put it,

"We have focused a lot on our R&D side. So many of the products are developed organically within the same area ... Because of that we have developed very good competencies, which increases the probability of finding something of high quality—compared to if you are a pharma company that is in many different therapy areas. We have been in diabetes for more than 90 years. This means that we have special competencies which cannot be readily developed if you don't have the same kind of history as us."

The R&D director stated,

"We have people who have been in the field of diabetes for more than three decades."

Or, as one vice president of clinical trials mentioned,

"As far as I recall, we have never bought any significant molecule or product at Novo."

2008-2015 was an interesting period. While most pharmaceutical companies had problems delivering on innovation, therefore resorting to mergers and acquisitions (M&As), Novo Nordisk continued with its organic growth model and promising diabetes pipeline. In contrast to many other companies, and especially the so-called 'Big Pharma,' Novo Nordisk's R&D organization innovated within a much narrower field—and had been doing so for several decades. That made the probability of finding the right drug candidates higher, thus making their model feasible.

However, in spite of Novo Nordisk's excellent R&D capabilities, they were eventually unable to escape the pressure from more rigorous and demanding payers. In 2013, the FDA rejected the marketing authorization for Novo Nordisk's long-acting basal insulin Tresiba®, instead requesting additional data from a dedicated cardiovascular outcomes trial before approval could be granted. Such as study would likely delay the launch of Tresiba® in the US by two to three years. After the great success of Victoza®, which had one of the most successful drug launches in history, this action came as a shock to many inside Novo Nordisk. As summarized by an executive assistant,

"Yes it was a big surprise when we didn't get the Tresiba approval. It was even a shock for [top management] I think ... because suddenly we had to run very fast in marketing and figure out what to do. There was not really a Plan B everything had been set up and prepared for the Tresiba launch. In hindsight, we should probably have had an alternative plan, but on the other hand you

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have to believe [...] We ended up launching a new campaign for Levemir® even though our focus at corporate is on future insulin products."

As a consequence of the increasing difficulties with payers and regulators, top management decided not to change Novo Nordisk's BM but to redirect attention away from the more peripheral value creating activities (such as sustainable management) and toward value appropriation, especially market access.

Toward a marketing organization

Throughout 2008-2015, a few notable changes were made to Novo Nordisk's underlying organizational design to deal with the increasing pressures from payers and regulators. In collaboration with the board, the CEO changed the composition and responsibilities of the top management team. At the same time, new core capabilities within marketing were developed, specifically for the early stages of drug launch. As summarized by one vice president of HR,

"I think in the past three or five years we have been recruiting more market access people at corporate ... And in many markets you are moving away from the traditional sales rep because physicians don't want to talk to them anymore. Instead you see a trend toward medical liaisons ... a more advanced rep who can talk to authorities and specialists."

The most critical events during this period surrounded the launch of Victoza® and Tresbia®, in 2009 and 2013, respectively. The launch process for Victoza® started in 2008, one year before the actual launch. The activities surrounding the launch drew on previous experience; the successful roll-out of Levemir® in particular provided valuable insights into coordinating multiple individual launches. The Victoza® launch team was headed by the senior vice president of global marketing, Jakob Riis. Not only had he held key positions in strategic markets (e.g., the US and Japan), but more importantly, he had gained knowledge from both sides (i.e., subsidiaries and headquarters) during the roll-out of Levemir®. The importance and potential of Victoza® was further underlined when top management relieved Riis of his other duties as senior vice president of global marketing

so that he could mobilize all of his efforts toward the launch. As one senior manager of medical affairs stated,

"The Victoza® launch was crazy almost from the early get-go ... The atmosphere was fever-pitch ... and we worked unbelievingly long hours because we had to prepare so many different launches."

Jakob Riis later explained in an interview that he initially thought it was possible to devise and forcefully implement a structured plan. However, he quickly came to realize that the health care environment had become much more dynamic and diverse compared to five years earlier, when Levemir® was launched.

New coordination mechanisms. To address the changed landscape, cross-functional and boundary-spanning teams (so-called 'global commercial teams') were set up and granted the necessary decision-making rights. This permitted the gathering of insights ranging from specific prescriber behavior and payer needs, to competitive dynamics and patient profiles. The organizational setup also had the required power to rapidly operationalize decisions based on those insights. In addition, the launch lead was allowed to build his own team—he could select from among Novo Nordisk's top talent within the various functional areas. A vice president of clinical trials described how employee performance records are used to select such teams:

"Then we go from little league to professional league. Prior to that I cannot just say to line management that I need her or him ... Everything is in the system ... Twice a year I give feedback to line management on how their staff members have performed on a given project. And I can track those reports years back. For example, I can see how Anders has performed the past three years if I don't know him very well. We have that on all people in Novo Nordisk."

Access to such granular employee-level data was crucial to building the right team, as one vice president of marketing nicely summarized:

"It becomes easier for me to spot if it's someone who's all mouth and no action."

Identifying the right people was essential, because even if authority was granted, this did not necessarily mean that people would be able exercise it. Essentially, the complexity surrounding the launch created literally thousands of decision-making situations each week, which required prompt corrective interventions. One example would be a change in prescriber behavior or payer needs—something that could change from month to month, and thus required an immediate remedy. Ultimately, the Victoza® team carried one of the most successful drug launches in history. Following that launch, a so-called launch excellence framework was developed on the basis of insights gained from Victoza®, and this was later used for Tresiba®. The Victoza® launch also demonstrated the growing importance of marketing, which a couple of years prior was merely considered a support function. Many informants commented about this shift. One vice president of HR commented,

"If you have been following the business press then you can see there is lots of talk about him [Jakob Riis] being the next CEO. I don't think it's entirely true, but he has definitely achieved a hero status inside Novo Nordisk."

Changing roles and responsibilities. This was further strengthened when Jakob Riis became part of Novo Nordisk's top management team in 2013, taking the role of executive vice president of global marketing and medical affairs. This also meant that Lise Kingo's remit became narrower; as a result, she decided to leave Novo Nordisk in 2014. Such a rotation indicated not only a shift toward a greater influence of global marketing, but also a shift in the BM toward value appropriation.

In 2013 came the disappointment of FDA's rejection of Tresiba® due to insufficient clinical trial data on cardiovascular outcomes. Not only had Novo Nordisk lost valuable early time in the marketplace, which is critical for any drug launch, but it also had a larger US sales force that would have to redirect its efforts toward Victoza® and Levemir®. In 2015, the company finally managed to obtain FDA approval. However, shortly after, it encountered problems with the German health care authorities, who declared that the product failed to offer any significant benefits over existing insulin products in the marketplace. As a consequence, top management decided to pull Tresiba® from the German market. As executive vice president of marketing and medical affairs Jakob Riis explained in an interview,

"We are very sad that it has not been possible to reach a price agreement with the insurance fund ... The pricing decision didn't acknowledge Tresiba's important benefits and ... accepting the offer would undermine R&D efforts."

This occurrence illustrated the increasing power of health care payers. In a few years, the environment had completely changed. A general manager provided a very nice summary of the situation:

"The last launch [Tresiba®] [found it] more difficult than usual to receive reimbursement and agreement about price with the authorities in Europe. Now we have been on the market for two years and it is only few countries where there is good access to the product. So where we have good access, sales are good, because it is a very good molecule and physicians can see the benefits. But because we demand a price premium on the product that corresponds to the innovation—at least we believe that—authorities are not willing to pay ... If you compare Tresiba's® first two years with earlier launches (Victoza® and Levemir®), there are a lot fewer countries where we have received market access compared to earlier.

A director of market access elaborated,

"The launch of Victoza® was in 2008-2009 ... It was a good product and we got access relatively easy. But Tresiba® is also a really good product with clear benefits, yet even five years after the crisis getting access is much tougher compared to the Victoza® Launch."

The launch period is probably the most critical moment in the lifecycle of pharmaceutical drugs. In fact, in 85% of pharmaceutical launches, the demand trajectory is determined in the first six months. (McKinsey & Co., 2014). This is because physicians typically get quickly accustomed to prescribing certain drugs. Thus, if a product fails to gain access within the first couple of years, even if it is superior to competing products, physicians will just use the other products because they have become accustomed to doing so in their prescribing behavior. For these reasons, marketing

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and market access in particular became increasingly relevant. A wide selection of advanced analogues carries little value without proper market access.

Summary of findings

Novo Nordisk's BMI process went through four distinct but related stages (see Figure 6.1). First, the incumbent BM was redefined by the divestment of the enzyme business and the introduction of patient centricity and sustainable management. The goal was not only to focus on Novo Nordisk's core capabilities (i.e., developing protein-based treatments for people with diabetes), but to extend well beyond the original scope by placing the patient at the center of the therapeutic relationship. Thus, top management pursued changes that would not disrupt or radically transform the incumbent model, but rather would add supporting features in an incremental manner. The second stage built upon the previous one by expanding the value proposition beyond products to provide HCPs with services in the form of training and education seminars. The third stage resembled the earlier stages, with the introduction of a new service element (Changing Diabetes®) that was informed by earlier efforts, while the small molecule business was discontinued to permit an even more focused value proposition. In the final stage, Novo Nordisk's BM not only reached its potential (through Victoza®'s success), but also its limits (with Tresiba®'s failure) in an environment characterized by increased pressure from health care payers and regulators. Despite the limits, top management did not find it necessary to implement further BM changes. Instead, they changed the relative importance of value creation and value appropriation by placing more emphasis on obtaining good pricing and reimbursement terms, and reducing the emphasis on patient centricity and sustainable management.

Changes to Novo Nordisk's BM were accompanied by concomitant changes in the organizational design. These changes sometimes preceded changes to the BM. For example, the newly established Global Stakeholder unit championed a number of BM changes, including DAWNTM, the differential pricing policy, and Changing Diabetes®. In this regard, the firm's organizational design served as a driver of BMI. In other situations, the organizational design offered the stability that allowed previous BM changes to become embedded and manifest themselves in the organizational context. In other words, Novo Nordisk would not have been able to

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continuously refine and improve its BM without mobilizing organizational action in the form of new organizational units, tasks, performance measures, roles and responsibilities.

7

UCB: BM Transformation

BM transformation involves substantial and radical changes (i.e., changes that break with the dominant BM design), which are made to the firm's core BM elements and often must be embedded in a fundamentally new architecture. Companies that enact this type of BMI can be characterized as "first movers" or "pioneers," who forge radically new BMs that change the dimensionality of the customer decision and provide the impetus for wider industry transformation. These companies' value propositions are designed to provide customized solutions, that is, unique combinations of products and services that address specific customer needs (cf. Brady, Davies, and Gann, 2005). To implement such a value proposition, radically new partnerships (e.g., co-creating with the end customer) are required in order to tap into external sources of knowledge, while the organization is designed specifically to rapidly transform information and knowledge into insights, and insights into solutions.

The case of Union Chimique Belge (UCB) demonstrates the radical and far-reaching aspects of "transformers" BMI efforts. The company was founded in Brussels by Emmanuel Jannsen in 1928. Several decades later, UCB made some significant breakthroughs. In the period of 1980-1990, UCB launched Zyrtec® (a new antihistamine product) and Keppra® (an anti-epileptic drug). Both turned out to be blockbuster drugs, paving the way for global growth. Today, UCB is a global biopharmaceutical leader (notably in epilepsy) that focuses on patients suffering from severe diseases in two therapeutic areas, namely neurology and immunology. The company is widely recognized by industry experts and their peers as being one of the most—if not the most—patient centric company in the pharmaceutical industry. It is headquartered Belgium, employs more than 7,700 people across 40 countries, and posted revenues of 4.2 billion euros in 2016, of which 48%

and 3470 were generated by the neurology and immunology businesses, respectively. In the following subsections, I will describe in detail UCB's BM transformation and the accompanying organizational design choices made by management as the change unfolded from 2000 to the end of 2015 (Figure 7.1).

2014-2015	No changes	 Expansion of the top management team (+) Patient Value Units (+)
2011-2013	No changes	New Journey Board (+)
2008-2010	 New radical co- creating partnerships (e.g. OXO and PatientsLikeMe) (+) Primary care (-) 	 SHAPE Program (+) Patient Solution Teams (+)
2005-2007	 Patient centricity (e.g. crohnsandme) (+) New radical partnerships (+) Connectivity (+) 	 Acquisition of Schwarz Pharma Schwarz Pharma Choine New performance management System (+)
2004-2005	 Film and chemical businesses (-) Large molecules (+) Moving into primary care (+) 	 Acquisition of Celltech (+) Centers of excellence and multidisciplinary teams (+)
2000-2003	No changes	Surface Specialities (+)

Note: The upper dark grey boxes represent BM changes, while the lower light grey boxes represent organizational

design changes. The (+) and (-) notations indicate the addition or removal elements, respectively.

Figure 7.1 UCB's BMI process

2000-2003: UCB's Conglomerate Model

During the early 2000s, the UCB Group was a conglomerate, diversified across pharmaceuticals, chemicals and films. The pharmaceutical division specialized in two therapeutic areas—allergy/asthma and neurology—while forming a global presence in the most significant pharmaceutical markets—Europe, Japan, and the US. The chemical division was focused on industrial resins, which are useful for, among other things, graphic arts, printed circuits, artificial woods (office furniture), and real wood (parquet). Most notably, the UCB Group was a market leader in the environmentally friendly Radcure resins segment, with approximately 30% of market share. The film division was concerned with bioriented polypropylene film; with a capacity of 75,000 tons per year, it was the sixth largest manufacturer in the world.

Refocusing the BM through consolidation

At the end of 2002, top management decided to consolidate the chemical and film divisions into a new unit called "Surface Specialities." In addition, the UCB Group acquired the Resins, Additives and Adhesives activities from Solutia, further strengthening its pipeline and R&D capabilities. The intention behind the consolidation was twofold: (1) to realize synergies between the two divisions, which was urgently needed due to a growing demand for integrated technical solutions; and (2) to concentrate efforts on the pharmaceutical division, which had increasingly become the UCB Group's main activity. This was largely driven by the "blockbuster" anti-allergic drug Zyrtec®, which was widely popular among physicians in the US; in fact, it was the only antihistamine that could be prescribed for babies from six months until two years. Meanwhile, the company's new antiepileptic drug Keppra® was also immensely successful, with a sales increase of 89% in 2002, from 122 million euros in 2001 to 231 million euros in 2002, of which 164 million were generated in the US.

The internal consolidation was a way to refocus the BM around two core units instead of three. Although the conglomerate model remained intact in the sense that no elements were added or removed, the attention on some elements and units was increased, while others received less.

2004-2005: A New BM, Divestments and the Acquisition of Celltech

The UCB Group (UCB) reached the point where its conglomerate model was no longer viable. Although the Surface Specialties division acquired the resins, additives and adhesives activities from Solutia, Inc., the Pharmaceutical division contributed 83% of the Group's ordinary profits. Thus, it seemed reasonable to divest the Surface Specialties division—particularly when there were no apparent synergies to be gained between the two distinct operating entities. The potential of having another blockbuster drug (Keppra®) also triggered divestiture, as significant resources would be needed in that process. But more importantly, the divestment of Surface Specialties allowed top management to acquire in 2004 the UK-based Celltech Group (Celltech), one of Europe's leaders in biotechnology. Meanwhile, Roch Doliveux had been appointed as the new CEO of UCB, and was tasked with leading the transformation from a conglomerate into a pure biopharmaceutical company. Figure 7.1 shows the set of changes made to UCB's BM and underlying organizational structure during the 2004-2005 period.

Architectural BM change

As mentioned above, the conglomerate model became obsolete owing to limited synergies, a potential blockbuster drug, and a strategic acquisition that could propel the pharmaceutical business to new heights in terms of scale, business opportunities and profitability. In other words, the Surface Specialties division represented a constraint to the company's health care business. As the vice president of new patient solutions and alliance and portfolio management summarized,

"[The] biggest change ... was probably the divestments of our Film and Chemical divisions in the early 2000s ... and the acquisition of Celltech, which transformed us into a biopharma company. Those divestments enabled us to focus more on the pharma side."

Reactivating by removing and adding activities. In just two years, the new CEO and his colleagues managed to transform the BM through a host of interrelated changes. To begin with, they removed the film and chemical businesses, which constituted separate BMs in their own right. This freed up substantial resources for the acquisition of Celltech—an acquisition that set in motion a series of changes.

Not only did the acquisition expand UCB Pharma's value proposition by enriching the late stage pipeline—notably within central nervous system (CNS), inflammation and immunology and oncology—but it also allowed access to Celltech's promising R&D engine, which had particular expertise in large molecules. Specifically, UCB would be able to adopt a dual R&D strategy, encompassing both small and large molecules. This was beneficial because it provided the ability to address disease pathways at different points within targeted therapeutic areas. Large molecules, for example, are often the only option for blocking protein interactions, while drug targets of a more intracellular nature are better addressed using small molecules. Furthermore, having both small and large molecules are taken orally, large molecules are generally administered by injection but can act more rapidly and for a longer period of time. The investment risks associated with each type of molecule differed at various stages of development, and therefore resulted in a more balanced risk profile.

Relinking and reactivating. Next, top management changed the role of R&D (resequencing) by introducing the notion of 'Centres of Excellence'—with the intention of reducing bureaucracy and other constraints related to large organizations. Finally, UCB wanted to serve the enormous primary care segment (reactivating) by partnering up (regoverning) with major pharmaceutical players like Pfizer. Prior to this, UCB almost exclusively focused on physician specialists and the market of severe disease treatments.

The level of BM change that UCB attempted during this period was substantial and fundamental, especially because it included changes to the model's core elements. Not only did top management dissolve the conglomerate operating model, but they also significantly expanded the value proposition to include a broader scope of treatment options (small molecules) and market segments (primary care). The change process was difficult because it involved changes to the firm's core BM elements; such elements tend to be path-dependent (Cohen and Levinthal, 1989, 1990, 1994; Collis, 1991; Mahoney, 1995), linked with organizational survival (Romanelli and Tushman 1994), and highly interdependent with other elements and organizational units (cf. Siggelkow 2002). In other words, an element derives its "coreness" from its architectural features—notably the extent to which it is embedded in the larger organization's strategic planning processes, goals, boards, resources, communication structure, and so on. That means it cannot be changed without setting in motion subsequent changes to other parts of the organization and their respective BM

elements. As the vice president of new patient solutions, and alliance and portfolio management summarized,

"When change is of that magnitude and is radical, then you have to change many things fast to avoid too much disturbance in the organization ... But of course ... you cannot avoid that people get hurt and you lose some ... And it will take some time to establish new relations and get the organization up and running again."

The decision-making authority needed to "change many things fast" typically rests in top management. In sum, the fundamental and radical adjustments undertaken by UCB reflect processes of 'BM transformation,' which contributes to the development of new core elements as the basis of an entirely new BM.

Organizational design as a barrier to and facilitator of BM change

The organizational design played multiple roles in the transformation of UCB's BM. On the one hand, it acted as a barrier to UCB's transformation, since a multidivisional structure did not seem appropriate for a BM with a much narrower scope. On the other hand, the structure provided the vehicle for acquiring Celltech, and subsequently allowed for a smooth integration. As one R&D director noted,

"Compared to Schwarz this was one of the happier M&A episodes. My answer is probably very biased because I was part of the pharma division back then. It was two different companies operating in different industries—one in pharma and another in the film sector. Even though we were part of the UCB Group we didn't have much in common ... When we acquired Celltech we got nearly 2,000 new colleagues with supplementary expertise in large molecule drug development."

The transformation journey was spearheaded by the new CEO, Roch Doliveux. He and his team needed to create a fundamentally new BM, which included defining a new value offering that would be accepted by customers and would thrive in the market at a profit; developing the required

technological and commercial capabilities related to the offering; and most importantly, designing an organizational structure that would support the implementation of the chosen BM. The last point involved assigning new roles and responsibilities, defining new tasks, changing resource allocations and budgeting procedures, and so on.

New units and cross-functional coordination. Some of the more notable structural design examples included the introduction of centers of excellence and multidisciplinary teams. More specifically, the R&D organization was split into three therapeutically-focused centers of excellence located in Braine-I'Alleud (Belgium), Slough (UK) and Cambridge (UK)-covering oncology and immunology, and inflammation, including multiple sclerosis and CNS disorders. The unit in Slough (UK) was the Celltech Antibody Centre of Excellence, which provided antibody expertise for the three other centers. Each center had its own dedicated resources, such as R&D facilities, scientists, time and money. This created a context in which to focus on therapeutic priorities, free of the organizational rigidities and other constraints often associated with the previous R&D organization. In addition, scientists were encouraged to spend time on their own personal research interests and projects. In fact, three of UCB's most sophisticated products-Zyrtec®, Keppra® and CimziaTMoriginated that way. Moreover, each center had a multidisciplinary team consisting of members from development, manufacturing, intellectual property, sales and marketing, and other important functions. The purpose of the teams was threefold: (1) to reduce the time needed to turn molecules into commercial realities; (2) to improve knowledge sharing across subunits, especially between centers of excellence; and (3) to start life-cycle management early on.

More importantly, the centers of excellence and accompanying multidisciplinary teams served as an important integrating mechanism between UCB and Celltech. Specifically, by breaking up the formal organization, it became easier for Celltech employees to reconcile with UCB employees and vice versa. As the vice president of global manufacturing explained,

"I would say ... on one hand, it was competence destroying because you ruin ties between people when you move them around. But on the other hand, Celltech very quickly became part of UCB—because the changes [i.e., the centers of excellence and multidisciplinary teams] were new to us all." If top management had decided not to restructure the organization by introducing the multidisciplinary teams and centers of excellence, it would arguably have been far less likely for the integration to have led to effective synergy realization. Specifically, without a re-organization, the need to establish new working ties would not have been salient.

An equally important aspect of UCB's transformation pertained to speed. Not only did the faster integration help reduce uncertainty among UCB and Celltech employees, but the time spent in a suboptimal configuration was minimized (cf. Angwin, 2004; Homburg and Bucerius, 2005). As a result, UCB was able to realize greater and faster synergies than initially anticipated. A few of the more important outcomes are highlighted in UCB's annual report of 2005:

"The synergies are reflected through higher sales made possible thanks to an enhanced share of voice; economies of scale and industrial improvements in manufacturing; savings in purchasing; [and] reduction of manpower promotion expenses." (Annual report, 2005: 59)

Top management used the gains to accelerate the potent R&D pipeline, and particularly to capitalize on Celltech's most promising molecule, CimziaTM, which would be UCB's first large molecule drug.

2005-2007: Adding New BM and Organizational Design Dimensions

The previous period brought fundamental changes to UCB's BM and supporting structure. Similarly, 2005-2007 brought about far-reaching changes, especially to the company's organizational design. Most notably, the changes included another, but far more complicated, merger, as well as new core BM elements, namely those of connectivity and services. The period emerged as the final phase of UCB's transformation, as the CEO explained in an interview with PMLiVE (Marts, 2011):

"The first measure we took to ensure long-term growth was to transform completely from a diversified chemical group into a pure, high-end biopharma company specializing in neurology and immunology [...] by divesting all non-

pharma businesses and acquiring Celltech and Schwarz Pharma. What we've done is create a new company out of three different entities."

Servitization and BM elaboration

As illustrated in Figure 7.1, UCB's BM once again underwent fundamental alterations in terms of its composition of core elements. The changes started with the 2006 acquisition of Schwarz Pharma, a Germany-based pharmaceutical firm specialized in neurology and with several attractive late-stage products. The acquisition as such did not lead to the removal or addition of (new) BM elements, but rather to an elaboration of existing elements. The acquisition brought about three new products in advanced late-stage development, including two with a broad range of indications in the central nervous system, contributing to UCB's long-standing expertise within this field. The indications encompassed Parkinson's disease (Neupro®, a special transdermal patch, approved for marketing in Europe and filed for approval in the US); restless leg syndrome (*rotigotine*); epilepsy (lacosamide); and diabetic neuropathic pain (lacosamide). As a result, the CNS core element was improved by allowing UCB reach new customers, such as patients with restless leg syndrome and Parkinson's disease, as well as by providing a product with a new mode of action for treating epilepsy (30% of epileptic patients were not treated optimally by the current therapies). An equally important aspect was related to possible strategic complementarities between Schwarz Pharma's advanced CNS products (value creation) and UCB's marketing capabilities (value appropriation) in the field of CNS. As the senior vice president of marketing noted,

"It was really a perfect match because we had the infrastructure, so to speak ... the strong direct links with patients, their caregivers, CNS specialists, and most importantly, neurologists, while Schwarz provided much needed products and expertise."

More specifically, not only would UCB be able to serve new patients within the CNS segment, but they would markedly improve the BM of neurologists by arming them with a wider treatment regimen. This could potentially influence sales force productivity by allowing them to promote more products to the individual neurologists. Relatedly, with Schwarz Pharma, UCB would be able increase its presence in Eastern Europe and China, where Schwarz Pharma was already well established. In other words, there was a possibility that the improved value creation would translate into increased bargaining power, which would in turn result in higher value appropriation.

New services and opening up the innovation process. Meanwhile, additional core elements were incorporated into the BM. First, the element of patient centricity went from being a non-core activity to a core activity, facilitating the next phase of UCB's transformation. Patient centricity was no longer a peripheral activity but a mainstay of UCB's BM. This change was evident in the growing number of patient-centric projects—ranging from creating patient communities, to connecting patients with HCPs, to ensuring that all employees meet patients with severe diseases. These new services were radical in the sense that they were not only some of the first services offered by a pharmaceutical company, but they were directly aimed at the patient. An interesting example was the 'Canine Assistance Programme,' designed to sponsor the training and care of seizure response dogs that would aide patients with epilepsy across the US. UCB formed a novel partnership (relinking) with Canine Assistants, who would train the dogs on more than 90 general commands, including picking up medicine, opening doors, and advanced commands related to helping patients experiencing a seizure safely move to the ground and then going for help. As one patient affairs manager noted,

"Epilepsy is often associated with profound physical, psychological and social consequences that significantly impact the quality of life. Many patients isolate themselves from social, educational and employment activities ... usually out of fear of having another seizure."

Jennifer Arnold, founder and Executive Director of Canine Assistants elaborated further in an interview with Marketwired:²⁹

"The impact these dogs have is enormous—recipients want to go back to school, they get involved in extracurricular activities again and they come out of their shells to lead more independent lives with a renewed sense of confidence."

²⁹ Retrieved January 2016 from <u>http://www.marketwired.com/press-release/adopt-an-assistance-dog-in-training-from-</u> canine-companions-2081397.htm.

While Canine Assistants was responsible for the training of the special seizure response dogs, UCB provided financial aid in terms of care, training and lifetime veterinary costs for all dogs given to patients with epilepsy.

The notion of 'connectivity' was introduced as another core element—composed of three interrelated areas, as delineated in the annual report (2006: 2):

"Connecting with patients so that we can understand more deeply the daily realities of their diseases."

"Connecting science in new ways, notably chemistry and biology, so that we can leverage the potential of these two disciplines, as well as illuminate the biological pathways involved in severe diseases."

"Connecting people in new ways so that we can capitalise on and cross-fertilise the creativity, knowledge and entrepreneurial spirit of our global team."

Top management knew that the ability to connect with world-class stakeholders across the entire value chain would be essential to the organization. Many informants alluded, for example, to UCB's size as a motivation for the increased openness to external collaboration. As nicely explained by one HR director,

"Being a mid-sized pharma company, we need to be very selective about where our efforts are applied. We can't grow new capabilities overnight like Big Pharma. I would also argue that it is a more patient-centric approach, since patients ultimately get a better solution."

The ability to connect is at the heart of the BM construct. For example, Amit and Zott (2001: 494) state that the BM is "a unifying unit of analysis that captures the value creation arising from multiple sources." Others have similarly pointed to the BM's boundary-spanning nature, stressing the possibilities in having tasks for the focal organization that are outside of its immediate boundaries (Chesbrough, 2006; Lee and Cole, 2003; Von Hippel and Katz, 2002). The online community (Crohnsandme) for people with Crohn's disease and the Canine Assistants Programme

are good examples of UCB's increased openness. While the former was created in collaboration with patients and patient associations, the latter constituted a partnership with a supplier not typically associated with the pharmaceutical industry. At the time, it was rare to see pharmaceutical companies engaging in such collaborative problem-solving initiatives. As the vice president of patient solutions and alliance management, who started working for UCB in 1993, noted,

"I remember most people got a shock when he [the CEO, Roch Doliveux] started bringing patients into meetings. Before that, it was all about the specialists and GPs [general practitioners]."

The new partnerships enabled UCB to fill specific resource and capability gaps, permitting the organization to not only extend its resource and capability base, but also to capture external ideas and insights. The changes were also a consequence of UCB's target market—namely, severe diseases (e.g., epilepsy and Crohn's disease); those diseases are extremely complex to address, often affecting several parts of the body and producing a host of socially and physically devastating symptoms which vary from patient to patient. Such conditions therefore call for an integrated approach and concerted efforts on the part of multiple stakeholders; they cannot possibly be solved "by a single company or a single science" (Annual report, 2006: 2).

New ways of organizing and managing BM change

The introduction of new core elements, and the accompanying merger of Schwarz Pharma, could not have been achieved without changing the organizational blueprint. 2005-2007 was yet another period characterized by notable changes related to roles, processes, systems, resource allocations, and so on. Even though the organization had barely emerged from the previous integration of Celltech in 2004-2005, top management decided to undertake another merger with Schwarz Pharma. This was an unusual merger in many ways and significantly more complex than the previous one. Typically, the acquirer imposes its own culture and management systems on the acquired (Nahavandi and Malekzadeh, 1988). However, in this case, UCB (the acquirer) announced a so-called fifty-fifty merger between the two organizations. As the vice president of patient solutions and alliance management explained,

"We tried to get the best of both worlds. In fact, every key position was scrutinized from A to Z to figure out who was the best match [UCB or Schwarz Pharma] for the new organization. It was not the case that just because we acquired Schwarz that meant UCB employees would be safe."

As a consequence of the 50/50 merger, large parts of UCB's marketing and sales organization remained, while areas of R&D, particularly clinical development, came to be dominated by Schwarz Pharma. Schwarz Pharma's proven way of organizing R&D project teams, including streamlining the corporate governance structures and delegating decision rights, was adopted by UCB. Although superior capabilities from both sides were retained, the setup was not optimal. Achieving proper coordination between R&D and the sales and marketing could have proven difficult, as they were essentially two different companies, with their own distinct ways of doing things (processes). If not properly dealt with, the situation could easily have resulted in a highly divided organization, with little common notion of purpose, and few shared coordinating mechanisms. To address this issue, and to avoid developing a 'silo mentality,' the new top management team arranged a series of workshops intended to: (1) define areas of agreement and differences; (2) improve participants' understanding about each other's roles; (3) foster communication and interaction; and (4) get an idea of how participants would actually organize themselves. Despite the initial concerns, the integration process between UCB and Schwarz Pharma was approached in a highly collaborative manner, as one former Schwarz Pharma manager noted:

"It was a very positive experience because you had senior leaders from both sides playing equally important roles. We never really had the feeling of coming into someone's house or being alienated. But our core values were quite similar which helped tremendously."

As a result of this cooperation, the integration was completed successfully 18 months ahead of schedule and generated synergies of \in 380 million, well over the initial \in 300 million target (Annual report, 2008). Not only did the rapid integration prevent significant pockets of resistance from emerging, but it allowed for additional changes—those that were needed but postponed during convergent periods of relative stability—to be implemented (Miller and Frisesen, 1982).

Specifically, the implementation of the new core elements of patient centricity and connectivity simultaneously with the integration of Schwarz Pharma made possible a series of organization-wide changes that would otherwise have constituted a considerable transformation by themselves.

New communication and collaborative mechanisms. Patient centricity and connectivity became widely embedded in the organization's business processes. For example, patients and representative groups were now included in the early clinical development phase of new drugs to make certain that the products are attempting to solve the associated, everyday problems of people living with severe diseases, rather than purely scientific ones. An accompanying intranet platform, 'UCB Plaza,' was launched to increase cross-functional collaboration and exchange of knowledge. As one senior director explained,

"The UCB Plaza is a very effective tool for knowledge sharing and finding the right people. Before Plaza, I relied very much on my internal network if I had to do a project or somehow became involved in a project. But with Plaza, I can instantly go in and find the competences I need, because each user must provide a very detailed description of their knowledge, skills and goals. Actually I was quite surprised to find that we did employ people with knowledge about A, B, C and D ... Without Plaza it would have taken a longer time to discover that."

One could argue that through UCB Plaza, the firm's capabilities became more visible, transparent and accessible among organizational members, making several important contributions. First, all cross-functional projects would be registered in Plaza so as to avoid overlapping projects. As one senior vice president of marketing stated,

"There have been occasions where people in, let's say, the US, worked on almost similar ideas to those of Italy without even knowing it."

Put differently, coordination efforts improved due to the instant synchronization feature offered by the Plaza platform. Second, the ability to identify the right capabilities rapidly reduced the reliance on external consulting expertise. Finally, and most compellingly, the platform allowed multiple employees, middle managers, and even top executives across UCB to contribute ideas and content

to improve the quality of various projects. The presence of top management weeded out subpar comments and ideas, while providing an incentive for people to use Plaza.

New complementary goals and rewards. To support the new formal organization, a new performance management system was rolled out. It was built around three basic elements: (1) setting clear goals, especially with regards to patient centricity; (2) prioritizing staff development by means of, for example, job rotation and coaching; and (3) rewarding individual contributions and achievements through a stronger emphasis on variable remuneration and other incentives. The new system was complementary in several respects. For example, the move from products to solutions required employees with broader skills, who could view patients in a holistic manner and generate insights from multiple heterogeneous sources. In addition, top management wanted to free the creative capacities of UCB employees by rewarding such behavior.

2008-2010: UCB shapes the organization

The challenging transformation from a conglomerate company comprised of unrelated businesses into a biopharmaceutical company, with a patient-centric BM, had been completed. However, top management did not intend to slow down the pace of change. Although UCB's BM was left largely untouched in terms of adding or removing elements, the underlying organization was faced with the most difficult changes in the company's history, including a reduction in UCB's workforce by 2,000 positions. This downsizing was part of the so-called 'SHAPE Program,' which was launched as an effort to shape the organization for the future.

UCB's BM remained relatively stable during 2008-2010, with almost no changes to its core elements. Instead, it was a period in which BM elements were intended to be integrated into a coherent whole and in which a new growth phase would be facilitated. As explained by one senior director,

"You could describe in this way ... we came from a period where we had collected all the pieces needed for the future and then it was time to really glue them together to maximize the value output."

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However, there were a few exceptions to the relatively stability. Notably the core element of connectivity was elaborated through radically new partnerships with companies from markedly different industries, and the company also exited from the primary care sector in the US.

Opening up the value network

The core element of connectivity had been introduced in the previous period, but with an overly internal locus, emphasizing cross-functional collaboration and communication along the horizontal dimension of the organization. However, to realize the potential of connectivity, top management knew that it had to be extended beyond firm boundaries, especially given the changing industry structure. As several informants noted:

"Payers are looking for data or solutions that help improve patient outcomes ... There are a lot of consumer goods companies like GE, Phillips, Wal-Mart, Nestlé, and P&G that are coming into that segment. All of them have different strategies ... but they are all data-driven and try to create solutions that are tailored to specific patient segments." (Senior vice president of marketing)

"No, they [GE, Phillips, Wal-Mart, etc.] are not a threat at all ... It's part of a continued evolution of what we are providing to patients. You know, we've got a piece but there are other pieces that patients are needing and so we come together in that and that's why we have a pretty open network and look at partnering with companies to find common solutions." (Vice president of patient solutions and alliance management)

UCB entered two partnerships, one with OXO and another with PatientsLikeMe, not only to collaborate, but also, and more importantly, to learn about customer orientation (relinking and repartitioning). OXO was specialized in developing and designing user-centered consumer products for a broad spectrum of users, including those with limited dexterity. For example, self-injection presents a considerable dexterity challenge for most people with rheumatoid arthritis. Therefore, top management decided to enter a partnership with OXO in order to develop a more patient-friendly syringe. Design and engineering teams from both companies co-created, along with rheumatoid

arthritis patients, a prototype of the new syringe. Input from the patients led to various iterations of syringe features, such as an extended flange to support different grip styles and strengths; a larger, soft plunger-thumb pad; a magnified barrel for easy reading; and easy-to-open packaging. In the end, the syringe received the Ease-of-Use Commendation from the American Arthritis FoundationTM. In 2010, UCB also formed a unique partnership with PatientsLikeMe, the leading online community for people with life-impacting diseases. With the intention of learning from patients' real-life experiences, a free online community for people living with epilepsy in the US was created. The platform allowed members to create individualized profiles so that they could record and share knowledge about treatments and symptoms, as well as about the type, frequency and severity of their seizures. As the Chief Medical Officer explained³⁰,

"As a patient-centered company, we are constantly seeking innovative ways to enhance and adjust our approaches to meet patient needs. We believe this community will be a source of information that will allow us to better understand people living with epilepsy and may help us design clinical programs that incorporate real-world patient needs and experiences in a measurable way."

Although pharmaceutical companies had become generally more open to external collaboration, it was mainly related to the possibilities of (1) reducing the risk and uncertainty associated with drug development by sharing it with other partner(s), (2) reducing time-to-market by outsourcing tasks to research and manufacturing contractors in order to avoid bottlenecks, and/or (3) reducing development costs by outsourcing stages of the clinical trial process to regions such as India and China (Cf. Quinn, 2000; Howells, Gagliardi and Malik, 2008). In addition, pharma firms would typically partner with companies that were accustomed to handling the requirements of pharmaceutical regulatory standards. However, UCB's the new partnerships with OXO and PatientsLikeMe were radically different in many respects. First, the partnerships were used as means to improve the value proposition by offering new services. While the online community provided an opportunity to meet and share experiences with like-minded individuals, the patient-

³⁰ Retrieved March 2016 from https://www.patientslikeme.com/partners/9-ucb

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friendly syringe provided greater convenience for people living with rheumatoid arthritis. In contrast, traditional pharmaceutical partnerships put emphasis on traditional value chain activities, e.g. improving the effectiveness and efficiency of drug development. Second, the partnerships were focused on addressing patients' psychosocial and lifestyle issues rather than physical ones. Third, and relatedly, the services were an outcome of a co-creation process in which patients, UCB, OXO and PatientsLikeMe played a key role and where value was socially constructed. Finally, both of UCB's new partners operated in industries that allowed high levels of direct customer interaction; they therefore excelled at customer orientation, unlike pharmaceutical companies, which traditionally focused on products and the prescribing physician.

The removal of primary care

In 2010, top management made the decision to withdraw from the primary care market in the US. This move was notable because most pharmaceutical firms did appear to be undertaking efforts toward primary care when it came to marketing their products and building brand loyalty. However, UCB was not reliant on the primary care market to the same extent as others, because its focus on severe diseases required a focus on specialists. This also meant that UCB could operate with a relatively small sales force compared to those operating in the primary care segment. Niles (2005) estimated that the average sales force expenditure for pharmaceutical companies is \$875 million annually. As one vice president put it,

"We have a smaller sales force than other pharma companies due to the smaller population of specialists. Moreover, targeting primary care is becoming increasingly harder due to a loss of power of the prescribing GP. Therefore, we decided that it's not worth it from an economic perspective to have a primary care sales force. Does that mean that we don't care about them anymore? No, but instead we to want help GPs and patients through web-based solutions such as the Parkinson's Well-Being MapTM, Crohnsandme, and so on."

The change made it possible for top management to channel resources previously reserved for primary care into R&D, and particularly into cooperative programs focusing on solutions beyond the product. More specifically, the decision resulted from an assessment of potential

complementarities, in the sense that UCB would not only focus on severe diseases, but its new BM changes would enable the organization to target the primary care segment in a more economically viable way.

Organizational restructuring

After nearly a decade of change (including substantial mergers and divestments) that repositioned UCB as a biopharmaceutical company, it was time to restructure the organization to accommodate the new BM. Therefore, in 2008, top management launched "SHAPE," a major organizational change program aimed at (1) re-allocating resources toward growth drivers and core assets (i.e. CNS and immunology); (2) simplifying the organization, including flattening the hierarchy and consolidating core functions into core areas; (3) developing core capabilities for the future; and (4) increasing the use of outsourcing for non-core activities. Most notably, the program reduced UCB's workforce by 2,000 positions across the organization, constituting an approximately 17% reduction in the total workforce. According to top management, the layoffs were necessary due to the expiries of major product patents (Keppra® and Zyrtec®) and, more importantly, to create new capabilities. As summarized by the CEO,

"Patent expiries are challenging times ... The time is now to take action to shape UCB for the future and become a specialist company focused on successfully delivering our new medicines to patients ... Our priority will be to look for solutions that lead to a new future."

The layoff process involved making 2,400 positions redundant and creating approximately 400 new positions, as well as re-deploying around 300 positions to the organization's core sites. As one HR vice president explained,

"It was really a mix of different people, ranging from sales reps [and] marketers, to researchers. So in that way it was quite different from other pharma companies who mainly reduce the salesforce. Despite the mix, there were a few common denominators. First, I would characterize most of the positions as non-core, i.e., not part UCB's future scope. Second, people with high resistance to change ... in fact many of them were already on their way out

because they didn't see a fit with the direction UCB was going. Finally, the traditional pharma salesforce was reduced because we wanted to focus on our newer, higher-margin products."

Implementing radical change through layoffs. Layoffs are traditionally associated with cost cutting, and they can also play a prominent role in adjusting workforce competencies (McKinley, Zhao, and Rust, 2000; Ostermann, 2000). As argued by Zatzick and Iverson (2006: 999), "layoffs increase a firm's flexibility over the transition process; firms can quickly and efficiently remove employees whose skills no longer fit the firms' strategies or add to their market value." Such flexibility was probably needed in order for UCB to pursue its radical and architectural BMI, as nicely explained by the senior vice president of marketing:

"When your goal is to transform or radically change something ... then it naturally implies that you have to remove something and replace it with something else. Otherwise, it's incremental or an evolution of the existing business model. However, in the past 10 years the pharma environment has changed to an extent that requires a drastic departure from the conventional model."

Although the layoffs represented a significant reduction of the total workforce and undoubtedly contributed to a competence drain, this was perhaps less of an issue due to the fundamental nature of the change; irrespective of the old competencies' initial value, they would eventually become obsolete in a fundamentally different configuration. Moreover, the speed and scale at which the layoffs were conducted may have reduced uncertainty for the remaining workforce. As explained by one HR vice president,

"I know it looks massive to make 2,000 positions redundant, and it is. But you also have companies that lay off people each year, and then rehire the same people the following year. I think that creates a constant flow of uncertainty ... and illustrates a lack of strategic direction. We made a huge change to the organization, but everybody knows the direction of the company."

Nevertheless, several informants also described the change process as "network destroying," "too fast," and resulting in "a tough reputation," suggesting the existence of managerial tradeoffs between implementation and degree of change. For example, implementing a new BM can prove difficult if the informal networks are destroyed due to layoffs. On the other hand, implementation might be less relevant if, for example, the intention is to radically change the BM but the actual outcome is instead a slightly modified BM because the supposed change agents resist the change. It might also prove increasingly hard to attract new employees due to the negative impact of layoffs at that magnitude. However, such a drastic move might serve as useful self-selection mechanism, as the vice president of new patient solutions, and alliance and portfolio management summarized:

"We move and change things fast at UCB, and it is not a tempo that is suitable for all ... Those people will quickly find another place to work. However, we want people who like this dynamic and entrepreneurial environment, and who are adaptable. I also think UCB has that reputation in the industry ... Not many have changed as much as UCB in the past ten years."

Toward a project-based structure. The SHAPE program was accompanied by the introduction of "patient solution teams"—called so to emphasize value-creating activities that go beyond the drug itself. In particular, the teams represented a new organizational structure that facilitated agility in bringing together and integrating diverse areas of knowledge or skills so that unmet patient needs related to, for example, psychosocial well-being could be addressed in potentially novel ways (Rasmussen and Foss, 2015). Each team was granted decision rights to self-organize—that is, they could create their own processes for almost everything that needed to be done with regards to developing and implementing patient solutions—resembling the flexibility and entrepreneurial spirit embodied in the design of start-up firms. As the senior vice president of marketing described it,

"The idea was to put a person there and give him or her enough power to create as much value as possible for patients. We thought, instead of having little projects that are seen as an annoyance by the functions ... the project had to be the most important dimension of the organization, because it's about bringing solutions to patients." One vice president of HR elaborated,

"We asked these guys to think about their goals, organization, processes ... and you know what happened? They said 'Great, I need three medical, five regulatory, two marketing [personnel],' and so they designed a small old UCB. But that was never the intention—we don't care if you're regulatory, marketing or medical. What we care about is brining superior and sustainable value for patients ... so organize yourselves around these dimensions. Then we started to see something interesting happening, especially with the PST [patient solution team] for Neupro®, which is all Parkinson's and restless leg syndrome. It was organized completely differently. Basically, they were structured around different patient segments, each with its own distinct mission. For example, they would take care of the young Parkinson's patient and the elderly patient who can't swallow pills."

Although the new structure seemed radical, it merely extended the scope of earlier BM and organizational changes. It did so by drawing on knowledge and experience gained from (1) working with centers of excellence and multidisciplinary teams, (2) organizing R&D project teams, and (3) making services a central part of the value proposition. Thus, the patient solution teams could be understood as the culmination of organizational and BM dynamics set in motion as a result of earlier decisions. Moreover, they also represented the first unit dedicated to systematically dealing with the value proposition's increasing service content. Top management recognized that services should not merely be considered as add-ons to the products, particularly if the aim is to become a customer centric organization. Customers are not interested in products or devices per se, but rather in the benefits to their day-to-day activities and concerns (Erl, 2005). The new organizational structure was also radical in the sense that budget responsibility was transferred from the functions to the patient solution teams. As the senior vice president of marketing noted,

"Before we got the PSTs [patient solution teams] project owners had to beg line management for resources and people ... So many projects got stifled because they never received any attention. However, we have turned that hundred and eighty degrees ... so now budgets are in the domain of the PSTs and line management [the functions], or the practices, as we call them, have to serve them. It was a really good decision, but it has also created a lot of tension, because you suddenly take power away from one part of the organization and put it another place."

The new structure consequently altered the power structure for the formerly less powerful project organization and functions. This not only indicated a shift toward a greater influence of generalists as opposed to specialists, but also a shift in the BM toward value creation derived from a variety of internal and external sources (cf. Amit and Zott, 2001).

2011-2013: In search of new territories while creating stability

This period of 2011-2013 came after more than a decade of fundamental BM and structural changes. It was a time of adjusting, learning and building new intra- and inter-organizational relationships to test the variability of the new model and its accompanying organization design. But, perhaps more importantly, the period was a time of stability, with no mergers and acquisition activities or organizational restructuring, as described by one R&D director:

"There were still a lot things happening at UCB ... the new journey board, training program and new partnerships ... but it was nothing like the scale of, let's say, SHAPE or the PSTs. It was very important for us to figure out the new organization ... experiment with what works and what doesn't without being interrupted by another restructuring program."

A small, agile and exploratory team

While the employees of UCB were getting used to new ways of working, top management assembled the "New Journey Board," which was made up of the most talented individuals throughout the organization. The team consisted of eight members—small enough to allow for the necessary agility to experiment with a variety of external conditions. Some of these conditions were commonly known and some extended the understanding of the role of a pharmaceutical company. The team comprised a diverse group of individuals with different skills, experience, and formal as well as informal power—allowing for significant breadth in the unit's exploratory search activities.

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The team's small size was compensated for by extensive support from top management in terms of attention and budget. As noted by one member,

"You could call it a corporate playground ... For a year we could do just about everything due to the support from executive management. We visited many different companies in different industries. For example, we worked with architecture and design firms, where we created small miniatures of the future. We were allowed to test different things in the organization."

The role of the board was threefold: (1) to sketch out the landscape of the pharmaceutical industry in 2020, and more importantly, to identify potential future BMs for UCB; (2) to create new capabilities through building new partnerships and developing a firm-specific training program; and (3) to serve as crucial change agents.

2014-2015: From BMI to implementation

At the end of 2014, Roch Doliveux stepped down as CEO after successfully transforming UCB from a diversified chemical company into a customer-oriented biopharmaceutical company over the preceding decade. UCB's Board of Directors conferred on Doliveux the titles of Honorary Member of the Board and Honorary Chairman of the Executive Committee, as a tribute to his transcendental contributions to the organization. At the start of 2015, the Board of Directors appointed Jean-Christophe Tellier as the new CEO of UCB. Although Roch Doliveux had successfully transformed UCB, his succession did not come as a surprise, as described in a UCB newsletter:³¹

"This change is the result of a long and well thought through succession plan to ensure necessary experience and knowledge transfer. It creates the best conditions for the company's future growth, allowing it, together with its 8500 colleagues, to deliver on UCB's commitment to patients."

³¹ Retrieved March 2017 from http://www.ucb.com/presscenter/News//article/UCB-announces-CEO-succession-planin-anticipation-of-next-wave-of-product-launches

While Doliveux had successfully navigated UCB through several transformations (e.g., the acquisitions of Celltech and Schwarz Pharma, and the implementation of SHAPE), the patent expiries of former blockbuster products (Keppra®), the launch three new core products (Cimzia®, Vimpat® and Neupro®), and most importantly, the incorporation of a customer dimension into the BM (e.g., by offering a range of solutions addressing unmet needs), it was now time to grow the business and focus on implementation rather than impeding it with another series of fundamental changes. As nice summarized by the vice president of new patient solutions and alliance and portfolio management,

"We have in phase three, the late stage pipeline, products that have the potential to be between 50% and two times the size of UCB today. If that happens then we have to completely change the organization again and prepare it for that level of growth."

From patient solution teams to patient value units. Besides having played an instrumental role in establishing UCB's patient-centric strategy, Jean-Christophe Tellier also had significant expertise and career achievements in "Big Pharma"—specifically Novartis—which would be useful in implementing the organization's new growth strategy. Tellier did not hesitate to exercise his newly gained authority. First, the top management team was expanded to include three new members. Second, based on the learnings of the New Journey Board and the Patient Solution Team structure, most organizational units changed names and scope to reflect changes in their strategic importance. More specifically, the top management team was restructured into the following four areas: (1) Patient Value Units (encompassing new medicines, neurology, immunology and bone disorders); (2) Patient Value Practices (encompassing strategic marketing, development and medical); (3) Patient Value Operations (encompassing geographic operations, established brands, technical operations and business development); and (4) Patient Value Functions (encompassing finance, talent, company reputation and legal). As nicely explained by the senior vice president of marketing,

"We started changing what we were doing by experimenting with new things ... Then we developed a new structure and now we are looking into the processes. Some are still set up in the old way of doing things. But we are going back and

UCB: BM Transformation

looking at processes and beginning to modify them to better reflect all the new people coming into the organization."

The new structure indicated that the BM worked. Therefore, the time seemed ripe to put a structure around it, so as to realize the full benefits of the new model. In particular, the benefits revolved around customer orientation, which is inherently more complex than producing drugs for specific therapy areas. To cope with that level of complexity, it was necessary to expand the top management team. Thompson (1967) suggests that the size of the top management team can affect information-processing demands, noting that the number and complexity of decisions faced by CEOs often exceeds their comprehension. To alleviate this, the size of the top management team can be increased, thereby reducing the number of decisions that must be made and monitored by the CEO. Most notable were the introduction of the Patient Value Units and making Strategic Marketing part of top management. This new way of organizing represented the final evolutionary stage of a series of changes ranging from centers of excellence and multidisciplinary teams to patient solution teams and finally patient value units. Interestingly, they became small firms or BMs in their own right, each headed by a member of the top management group and each with its own distinctive patient mission, strategies, tasks, processes, and so on. The common denominator was 'connectivity' in the sense that each would take an outside-in approach, as nicely summarized by the CEO:32

"People need to get outside to understand what is changing, who is influencing who, who is making the key decisions, how the value chain is working, and I think it's a really significant shift."

Since the "who is influencing who" and the configuration of the value chain differ from therapy area to therapy area, it was necessary to create distinctive firms or BMs in order to adequately address the diverse set of unmet needs within each segment. Moreover, the CEO recognized the increasingly central role of marketing, and particularly market access. This was alluded to by many informants:

³² Retrieved April 2016 <u>https://www.accenture.com/us-en/insight-perspectives-life-sciences-inspired-by-patients</u>

"Market access has become so much tougher because power has shifted toward patients and payers" (Market access manager).

"Products that would have received reimbursement 2-5 years ago are receiving negative reimbursement decisions [rejected]" (Direct of market access).

"We are really good at market access and reimbursement. I think, if you look at it, we've brought three new products to the market in the last four or five years and managed to get pretty good reimbursement across geographies. In fact, it was the market access challenge that really triggered all the changes" (Senior vice president of marketing).

Marketing thus became part of the top management team in 2015 to better reflect the growing influence of health care payers and patients. In sum, UCB's one-and-a-half decade of BM and organizational design changes led to an entirely new configuration of integrated care, differentiated solutions, and patient and stakeholder involvement that would set the company up to increase its future "return on patient value creation, [which then would result] in a higher return for UCB and its shareholders" (Annual report, 2015: 15).

Summary of findings

UCB's BMI process unfolded over six separate but related stages (see Figure 7.1). The first stage represented the gradual dissolution of the firm's conglomerate model with the consolidation of its chemical and film divisions. In the second stage, top management completely abandoned the conglomerate BM by replacing it with a new and more limited focus on the firm's promising pharmaceutical business. More specifically, the divestment of the film and chemical businesses freed up resources that could be used to broaden the scope of the pharmaceutical value proposition. For example, UCB moved into primary care, while the inclusion of small molecules enabled the company to offer a more differentiated value proposition. The third stage was perhaps one of the most critical stages in UCB's BMI process. Most notably, patient centricity became the most important component of UCB's BM activities. A range of new services were launched, with the intention of making UCB an integrated solution provider. That is, rather than only offering

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pharmaceutical products to treat the physical ailment, a combination of products and services was offered to engage patients during various stages in their disease journey. During the fourth stage, another set of fundamental changes (new radical partnerships and the exit from primary care) were made to improve the implementation of previous BM decisions, particularly the aspects of patient centricity and connectivity. The fifth stage served as a learning and assessment period in which stability was allowed in order to investigate and test the viability of the new BM. The final stage represented the culmination of several years of painstaking organizational efforts to transform the incumbent BM. The efforts paid off, and as a result, the new UCB management team decided to restructure the entire organization around the new BM (i.e., the patient value units) in order to realize the full benefits of patient value creation.

What makes this case remarkable is that it clearly demonstrates the inextricably interwoven relationship between BMI and organizational design. On the one hand, UCB's organizational design served multiple purposes in the BMI process, either as a barrier or as a facilitator. For example, while the multidivisional and functional structures blocked the transition to a solution-based model during the early stages of BMI, new design mechanisms (in the form of new communication channels and cross-functional teams) were set up to facilitate coordination and convergence across the horizontal dimension of the organization, so as to gain a more holistic view of the patient. On the other hand, toward the end of UCB's BMI process, the designable parts of the organization became almost an embodiment of the firm's BMI activities—as exemplified first in the patient solution team structure, and later in the introduction of patient value units. As such, UCB's BMI efforts were heavily influenced by top management's ability to identify appropriate organizational designs that would not only guide and facilitate the implementation of BM changes, but would combine them in order to realize value-enhancing effects across the new BM configuration.

8

LEO Pharma: When BMI is Stuck in The Middle

The stuck-in-the-middle approach to BMI aims to exploit incumbent BM elements while simultaneously exploring fundamentally new BM opportunities. It not only requires innovation efforts along several dimensions of the BM (ranging from incremental to radical change), but also the ability to solve a host of managerial problems arising from the contradictory requirements of incremental and radical change. In short, stuck-in-the-middle companies must learn how to achieve and preserve an equilibrium between conflicting demands for BM flexibility and BM stability (cf. Miles and Snow, 1978). In particular, such companies employ modular structures that help them separate old and new BM activities. For example, new BM units are usually set up outside the existing management and planning systems and have their own dedicated resources, processes and structures, yet with linkages to the established organization through the management hierarchy (Stieglitz and Foss, 2015). Such a setup can potentially enable the firm to experiment with radical value propositions while avoiding harmful side effects to the incumbent ways of creating and appropriating value.

The case of LEO Pharma A/S (LEO) exemplifies the challenges that arise when the BMI process is stuck in the middle. LEO Pharma was founded in 1908 in Denmark by two pharmacists, August Kongsted and Anton Antons. In 1925, the company's insulin production was transferred to the independent Nordisk Insulin Foundation, and LEO redirected its focus toward hormone products. It was not until much later, however, with LEO's launch of Daivonex®/Dovonex® and Innohep®, that the company gained international recognition, especially for the treatment of psoriasis. Both of those products are still the most renowned medical innovations in the company's history. Currently, LEO is headquartered in Denmark as a global, independent, research-based

pharmaceutical company that specializes in drug development for dermatologic and thrombotic patients residing in more than 100 countries. It employs around 5,000 people worldwide and has sales and marketing subsidiaries in 61 countries. In 2016, LEO recorded revenues of 9.8 billion DKK, of which 64% and 26% were created by the dermatologic and thrombotic businesses, respectively. In the following subsections, I will describe in detail LEO's attempts to deal with the stuck-in-the-middle approach to BMI during the period from 2000 to 2015 (Figure 8.1).

Δ	2	
2014-2015	 New devices (e.g. Enstilar®) (+) New Partnerships (+) 	 LEO Innovation Lab (+) Restructuring and top management changes (+)
2012-2013	 The launch of Picato® (+) QualityCareTM (+) New radical co-creating partnerships (e.g. Psoriasis Frontiers and Vertic) (+) Columbus (+) 	 Global Patient Engagement (+) New functional names (+) Restructuring global sales and marketing (+)
2010-2011	 Patient centricity (e.g. pilots for BM experimentatio n) (+) 	 corporate Must-Win Battles (+) Pulse (+)
2008-2009	 Actinic keratosis Actinic keratosis (+) Repurchasing the rights from Warner Chilcott (+) 	 Acquisition of Peplin, Inc. (+) Battles Pulse (4)
2004-2007	 Animal health (-) HL 10 (-) 	No changes
2000-2003	• No changes	• No changes



Figure 8.1 LEO's BMI process 157

LEO Pharma: When BMI is Stuck in The Middle

2000-2003: LEO's Traditional BM

In the early 2000s, LEO operated with the traditional pharmaceutical BM. Specifically, it focused on the development and commercialization of small molecule drugs—focusing particularly on the areas of dermatology and critical care. As noted by the executive vice president of sales and marketing,

"It is very traditional. Even though it has been modified over the past fifty years ... it has not changed much. We are still very science-based, focusing on R&D, production and operations, and [we have] a large field force."

In many ways, the organization was still following the path laid down a decade earlier. LEO had launched Innohep® (critical care), and Daivonex®/Dovonex® (dermatology) in 1991. Together, these two drugs are recognized as the main drivers behind the organization's strategic priorities. This was mentioned by several informants:

"We have not been so successful in coming out with new drugs. The last time we really came out with something was in the early 90s, with Calcipotriol [Daivonex® and Dovonex®]." (Senior Director)

"It has been a while since we discovered a viable new chemical entity, but fortunately we have been really good at formulation." (Executive Director)

As a consequence of LEO's inability to come up with new successful medical products, the company became increasingly proficient at pharmaceutical formulation, particularly with regard to existing LEO drugs. New formulation is a process in which various chemical substances, including the active ingredient, are recombined to produce a new version of the old drug that is easier and more convenient for the patient to use. In 2001, LEO launched Daivobet®/Dovobet® as a new formulation for the treatment of psoriasis.

BM origins

One could ask, 'Why did LEO choose to adopt a BM that focuses primarily on dermatology and to a lesser extent on critical care?' This BM seems to have been emergent rather than deliberately planned and designed, as explained by one senior director of marketing:

"You could say that in many ways it's a coincidence that we are in dermatology ... It can largely be ascribed to the fact that we found Calcipotriol. If we had found something else, we could potentially have been in another therapeutic area with a different kind of set up."

Although LEO's BM was traditional, with an emphasis on R&D, patented-protected prescription drugs, a sales force, and so on, there were notable distinctions between therapy areas with respect to who the important stakeholders are, regulation, reimbursement and competition. Thus, while the company's main value proposition was discovered almost by accident, the other constituent BM parts were largely formed on the basis of contextual factors related to the specific therapy area.

2004-2007: Toward a More Focused BM

LEO experienced a significant setback in 2004, when it halted work on the much-anticipated HL 10, which was developed for the purpose of treating ARDS/ALI, or acute respiratory distress syndrome/acute lung injury. HL 10 was a very expensive treatment, and therefore needed to be markedly better than existing treatment options in order to be commercially viable. A number of phase II studies showed promising results, but the final phase III study did not show a statistically significant improvement compared to the existing treatment regimen. As summarized by the CEO at the time, Ernst Lunding,

"Having to close down HL 10 is a depressing announcement ... It is very disappointing to the people who have worked intensely with HL 10 and who have all made an incredibly good and firm effort. The depressing result is not in any way related to the preparation of the project or to the scientific rationale. Rather, the reason lies with the statistics, which have played a trick on us by indicating incredibly good results in both phase II studies."

LEO Pharma: When BMI is Stuck in The Middle

The HL 10 failure led top management to rethink and redefine its goals and overall ambitions. More specifically, they decided to abandon their so-called 2010 vision of including a third value proposition alongside the organization's dermatology and critical care businesses. Instead, LEO would now focus on its core BM elements, particularly leveraging its strength within dermatology. This involved the divestment of its animal health subsidiary in 2005 and the launch of Taclonex®, a topical treatment for patients with mild psoriasis, in the US in 2005. Despite the failure of HL 10, LEO still managed to record impressive numbers in 2006, including, among others, 15% growth and a 49% profit margin.

BM refinement and risk aversion

The 2004-2007 period arguably represents a defining moment in LEO's History. Not only was it Ernst Lunding's last years as CEO after having held the position since 1995, but the BM choices, in many ways, set the direction for the future.

Reactivating by removing. To avoid further losses and improve short-term value creation and appropriation, it seemed reasonable to divest non-value-adding activities (such as HL 10 and the animal health subsidiary) and focus on core activities (such as dermatology and critical care). As Lunding explained in an interview with finans.dk³³,

"Our pipeline ... is looking a little thin. For that reason, we will therefore be more selective and provide an even stricter prioritization of our development projects. Rather, [we will] bet on fewer projects, which can be accelerated instead of many projects that only progress slowly."

Reluctance to explore new BM opportunities. A number of the accelerated projects mentioned by Lunding were not new drug development. Taclonex®, for example, was developed based on "reformulation"—that is "the development of different formulations for the same pharmaceutical drug" (Murteira, Ghezaiel, Karray, and Lamure, 2013: 2). Resorting to "reformulation" is an attempt to reduce both the cost and the risk associated with *de novo* drug development. As noted by a senior director of marketing,

³³ Retrieved April 2016 from <u>http://finans.dk/artikel/ECE4225281/Leo-Pharma-ramt-af-ny-milliard-fiasko/</u>

"If you think the organization is conservative now and resisting change, that is nothing compared to the days with Ernst Lunding. Although we had a little bump on the road with HL 10, LEO and the foundation were still generating, and loaded with, an abundant amount of cash. I think we even had the highest profit margin of any company in Denmark, but still you had to almost beg for money to do anything. In hindsight, it would have been the perfect time to change LEO because we had the necessary resources and our products were not at the brink of losing exclusivity."

It seems that after the failure of HL 10, the focus was on protecting or strengthening the old BM, especially those activities at which the organization excelled, such as reformulating existing drugs within the area of dermatology. LEO Pharma's top management team did not make any deliberate attempts to set a new direction for the company or its underlying BM. Conversely, the decision to focus on the core and not explore new and more risky opportunities discouraged organizational members from trying new things, even though LEO Pharma was in a good position to do so in terms of resources and credibility.

Failures are a natural outcome of BM change or experimentation (Chesbrough, 2010). However, it is the ability to learn from such failures and distinguish them from mistakes that enables firms to discover viable new BM elements (Chesbrough, 2010). However, in order to do that, an organization might need to have the appropriate structures and processes in place to learn from failures. Arguably, this was not the case for LEO Pharma, which instead became an even more risk averse organization after HL 10.

2008-2009: Generation Shift, a New Strategy and the Acquisition of Peplin

Coming off a disappointing year in 2007, with only a 2% growth in sales, the time seemed right for a generation shift at LEO. After having established the foundation for the Danish pharmaceutical industry and holding the leading position for decades, LEO had now been overtaken by peers like Novo Nordisk and Lundbeck. A 41-year-old female, Gitte Aabo, was to take over as CEO in 2008, while the resigning CEO, Ernst Lunding, would take on a new role as Chairman of the Board. Gitte Aabo had been part of LEO since 1992. She first worked as a personal executive advisor to Ernst

Lunding for a couple of years before assuming responsibility for the organization's finance and IT department. So, she was indeed a protégé of the former CEO, as noted by several informants. For example, one director stated,

"The announcement of Gitte did not come as a surprise. In many ways I think it speaks to the power of Ernst Lunding, as he is still very much in control of the company."

One vice president of project management elaborated,

"She is a true LEO ... for better or for worse. She knows the company and its culture extremely well, but she is also part of its corporate DNA ... Having worked with the former CEO for many years ... undoubtedly makes it very hard to turn things around."

Nevertheless, it was now up to the new CEO to implement strategic actions that would lead the century-old pharmaceutical company toward new growth and global expansion. As a result, the so-called "Going for Gold – step by step" strategy was launched with the stated goal of growing the company and reaching double-digit sales growth. This was to be accomplished through (1) establishing a presence in the US and other key markets; (2) vigilantly scanning for potential acquisition candidates; and (3) fostering a customer-oriented mindset.

Preparing for internationalization with incremental BM improvements and neglecting customer orientation

Reactivating by adding. While 2008 was all about formulating the new "Going for Gold – step by step" strategy, the following year was dedicated to realizing it. The first step involved the acquisition of Peplin, Inc. in 2009. A US firm with operations in Australia, Peplin specialized in treatment of the pre-cancerous skin lesion actinic keratosis—a so-called "non-melanoma skin cancer." With the acquisition, LEO intended to expand its dermatology portfolio to help patients with actinic keratosis. As one senior director of marketing explained,

"At the time, the notion of integrated care was becoming increasingly popular among health care providers ... and this was no different at LEO. Management was firmly committed to making LEO a one-stop shop for dermatology patients."

The acquisition also had the potential to bring forth a number of strategic complementarities. First of all, LEO had a very solid reputation among leading dermatologists. This was critical, because key opinion leaders often dictate the prescribing behavior of other physicians. Secondly, LEO already had a very strong dermatology sales force in place to promote the new product. In sum, not only would LEO be able to serve new patients within the dermatology segment, but they would be creating more value for dermatologists by arming them with a broader treatment regimen. In addition, sales force productivity could potentially be increased by promoting additional products to the individual dermatologists.

Relinking by regoverning. Shortly after the Peplin acquisition, top management initiated the second step by repurchasing the company's rights to its psoriasis portfolio and dermatological pipeline in the US from Warner Chilcott. This was considered a stepping stone for LEO's internationalization process, and more importantly, it allowed the company to gain a share of the lucrative US market. The President and CEO of the US division commented in an interview with FirstWordPharma³⁴,

"It is our intention to now establish LEO as a leading company within the American Dermatology market. Armed with one of the strongest pipelines within dermatology, the US presence will create a platform allowing LEO to bring all future products to markets through our own affiliate, including the products coming out of our Peplin acquisition."

In 2009, LEO generated most of its sales from the European market, while many other pharmaceutical companies generated the majority of theirs from the US market. However, because the European market was facing pricing pressures from health care payers as well as increasing regulatory requirements from regulators (cf. Garnier, 2008), it became important to gain a place in the US market.

³⁴ Retrieved November 2015 from <u>https://www.firstwordpharma.com/node/377635?tsid=17</u>.

Interestingly, top management opted to not implement the third planned step—namely, the transition toward a more customer-oriented BM and organization. As evidenced above, the changes made to LEO Pharma's BM during this period were of an incremental nature (i.e., improvements were made to the traditional operating model), rather than, for example, adding products or services that are unusual for the archetypical pharmaceutical BM (such as adding a new service dimension or pursuing new radical partnerships). As the CEO commented in an interview with FirstWorldPharma (September, 2009),

"We have, over the last decade, focused our strategy on our core pharmaceutical business within dermatology and critical care. This strategy has placed us in a very attractive financial and organizational position to actively pursue opportunities that fit with our strategy."

Thus, it seems that the main objective of BMI was centered on the first two strategic priorities, as opposed to radically reforming the existing model. The organizational design changes were also indicative of this choice, as no new units or resource allocations were made for customer orientation purposes. Instead, resources were funneled toward establishing LEO Pharma in the US and toward the Peplin acquisition. As noted by a senior strategy manager,

"Senior management was fixated on the US, and especially Picato® [Peplin, Inc.'s promising phase three candidate for actinic keratosis]. In fact, many believed that Picato® could possibly turn into a blockbuster. The idea about patient centricity and new services was merely considered a last resort if Picato® failed."

2010-2011: Implementation, or the Lack Thereof

In spite of the implementation efforts during the previous period (2008-2009), top management was not entirely satisfied with the progress made. Therefore, they decided to revise the new strategy in 2010-2011. Among other things, this led to new mission ("We help people achieve healthy skin") and vision ("We are the preferred dermatology care partner improving people's lives around the world") statements that more clearly reflected LEO's commitment to people suffering from skin

conditions. But, perhaps more importantly, the revised strategy (known as "The LEO powerhouse") included a range of organizational design changes (the so-called "corporate Must-Win Battles") intended to speed up and ensure more effective implementation of the refined BM. As stated in the annual report (2011:11),

"The five corporate Must-Win Battles ensure that we optimise our prioritization of the Group's resources in efforts to achieve our overall growth targets."

The five corporate Must-Win Battles (cMWBs) consisted of the following: (1) "Growing People, Growing LEO"; (2) "Innohep® - Full speed ahead"; (3) "Dermatology – Expanding our footprint"; (4) "USA – Yes we will"; and (5) "New markets – Future opportunities." The first cMWB was intended to develop new capabilities and improve knowledge sharing by launching a new leadership program in collaboration with IMD in Switzerland, and a new communication platform (known as "The global intranet Pulse") to improve lateral communication. The second cMWB focused on LEO Pharma's critical care business by creating a clearer strategy for Innohep®. The third cMWB was primarily about securing the marketing authorization for Picato®, but it also included a number of new initiatives to ensure patient-centered care. The fourth cMWB was dedicated to setting up the US organization (e.g., increasing the number of employees from 33 in 2010 to 194 in 2011), and preparing to file the marketing authorization with the FDA. The fifth cMWB was meant to secure marketing authorization in Brazil and set up an independent function focusing on business development in China.

The role of contextuality

The most important aspect of the revised strategy was related to the cMWBs, which were intended to drive implementation through changes to the underlying organizational design. This occurred largely through the reallocation of resources, as noted by a director of marketing:

"To be a corporate Must-Win Battle, that means that you get access to the big budget instead of being trapped in the limited budgets of line management. For example, you have larger budgets for consultants, external vendors, headcounts, etc. And then you have a champion from the top leadership team who can push the agenda and who acts as a problem solver to help overcome barriers." In other words, it seemed that top management believed that increased managerial attention coupled with more resources would be sufficient to drive implementation, rather than assigning new tasks and responsibilities, or a new incentive system and performance measures. Several informants noted:

"Sometimes LEO is like the Wild West ... If you want to get things done you need to know the right people [the informal organizational channels]. This works for some people, while others hate it and they go to work for companies like Novo Nordisk with more formal procedures." (Vice President)

"For the last decade or so we have been structured in much the same way." (Senior Director)

"There are certain ways of doing things at LEO." (HR Partner)

Or as explained by the executive vice president of global sales and marketing,

"I don't believe that you can organize change or drive it through internal reorganizations. Instead, it is people, the history of the company and its culture that over time move people toward a new target."

These are all valid and interesting reasons for top management's choice not to include additional organizational design elements as part of the interventions to deal with the implementation of the new strategy. Thus, it seems that contextuality plays a fundamental role in determining how things get done in an organization. It could also be argued that since the main objective was not to radically transform LEO's operating model, the option to, for example, change tasks and responsibilities, did not seem too relevant at the time.

Organizational design as a barrier to initial BMI efforts

The third cMWB of "Dermatology – Expanding our footprint" was partly set up to explore new socalled "patient-centred care" initiatives or BM innovations. While the current BM focused on developing and selling medical treatments (products), the "patient-centred care" initiatives were dedicated to developing and selling solutions that make life easier for people living with skin conditions. In other words, while the first model targeted all the physical symptoms of skin diseases, the second model was aimed at addressing the emotional and psychosocial wellbeing of people living with skin diseases. This represented a fundamentally different BM, as explained by the executive vice president of global sales and marketing:

"It requires a complete shift in mindset, recognizing that patients are the most important customers, and it is not enough just to have a large sales force that pushes products to the physicians."

At the beginning of 2010, top management sent out a directive ordering all subsidiaries to launch at least one "patient-centered care" initiative by the end of the year. This was LEO Pharma's initial step toward adopting a new customer-oriented BM. More specifically, the directive encouraged subsidiaries to launch a series of BM pilots for experimental purposes, as explained by the general manager of LEO Pharma Spain:

"The main objective was to learn about patient-centered care—identifying drivers and barriers to such initiatives—and hopefully develop a sort of catalogue that would allow individual affiliates to select different initiatives that have already been tested and proven to work in a similar environment. However, most of the projects did not really amount to anything new and there was considerable resistance toward the adoption."

One of the senior directors of marketing added,

"When we examined the initiatives in more detail, most of them reflected business-as-usual projects, rather than specifically incorporating patient centricity. Interestingly, they had just changed the name [of the initiative] to something about patient centricity."

Despite the good intentions, the BM pilots largely failed due to a lack of commitment, resources, capabilities, processes and structures. Although the directive came from top management, subsidiaries were not held formally accountable for the success of such projects.

Instead, subsidiaries were held accountable for sales volumes in their respective regions, as opposed to the quality of their BM experimentation efforts. As one of the regional vice presidents explained,

"Of course we try to implement the things from Ballerup [headquarters] as well as patient centricity, but at the end of the day we are here to generate sales and contribute to the profitability of LEO. Sometimes headquarters forgets that. Ideally we would like to come up with innovative solutions to help patients, but we are also expected to deliver on sales. In my opinion, as long as affiliates manage to deliver good sales numbers, I can easily tolerate less successful innovation projects."

It was also apparent from reviewing a series of internal documents (from the period of 2008 until 2011) that the element of "patient-centered care" was merely treated as an afterthought or footnote at the time of the revised strategy's introduction. The "patient-centred care" initiatives were merely one bullet point and served as the last strategic priority of the "Dermatology – Expanding our Footprint" cMWB. This was further confirmed by a number of informants at the middle and lower management levels:

"All eyes were on the US and the Peplin team." (Manager)

"There were many good intentions with Going for Gold. However, there were probably too many strategic priorities ... and then you had senior management who was almost obsessively focused on Peplin and getting access to the US market." (Senior Director)

In an external newsletter dated 12 November 2009, the CEO stated,

"We are very pleased that the merger is now completed and look forward to focusing our energy on developing PEP005 [Picato®] as quickly as possible for the benefit of patients."

Evidently, the key priorities were on expanding the current value proposition within dermatology by acquiring Peplin, Inc., so as to address the market of people living with actinic keratosis, and on

gaining access to the US market—rather than changing the BM per se. Thus, the combination of organizational resistance, too many strategic priorities, and perhaps too few organizational design changes made it increasingly difficult to succeed with the first business pilots.

2012-2013: Striking a Balance between New and Old BM Dimensions

In spite of the unsuccessful BM pilots, 2010-2011 served as a learning period in which organizational members became familiarized with BMI and top management could determine whether the chosen organizational structure was appropriate for such activities. A series of secret meetings were held for the purpose of deciding whether LEO should make a serious commitment to a more customer-oriented BM. As one senior strategy manager noted,

"The results from the first pilots showed that concerted efforts were needed to make patient centricity a part of the LEO DNA. However, there was substantial disagreement on the direction that LEO should take ... One group wanted to preserve the traditional research-based pharma model, while the other group believed that patient-centricity and co-creating solutions with patients was the best direction for the future of LEO."

Since the CEO favored patient-centricity, the outcome of those meetings was that LEO should take the necessary steps to implement it. The previous period showed the need for increased organizational governance and accountability in order to drive the more radical BM changes (i.e., the "patient-centred care" initiatives). In 2012, top management introduced a new department called "Global Patient Engagement" (GPE) to support that need. GPE was tasked with extending LEO's incumbent model to include a service dimension, along with serving as an active and credible integrator of BMI activities across the organization (Rasmussen and Foss, 2015). A new global organization structure was also created "with the aim of bringing LEO Pharma closer to patients so that it [would be] in a better position to develop and supply innovative new therapies that meet patients' needs" (Annual report, 2012: 10). The organization was divided into five geographical regions: USA, Lamea (Latin America, Africa and the Middle East), EU5+ (Australia, Canada, Germany, Ireland, Italy, New Zealand, Spain and the United Kingdom), ZOE (covering the remaining Eastern European countries), and Asia. In addition, top management selected nine key

markets (USA, the UK, France, Germany, Brazil, Russia, China, Japan and South Korea) that would receive additional attention from global headquarters.

An important milestone was reached in January 2012, when LEO won its first approval for Picato®; the product was subsequently launched in April. In 2013, Picato® was launched in a number of European markets (including Germany, the United Kingdom and Denmark), as well as in Brazil, Canada and Australia. Unfortunately, the first sales figures were disappointing to many, as explained by a senior marketing director:

"All markets were selling very few units of Picato®. In some markets [sales were] lower than 100 units per month, which isn't a lot despite the high price of the product. The problem was that dermatologists preferred treating AK [actinic keratosis] with cryo-treatment because they ultimately made more money out of that."

A senior manager from finance added,

"The sales figures clearly indicated that Picato® had no chance of becoming a blockbuster. People started questioning whether it was a failed investment or not, and whether management had perhaps overcommitted resources toward something that would never amount to anything from a financial perspective."

To make matters worse, LEO Pharma lost patent protection on one of its core products, Dovonex® (for the treatment of plaque psoriasis) in 2013. The new organization in the US also struggled to find a footing in the complex market, as noted by a market access manager:

"Even after three years there were still very basic things that did not work well. The sales force productivity was surprisingly low ... It was as if there was a lack of commitment or direction. Although the US market is very complex, it should be possible to produce better results with that set up."

Servitization as a means of salvaging the old BM

Overall, the period of 2012-2013 represented a challenging time for LEO Pharma. Not only was the traditional model showing considerable weaknesses, but the organization was also experiencing considerable changes with the rise of patient centricity. Since the incumbent BM was under pressure (due to the disappointing Picato® launch and loss of exclusivity on Dovonex®), increased attention was directed toward the new GPE department, and especially its new patient support service QualityCareTM.

Reactivating by adding new radical BM elements. In many ways, the bedrock of the "Going for Gold" and "LEO powerhouse" strategies was crumbling. Thus, top management decided to put more emphasis on patient centricity, which moved from being a non-core activity to a core activity. This was exemplified by the roll out of the QualityCareTM program in 2012. The program comprised a range of services targeted at patients and their families. The aim of QualityCareTM was to expand LEO's value proposition beyond drugs in order to help patients during all stages of their disease journey. In particular, the program included an online platform with a considerable amount of content that could be customized to meet different patients' needs, as well as expert advice from specially trained nurses. The program was designed for both psoriasis and actinic keratosis patients, and was offered for free in several markets. As one senior director of marketing explained,

"Most people at LEO are quite skeptical toward QualityCareTM because its business model is quite different from the traditional pharma business case. I always get the question, 'How are we going to generate money when it's free?' First of all, by offering free and value-adding support, we hope to increase customer loyalty and thereby ensure better customer retention. Secondly, the tailored disease-related information should enable patients to better comply with medication. That means we'll probably be selling more products, because often patients do not even pick up their prescriptions, or they skip doses. Thirdly, we'll be generating huge amounts of data that can be used for new innovative solutions. Lastly, such a platform allows us to explore various crossselling opportunities. Despite the immediate lack of revenues, I firmly believe QualityCareTM will be profitable in the long run."

LEO Pharma: When BMI is Stuck in The Middle

Not only did QualityCareTM offer a novel way to help patients during the different stages of their disease, but it also had the potential of adding value to the traditional value proposition. This was LEO's initial step toward offering bundles of products, services, information, support and self-service features (Vandermerwe and Rada, 1988) that could potentially offer more value to patients. To support this step, LEO launched the so-called "Columbus" project, which was essentially a coordinated way of managing BM experimentation. The idea was to instill innovative thinking at the subsidiary level in order to come up with new solutions that could potentially be implemented across several markets. For example, the Dutch subsidiary experimented with a direct-to-consumer delivery model, while Germany looked into partnerships with payers. In 2013, LEO took another step toward servitization by launching the so-called "Psoriasis Frontiers" project aimed at allowing closer collaboration with end users (relinking and repartitioning). As the project manager explained,

"Pharma is highly regulated and in most cases you aren't allowed to communicate directly with the end users. However, Psoriasis Frontiers was created in collaboration with the National Psoriasis Foundation in the US and a third party vendor. That means we can talk to select patients as long as the process is facilitated by the vendor and the National Psoriasis Foundation. So for the first time, it's actually possible to receive feedback from patients.

This period marked the transition from the traditional product-based model toward an emerging service-based model. Due to the failed Picato® launch, top management realized that the traditional model was perhaps not as viable as it had once been. As nicely summarized by a senior market access manager,

"Skin diseases are not as sexy as diabetes. That means it's getting increasingly difficult to get proper reimbursement for our products ... And I believe it's just a matter of time before we risk losing reimbursement completely. This is why we are launching programs such as QualityCareTM—to create value in different ways and hopefully come up with ways to monetize it."

Organizational design as a double-edged sword

The organizational design played several roles during LEO's transition toward a more service-based BM. It served as an important driver of BMI. Although top management encouraged the organization to experiment with BMs in 2010, it was only with the introduction of GPE in 2012 that notable BMI efforts occurred.

Structural modularization. Even though GPE resided in the global sales and marketing department, it had much more autonomy than other units. As noted by the senior director of GPE,

"We decided to make GPE a part of global sales and marketing because we want to be closer to patients in order to co-create with them. However, we have more freedom than the product teams to experiment with more radical ideas. This kind of freedom is needed. Otherwise, many of the projects would be immediately killed or stalled by all the bureaucracy."

Unlike most other units at LEO, GPE was not held accountable for revenues or costs. Rather, they were created for the purpose of promoting an innovative organization by setting up processes, structures, and capabilities for BMI. This was confirmed by several informants. A senior strategy manager of GPE stated:

"Basically, the survival of our unit rests on the launch of QualityCareTM."

A senior marketing director expressed his frustration with the lack of accountability:

"I have a hard time understanding the business rationale behind GPE ... They have tons of resources and FTEs [full time employees], but they have yet to prove their ability to make money."

Cross-functional and cross-boundary integration. GPE also served as a facilitator of BMI efforts. The unit represented a cross-functional and cross-boundary interface by bringing together various sources of internal and external knowledge. For example, the development of QualityCareTM included, among others, people from subsidiaries, compliance, legal, IT, and medical affairs, as well as consultants from digital agencies. As one manager of legal affairs explained,

"Building QualityCareTM is so different from launching a new drug. Therefore it was crucial to gather different types of expertise in order to arrive at a workable design for the program. The process has been very valuable in the sense that we have created new knowledge, particularly about services, online platforms, data protection, etc., which we can leverage for future patient-centric solutions."

This type of cross-functional coordination helped employees rethink the systemic nature of existing activities. First, although GPE members possessed a basic understanding of services, they needed to know whether QualityCareTM was feasible from a legal and compliance standpoint. Second, the early involvement of adjacent functions and subsidiaries revealed important gaps in knowledge and processes that needed to be addressed if the organization was to succeed with its transition toward services.

Formalizing BMI. Besides establishing a dedicated unit for BMI activities, top management also changed the names of all the existing functions to stress LEO's commitment to patient centricity. For example, market access was renamed "patient access" and the product teams were renamed "patient solution teams." Many informants called the name changes "stupid," "pointless," and "confusing." However, these types of changes may have served to increase formalization. Given that many of the projects that GPE was working on (such as QualityCareTM) were radically different from drug development, it was likely that they would be constrained by their lack of legitimacy with important external stakeholders (such as patients, payers, and physicians). Formalization can help increase legitimacy by signaling management experience and know-how.

Lack organizational design and BMI fit. Finally, the existing organization also proved to be a considerable barrier to LEO's BMI efforts. Although the names of existing functions were changed and GPE was established, the basic incentive systems and performance measures remained unchanged. This made it increasingly difficult for GPE to drive and facilitate BMI activities, as expressed by several informants. The senior director of GPE stated:

"The implementation of QualityCareTM has taken much longer than I anticipated because people are more concerned with the conventional business, and especially getting Picato® back on track. This means that QualityCareTM and Columbus are not really prioritized in terms of resources and staffing."

A patient engagement manager elaborated:

"Last year we compiled a launch excellence list in collaboration with the affiliates about different things they needed to do in order to launch $QualityCare^{TM}$, but many of them are still far behind the milestones on that list."

One general manager expressed this situation as follows:

"I definitely believe in QualityCareTM, but the problem is that budgets are shrinking and our success as an affiliate is based on the number of drugs sold. So what happens is that GMs [general managers] tend to allocate a half a FTE [full time employee] or less to those activities, but ideally, one to two FTEs are probably needed to implement a program of that magnitude. In addition, you need to have people with the right skills, which are difficult to come by, especially when you are not allowed to increase headcounts."

Headquarters also relinquished considerable decision rights to the subsidiaries as part of the new regional based organizational structure. It was thus increasingly difficult for GPE to drive and facilitate BMI activities, since some regional vice presidents did not share the same enthusiasm for QualityCareTM, Columbus, patient centricity, and so on. Similarly, in 2012, GPE's projects were not included in the company's short- and mid-term business plans, which essentially meant that the other functions and subsidiaries were not going prioritize those projects. As summarized by one of the regional vice presidents,

"Most of what gets done at LEO is based on the bi-annual and annual business plans ... If your project is not part of that, then people will not prioritize it because there are already a million other targets."

It could be argued that top management perhaps underestimated the systemic nature of BMI. Although they introduced a dedicated unit to handle these activities, that unit was incapable of producing the necessary change in the existing organization. As noted by the executive vice president of global sales and marketing, "Our current business model is not fit for the new environment. The problem is that there are many internal forces who want to keep [the incumbent model] alive, especially the ones who are still working in it. So they have no interest in trying new things. It's like becoming fat and then changing your lifestyle and going on a diet."

Furthermore, even though GPE had considerable autonomy, they lacked hierarchical authority, and more importantly, organizational legitimacy. The head of GPE was a senior director—several levels below the higher management circles. As noted above, many organizational members had a hard time understanding the business rationale and organizational relevance behind GPE, and especially QualityCare[™]. The combination of limited hierarchical authority and organizational legitimacy made it increasingly challenging for the newly established unit to drive and facilitate BMI. Although the intention was to shield GPE from the day-to-day bureaucracy of the existing organization, GPE ended up becoming alienated or disconnected from the existing functions, processes and systems.

Relinking by regoverning and value network failures

The idea behind QualityCareTM stemmed from one of the earlier BM experiments from 2010-2011. At that time, the original vendor for the online service, Atlantis Healthcare, was unable to deliver a user-oriented platform that could be customized to different patient needs. Thus, in conjunction with the introduction of GPE in 2012, it was decided to terminate the partnership with Atlantis Healthcare. It was important to find a new supplier, because not only did LEO lack the capabilities to undertake the development of an online health care service, but they were also hindered by legal regulations. As noted by a senior manager in legal affairs,

"We own all the data generated by $QualityCare^{TM}$, but it must be stored by a third-party vendor, and we only have access to the data in an aggregated format ... even though it would be amazing to have access to individual-level patient data."

GPE was responsible for finding the new vendor. The choice was made to go with Vertic (a global digital ad agency) for the following reasons: (1) they had experience with user-oriented platforms; (2) they were somewhat cheaper than Atlantis Healthcare; and (3) they gave the impression that anything was possible from a customization perspective. During the initial stages of the development of QualityCareTM, no issues arose. Instead, many—especially those in the subsidiaries—were excited about the possibilities for customizing country-specific modules for the program. Unfortunately, developing an online health care platform proved more difficult than hitherto anticipated by Vertic. In other words, it would take longer time with significantly higher cost and lower reliability than a more generic version. In the end, GPE settled for the generic version, much to the disappointment of many subsidiaries, who had been led to believe that they could receive program customized to their specific market needs. As expressed by one project manager,

"There was poor alignment of expectations. In the beginning we were told it was possible to get a customized patient support program, but now it's like 'You can have every color, as long as it's black."

In late 2013, the first version of QualityCareTM was finally launched—but only after a five months' delay. Almost immediately following the launch, the first subsidiaries started reporting a range of technical issues with the main site. There were numerous bugs or errors that caused the program to behave in unintended ways, as stated by a patient engagement manager from GPE:

"To be frank, it was nearing a catastrophe. Let me say it like this: There were instances where the FDA or EMA could potentially have shut down the site."

Due to the problems, the remaining launches were postponed another two to three so that the most severe technical difficulties could be addressed. In this case, the importance of the value network cannot be understated, particularly during the development of more radical BMI, since the capabilities of business partners are a critical component of the successful implementation of such BM changes. Taking into account all the issues that LEO had faced with their previous vendor, it was probably a mistake to rush the decision to partner up with Vertic. The partnership ended up costing LEO a great deal of money for a subpar platform with numerous technical issues that

remained unresolved. Unfortunately, the problems with Vertic exacerbated the skepticism toward GPE and BMI. As one senior director of marketing stated,

"It is not looking too good for Global Patient Engagement and QualityCareTM. Many people are gradually losing faith, and I also think top management is starting to be impatient."

2014-2015: A Failure or a Success Waiting to Happen?

The previous period brought fundamental changes to LEO's BM, including the launch of a new service, new partnerships, as well as project to test BM experimentation. However, due to problems with the new vendor and resistance to change, it proved more difficult than hoped to provide services to patients. On the other hand, LEO was able to convert the initial failures into important learnings that guided the subsequent set of changes. As summarized by the executive vice president of global sales and marketing,

"It can take years transforming an organization, and we have only been experimenting with new business models and patient centricity for about two to three years. If I recall it right, it took Coloplast roughly a decade to implement the innovation culture that we see today. But we have learned a lot during the past years."

Based on the learnings gained, top management set out a new strategic direction for the company. The new strategy was known as "Helping Sarah – LEO toward 2020," and it was called so to address the people behind the disease. While patient centricity was also part of "Going for Gold" and the "LEO powerhouse" strategies, it became the central pillar in the new strategy. As the CEO explained on the first ever conference for patient leaders in Vancouver, Canada in 2015,

"Helping SARAH gives a name to the individual patients we serve, and guides our entire organization around the patient. Patients like SARAH need better care, as living with a serious skin disease has a profound impact on everyday life. At LEO Pharma, we will continue our efforts to meet the needs of the individual patients with skin diseases—even when there is no immediate commercial gain."35

As a result of this new direction, a series of changes were carried out during the 2014-2015 period, including new strategic partnerships, the launch of two new devices, a change of leadership in the US organization and, perhaps most importantly, the establishment of the LEO Innovation Lab.

The first co-creation outcomes and new strategic partnerships

While most of GPE's BMI efforts (such as QualityCareTM and Columbus) seemed to have failed, the Psoriasis Frontiers initiative, through which LEO co-created solutions with patients, proved to be extremely effective. LEO launched its first medical device in 2015, namely the Daivobet® gel Applicator. This applicator enabled people to apply Daivobet® gel on difficult-to-reach areas of the body. In addition, another new solution called Enstilar® Foam was approved by the FDA in 2015 and was expected to be launched in the US in 2016. The solution was also co-created with patients, and is the first-ever topical spray treatment for psoriasis patients suffering from itching. Such patients may have difficulties falling asleep or may be woken up repeatedly as a consequence of itching, significantly influencing their perceived quality of life (Annual Report, 2015). Furthermore, Enstilar®'s foam formulation makes the treatment less greasy than other gel or moisturizer treatments. Most importantly, LEO managed to achieve a favorable reimbursement level for the applicator, which means that it is more likely to be purchased by patients. The two new solutions not only demonstrate some positive outcomes of LEO's BMI efforts, but also show the company's commitment toward its end customer. Aside from being more convenient and easier to use, the new solutions allow patients to choose from a broader array of products, based on their individual preferences. This breaks with the traditional pharmaceutical value proposition by going beyond the current "one drug fits all" approach. LEO's patient-centric approach has also been recognized by patients and patient associations:

³⁵ Retrieved August 2016 from <u>http://www.leo-pharma.com/Home/LEO-Pharma/Media-centre/News/News-2015/First-ever-global-conference-for-patient-leaders-in-dermatology.aspx</u>

"It's great that there's a company that wants to hear directly from patients rather than doctors or researchers. What they're doing empowers the patient."³⁶

The reason that the Psoriasis Frontiers project enjoyed more success than the other GPE projects is likely because it was less radical and had a more solid business case. Although LEO had never been in the device business, they had the capabilities and organizational willingness to try. As stated by a senior director of new product development,

"Devices are not that different from drugs. In many cases you need less clinical evidence because the environment is less regulated for the time being. We also have many people who have worked in medical device companies, and we have been looking into the field for a while."

Moreover, Psoriasis Frontiers was not solely driven by GPE, in contrast to QualityCareTM and Columbus; new product development was a co-owner of the project. In fact, GPE was only responsible for facilitating the co-creation workshops, while new product development incorporated all the feedback received from patients into the initial device development phases. As a result, it was much easier to implement the project because it was not beyond current capabilities, and there was more support from the wider organization.

During this period, LEO also developed new partnerships to strengthen its portfolio of digital solutions (such as QualityCareTM). First of all, the contract with Vertic was terminated, as they had failed to deliver on their promises. Instead, LEO formed a new partnership with DigitasLBI, which had more experience with the underlying system software of QualityCareTM (known as "Sitecore"). Additionally, they had higher capacity and better digital infrastructure than Vertic to effectively run a global online heath care platform. As stated by the head of QualityCareTM,

"Sadly, the relationship with Vertic has not been as fruitful as we anticipated. The QualityCareTM site is simply too unstable. Many of the bugs and errors seem to be due to poor coding, and a general lack of knowledge about the basic features of Sitecore. Therefore we have decided to go with DigitasLBI instead.

³⁶ Retrieved August 2016 from <u>https://www.psoriasis.org/advance/features/psoriasis-patients-help-with-product-research</u>

The first meetings with DigitasLBI have been promising. In fact, there are features within the Sitecore platform that we haven't unlocked yet.

This change seemed to be an important step for the success of QualityCareTM. Besides adding more stability to the platform, DigitasLBI could help LEO Pharma unlock new features. This was critical, because although QualityCareTM had been launched in a number of countries with decent enrollment numbers, engagement was relatively low. A new senior project manager expressed the following concerns:

"The problem is that we get fairly many new visitors, but the conversion rate is terrible. This means that either we are attracting the wrong customers or the site does not offer the right solution to our customers. I think the main problem is that the flow of the site is too slow. Basically you have to click through too many pages to find the information or service that you need. So currently we are working with DigitasLBI to improve the flow and add more interesting content."

Top management also decided to invest in the privately owned SkinVision, a dermatologyfocused mobile app company located in the Netherlands. In 2014, GPE tested MyPso QualityCareTM, an app designed to track the various symptoms, triggers and trends of patients suffering from psoriasis. In addition, the app provides practical advice on, among other things, nutrition and stress, so that the patients can make small changes that can have a significant impact on their skin. The partnership with SkinVision is aimed at strengthening LEO's position within the digital health care space, as argued by the senior director of GPE:

"The potential of apps and digitalization in general is incredible. It provides new ways to communicate with our most important stakeholders ... We can make digital solutions that make life easier and more enjoyable for patients, while gathering significant amounts of data which can be used for new innovative solutions or clinical trials. Currently, health care is on the brink of a digital revolution."

LEO Pharma: When BMI is Stuck in The Middle

While the potential of digital solutions such as QualityCareTM and the MyPso app seem endless, there is a notable downside. Patients are already online on peer-to-peer platforms such as Facebook and Instagram, where they also share disease-related content. There are also virtual communities like PatientsLikeMe, which is solely devoted to discussing disease-related topics. In contrast, QualityCareTM is not a peer-to-peer platform on which patients can communicate with each other directly. From a pharmaceutical company's point of view, allowing peer-to-peer communication would simply be too dangerous and time consuming. As noted by a senior manager of pharmacovigilance,

"There is high likelihood that patients will be taking about our products, and whenever someone experiences a problem with our products and mentions it ... even if it's just for fun, then we have to submit an adverse event report to the FDA ... and investigate the issue further. If we had such a platform, then pharmacovigilance would have to monitor every single 24/7."

However, not allowing for peer-to-peer interaction perhaps makes QualityCare[™] less desirable than other already-existing platforms. This might explain why QualityCare[™] has such a low conversion rate. In other words, in exploring the digital space, LEO should be prepared to compete with the likes of Facebook, Google Health Care, Apple Health, and Philips Healthcare— all from companies that have much more experience with digitalization, and that are less constrained from a legal and compliance perspective.

BM spin-off and a new governance structure

After three years of GPE efforts, it was time to evaluate the outcomes of LEO's BMI efforts. First, as mentioned earlier, QualityCareTM was not performing as expected. Although it had been launched in several countries and DigitasLBI had managed to remove serious errors, it still suffered from a poor conversion rate. Second, Columbus had not amounted to much, aside from a few successful BM pilots such as a direct-to-customer model in the Netherlands, and Spain's e-detailing model (i.e., using digital technology for physician marketing, promotional and communication activities). And even so, the scalability of those pilots was severely restricted due to market heterogeneity, as one senior director of marketing explained:

"Columbus would probably be quite successful if it was possible to launch the pilots in several markets. Unfortunately, there are so many differences between countries, regions, and even locally ... that it isn't feasible.

Third, the Psoriasis Frontiers project had turned out to be successful in the sense that it contributed to the development of LEO's first medical devices.

From a revenue-growth strategy perspective, LEO's BMI efforts were not successful. With regards to implementation, GPE did not manage to get the necessary organizational commitment to drive and facilitate BMI. However, this was partly top management's fault in the sense they neglected the systemic nature of BMI. In particular, by not making BMI-specific goals, incentive systems and performance measures, the existing organization seldom recognized the importance of GPE's BMI efforts. Instead, top management hoped that GPE could serve as an important change agent. Although LEO did change significantly in terms of the development of new capabilities and embracing a patient-centric mindset, most of the business were still operating within the confines of the traditional BM. As summarized by a director of finance,

"LEO Pharma has experienced a lot of change in recent years, but I reckon that 90% of the resources are still allocated toward traditional drug development."

For these reasons, top management decided to spin off the more radical BM activities by establishing the so-called "LEO Innovation Lab," a separate business unit operating independently outside the traditional BM. The three years of GPE efforts showed that alternative means are required to drive and facilitate more radical BMI activities. The new Innovation Lab consisted of a CEO and a CFO. However, it was backed by considerable resources that could be used not only to expand the team, but also for potential investments into promising startups. More specifically, the LEO Innovation Lab has received 60 million euros in funding the LEO foundation for the next three years (2017-2020). The unit "focuses on all aspects of everyday life that can affect people living with psoriasis—and develops and integrates solutions and services to meet their needs."³⁷ It is small, and based on an agile organization and high performance team structure, where innovation can flourish and solutions can be brought to patients and tested more quickly (Annual Report,

³⁷ Retrieved September 2016 from http://www.leo-pharma.com/Home/LEO-Pharma/LEO-Innovation-Lab.aspx

2015). In contrast, most of GPE's projects were restricted in many ways by the existing organizational structure of LEO. While it was never entirely clear what the success criteria of GPE were, the LEO Innovation Lab was created for the purpose of helping people achieve healthy skin, with no immediate profit requirements. This indicated a strong commitment toward patients in an industry that has been considered notorious for profit seeking.

However, the introduction of new independent unit also led to increased uncertainty at LEO, and particularly within GPE. Basically, the LEO Innovation Lab would be doing similar activities (i.e., developing and testing digital solutions and services). As noted by a senior strategy manager,

"It seems strange that top management didn't decide to either consolidate the units into one or just simply remove GPE. Currently, people are anxious about what is going to happen and whether they will keep their jobs."

The decision not to remove or replace existing activities, units, processes, etc., seems to be a general trend at LEO. Top management have often decided to overlay new changes on top of the old ones. This has given rise to added uncertainty and organizational complexity, making coordination of BMI efforts increasingly difficult. One senior director of marketing expressed the following:

"This is typical LEO. We have too many strategic priorities, and new things are often introduced without considering the impact on the existing ones."

The new strategy was also accompanied by a new organizational structure. More specifically, the company's previous six regions were consolidated into three—namely, Region EUROPE+, Region INTERNATIONAL and Region US. In addition, the regional heads became part of the top management team. The goal was to ensure that decisions would be made more closely to patients and markets.

Although LEO has made several changes to its BM and underlying organizational design over the past five years, the progress toward a customer-oriented BM has been remarkably slow. The aim of balancing old and new BM activities has largely failed due to top management's neglect of the systemic nature of BMI. On the other hand, the last five years have contributed significantly to organizational learning, which is essential to BMI. Perhaps based on these learnings, LEO may be able to reap the benefits of BMI in the future.

Summary of findings

LEO's BMI process can be defined by six consecutive stages (see Figure 8.1). During the first two stages, no fundamental or radical attempts were made to change LEO's science-based BM. Rather, efforts were directed toward incrementally improving the BM through a greater focus on the company's most promising therapy areas (dermatology and thrombosis) and pharmaceutical formulations. In the third stage, the new CEO aimed to expand LEO's two-decade-strong foothold in dermatology by acquiring Peplin, Inc. In addition to that, the rights to the company's psoriasis portfolio and dermatological pipeline in the US were repurchased to strengthen the internationalization process. As such, the first half of LEO's BMI process can be considered a period in which the incumbent BM was refined and improved so as to provide a solid foundation upon which more radical BM changes could be introduced. The fourth stage brought the first wave of radical changes to LEO's incumbent model. In particular, the element of patient centricity was introduced for the first time in the form of a series of BM experiments. However, these attempts never amounted to much, due to the lack of corresponding organizational design changes. The fifth stage built upon the previous one—most notably by adding a service dimension (e.g. QualityCareTM and Columbus) to the company's science- and product-based BM. To realize this change, LEO formed new boundary-spanning relationships, including relationships based on co-creation (e.g. Psoriasis Frontiers) with the end customers. The final stage represented both the end of and a new beginning for LEO's BMI process. Top management decided to continue all of the incremental improvements, while spinning off the more radical BM opportunities into a separate entity, the LEO Innovation Lab.

This case of LEO is interesting because it not only illustrates the challenges involved in BMI, but it also demonstrates the implications of not getting the organizational design right. Although top management introduced a new, dedicated organizational unit, that unit's influence never penetrated very deeply into the wider organization. The fundamental problem was that although GPE was set up in a modular way (i.e., operating beyond the existing management and control systems), it still relied heavily on the existing organizational capacity to acquire enough resources and capabilities to

get the job done. However, the existing organizational units (e.g. global marketing and sales, and the subsidiaries) were under considerable pressure from top management to improve sales at the same time as their budgets were declining and key products were coming off patents. This, combined with the lack of organizational design changes, particularly with regards to incentive and performance measurement systems, meant that the existing organization largely ignored or even decried GPE's BMI efforts. In other words, it seemed as if LEO's management team did not fully recognize the role of organizational design in realizing the holistic potential of BMI. Because of these challenges, top management learned that BMI requires substantial organizational support in the form of top management commitment, motivation, targets, resources, personnel, clearly defined roles and responsibilities, and accountability. As a result, LEO established a new configuration in the form of a completely independent entity (LEO Innovation Lab), which would be able to grow and evolve in directions that were never possible within the LEO organization.

9

A Cross-case Comparison: Key Findings

This thesis has explored the context of *BMI* and how such innovation has unfolded within three selected players in the pharmaceutical industry, particularly focusing on the role of organizational design during BMI. The analysis of the individual cases has not only revealed different manifestations of BMI and organizational design, but has also illuminated important similarities across the cases. In this chapter, I will discuss the findings on the basis of a cross-case comparison.

Toward a New BMI Process Framework

Based on the analysis that will be presented in the following subsections, I have developed a process framework that not only shows the distinct stages of BMI, but also take the different organizational designs and BM dimensions into consideration. Figure 9.1 illustrates the new BMI process framework, which is based on the emerging second-order constructs and overarching dimensions from Figure 4.2 (see Chapter 4). More specifically, it indicates the influence of three external driving forces on the innovation of established pharmaceutical BMs: structural change, technological change, and regulatory change. As a consequence of these forces, the focal firm's BM either experiences a fit or a misfit with the changing environment. Depending on the perceived level of fit or misfit (as perceived by top management), the company may be motivated take steps to change specific BM element(s) in order to improve the environmental fit. Such steps might involve simultaneous or overlapping changes to the firm's organizational structure, task environment, communication channels, roles and responsibilities, etc.—all of which are reflected in the firm's organizational design. This in turn creates a new layer of complexity in terms of the fit (or misfit) between the intended BM changes and organizational design changes. Ultimately, this process

either leads to realized BMI that fits the contextuality of the firm, or a misfit that motivates another iteration process. The framework thus reveals three critical stages of BMI: (1) motivation for the BMI; (2) implementation; and (3) outcomes. Moreover, even though the three companies went through the same three stages, the decisions they made, as well as the issues they faced within each stage differed considerably. Each stage, as well as the relationships between stages, will be discussed below.

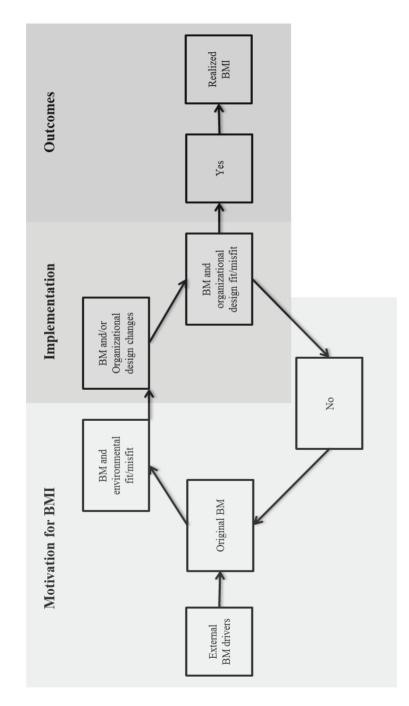


Figure 9.1 The different stages of the BMI process

Stage 1: Motivation for BMI

Drivers of BMI in the pharmaceutical industry

As described above, the core drivers of BMI in the pharmaceutical industry include structural, technological and regulatory change (for a more detailed discussion on drivers see Chapter 5). In general, these drivers were present in all the cases, although at varying degrees and at different points in time. In the early 2000s, all the companies started removing non-core activities from their BMs, while redirecting efforts and resources toward core activities. For example, Novo Nordisk divested its enzymes business, while UCB divested its chemical and film divisions. Aside from the strategic considerations, this was a response to declining R&D output. Most of the "low hanging fruits" had already been harvested, and as a result, the companies had to devote more resources to come up with new drug innovations. In addition, R&D costs have risen sharply since the early 2000s, while the number of drugs receiving marketing authorization and regulatory approval has been steadily decreasing (cf. Holland and Bátiz-Lazo, 2004).

Over time, a number of health care payers have imposed stricter pricing controls on new drugs. In other words, it is no longer possible to receive proper reimbursement and pricing for minor drug innovations. This was evident in all of the three cases. UCB and Novo Nordisk received negative reimbursement decisions on key products, and LEO might be unable to obtain reimbursement for dermatological therapies in the future. As a consequence, all three companies have made more or less drastic changes to their BMs to mitigate the growing pricing pressure from health care payers. Relatedly, payers and regulatory authorities are increasingly requesting data on quality of life and comparative effectiveness studies, in addition to the requirement of monitoring and collecting clinical trial data—thereby adding significant challenges to the companies' market access process.

The diffusion of new technologies, especially within ICT and Internet, has not only made it possible to gather data and develop new solutions, but has also led to more empowered and demanding end customers (i.e., patients). During the late 2000s, LEO and UCB invested heavily in such technologies, while Novo Nordisk was more hesitant. Instead, Novo Nordisk committed considerable resources toward HCP education and disease awareness, which helped satisfy the more demanding stakeholders.

Overall, the conglomeration of such drivers has motivated Novo Nordisk, UCB and LEO to reevaluate and, as necessary, modify or completely change their BMs to be consistent with the changing market conditions.

The original BM

Within companies, top management must assess the viability of the incumbent BM vis-à-vis the changing market conditions. I will briefly discuss each company's incumbent model by highlighting common features and differences, and how each was affected by industry dynamics. Aside from being located in different therapy areas, evidence from the cases shows that Novo Nordisk, UCB and LEO all converged on the same overarching BM elements in the early 2000s: (1) the value proposition focused on the development of new drug innovations (*What*); (2) which were then marketed to the prescribing physician (*Who*); (3) value appropriation was secured by means of favorable pricing and reimbursement conditions, and patent protection (*How much*); and (4) all this was realized through vertically integrated structures and the use of a few strategic R&D partnerships, while divesting non-core assets (*How*). This has been referred to as the "blockbuster model," with its emphasis on a high-volume, "one drug fits all" approach, facilitated by mainly internal and very substantial R&D input, as well as by economies of scale in R&D, production, marketing and sales (Gilbert et al., 2003; Mattke et al., 2012).

Although Novo Nordisk, UCB and LEO had all adopted the blockbuster model (to a greater or lesser extent), the outcomes differed significantly between the three companies. While it seemed that Novo Nordisk had a steady flow of new and superior drugs and devices within diabetes care, UCB, and especially LEO's R&D pipeline, seemed stagnant or almost non-existent in some areas. In other words, Novo Nordisk was simply better at leveraging the blockbuster model than the others. This may be partly attributable to the company's long standing research interest in diabetes, and partly to a much narrower spectrum of therapies. For example, while LEO and UCB focused on multiple diseases, Novo Nordisk's main focus was on diabetes care in the early 2000s. This allowed Novo Nordisk to funnel more resources and expertise into a single therapy area, which led to several successful product launches. Thus, in spite of the changing external conditions, Novo Nordisk's incumbent BM still remained viable in the early 2000s. In contrast, UCB's and LEO's blockbuster models were under more pressure due to their declining or absent R&D output. Moreover, Novo Nordisk specialized in large molecule drugs (biologics), while LEO and UCB focused on small molecule drugs (i.e., chemically manufactured active-substance molecules). Given that biologics are produced in "living organisms, including plants, animals, and microorganisms such as yeast and bacteria" (Revers and Furczon, 2010: 184), they are more difficult to copy than conventional small molecule drugs. Thus, even when they go off patent, it may take longer for competitors to introduce biosimilar products.

Stage 2: Implementation

BM changes

A BM change refers to any change to the focal firm's BM. In the following, I discuss in detail the dimensions of each company's BM changes by specifying the different and similar characteristics among them.

Reactivating. It was evident that all three companies were primarily preoccupied with changes related to the reactivation of the value proposition. For example, Novo Nordisk removed its enzyme and small molecule businesses, and added increased service content to its value offering by, among other things, expanding its disease awareness activities through the DAWN program. Similarly, but to a larger extent, UCB removed its film and chemical division and transformed itself into a biopharmaceutical company (i.e., focusing on both small and large molecule drugs). Then, top management added an impressive service dimension through patient support programs such as "Canine Assistance," "Crohn's and MeTM," and "Parkinson's Well-Being MapTM." Next, UCB made the decision to withdraw from the primary care market in the US. In similar fashion, LEO divested non value-adding activities (such as HL 10 and the animal health unit), while expanding its dermatology offering by acquiring Peplin, Inc. Next, top management put considerable efforts into servitization by launching new devices (e.g., Daivobet® gel Applicator and Enstilar®) and patient support activities (e.g. QualityCareTM and Psoriasis Frontiers).

Interestingly, while Novo Nordisk and UCB removed or discontinued very strategic BM activities (such as withdrawing from small molecules and primary care), LEO kept its incumbent model intact while adding several other features. This meant that resources and managerial attention were distributed over a wider range of activities, which in the end hindered LEO's BMI efforts.

Given the distribution of activities at LEO, the allocation of resources and responsibilities; the identification of activities; and the measurement and evaluation, and more importantly, the coordination, of activities, became a non-trivial task. As a consequence, top management decided to spin off the more radical BM activities. Conversely, UCB and Novo Nordisk were able to concentrate their resources, expertise and managerial attention on more clearly distinguished strategic priorities, which allowed them to progress beyond the initial experimentation stages of BMI.

Relinking. Likewise, relinking was used to a great extent in all three cases. It was usually carried out by either changing the governance of transactions between the market, hierarchy, and hybrid forms (i.e., *regoverning*), or by changing the order in which organizational units perform certain activities, as well as shifting the interdependence among organizational units and BM activities (i.e., *resequencing*) (Santos et al., 2015). The most extreme case of relinking was that of UCB, which not only initiated a range of strategic partnerships with non-traditional stakeholders (e.g., OXO and PatientsLikeMe), but also fundamentally altered the sequence and interdependence of BM activities occurring due to their change efforts. Essentially, the company underwent four massive restructurings within ten years (e.g., the acquisitions of Celltech and Schwarz Pharma, the SHAPE project, etc.), with the purpose of arranging BM activities and organizational tasks to fit the customer-oriented BM. LEO also relied heavily on relinking BM activities, for example, by introducing new organizational units responsible for BMI (e.g., GPE and LEO Innovation Lab) or by changing the allocation of resources and responsibilities (e.g., cMWBs and a new governance structure). However, LEO's relinking efforts were dwarfed in comparison to UCB's massive organizational changes. Meanwhile, Novo Nordisk refrained from massive restructuring, nor did they engage in notable strategic partnerships. Instead, they mainly refined and extended their incumbent BM activities by, for example, changing roles and responsibilities within the existing organizational hierarchy (e.g., Global Marketing and Medical Affairs became part of top management). In addition, top management introduced a new management and performance system ("The Triple Bottom Line"), which aided in integrating features of social and environmental responsibility into the existing BM activities.

Repartitioning. In contrast to reactivating and relinking, repartitioning was used to a lesser degree within the three companies. This type of change involves outsourcing or insourcing specific

BM activities. LEO and UCB attempted to outsource some of their innovation tasks by opening up to external knowledge. For example, the Psoriasis Frontiers project allowed end users to contribute to the design of LEO's new devices, while UCB outsourced parts of its market research activities to IBM and PatientsLikeMe—particularly those related to data mining and customer insights. In contrast, Novo Nordisk did not utilize any repartitioning as part of their BM change efforts. The reason for this was twofold. Firstly, Novo Nordisk was focused on improving and sustaining the incumbent BM rather than radically changing it. Therefore, it could be argued that Novo Nordisk was not reliant on external expertise to develop new and innovative solutions, as was the case with UCB and LEO. Secondly, the performance of Novo Nordisk's supply and value chain management served as benchmarks for the industry. In other words, there was little incentive to outsource important activities to subpar suppliers or contract manufacturers. This is an interesting finding because Novo Nordisk's objective was to improve and preserve the incumbent BM, and one of the ways in which large and successful companies optimize their BMs is through short-term cost cutting by means of outsourcing.

Relocating. BM changes related to off-shoring and/or on-shoring were seldom or not at all used in the cases. Novo Nordisk did establish an R&D center in Beijing in 2001 to bridge the scientific communities in Europe and China. However, LEO and UCB did not rely on relocating BM-specific activities. Usually, the primary motivation for offshoring to obtain cost savings. UCB and LEO were instead focused on bringing about more radical solutions and building up internal BMI capabilities. Recently, firms have also started to offshore more advanced tasks or innovative activities (Farrell, 2005) in order to, for example, tap into global talent pools. This is very much what Novo Nordisk was doing. On the other hand, offshoring such activities can be a daunting task (Larsen, Manning, and Pedersen, 2013). According to Jensen and Pedersen (2010: 6) "offshoring advanced tasks involves the creation, distribution, and sharing of knowledge in a dynamic process with many feedback loops. This process must be managed and integrated between the locations to be effective. This requires a deep understanding of the interdependencies between the different tasks." This type of offshoring makes sense for Novo Nordisk because they have a deep understanding of their R&D activities, while UCB and especially LEO have yet to develop such an understanding of their more radical BM elements. It is also arguable whether it makes sense for LEO and UCB to offshore activities to differentiate their offering in order to obtain competitive

advantage. At worst, such efforts can degenerate into a "learning race," where foreign partners try maximize the knowledge they gain while minimizing knowledge sharing (Khanna, Gulati and Nohria, 1998).

Which part of the BM is being innovated? The evidence from the cases indicates that changes to the value proposition (reactivating) and the architecture of the BM (relinking) are the most commonly used types of changes, while repartitioning and relocating are used to a lesser extent. I suggest that reason for this may be that changing the value proposition and architecture of the BM has greater implications for value creation and appropriation vis-à-vis offshoring/onshoring or outsourcing/insourcing select activities. First of all, the value proposition refers to the bundle of products and services that a firm offers to create value for one or several customer segment(s). For example, adding a new service may attract new customers and make existing customers buy more. Thus, value creation is improved because not only is the firm creating additional value for its existing customer segment(s), but it is also bringing value to new customer segments. Similarly, value appropriation is improved as the new service allows for new sources of revenue. More specifically, services can complement the sale of products by, for example, helping end users achieve the desired functionality. LEO's and UCB's patient support programs were designed to empower people to take control over their disease, as well as improve their adherence to drug treatments. Moreover, removing non-value-adding activities frees up resources for more productive purposes. As such, the value proposition may be regarded as a major BMI driver in its own right. Further, the introduction of new products or services may also trigger additional changes in neighboring BM elements. At UCB, for example, the provision of services was supported by subsequent changes to the value network.

With regard to second locus of BM change, Teece (2010) argues that the "architecture" of the firm's value creation and appropriation mechanisms is the essence of a BM. Foss and Saebi (2015:3) elaborate on this point further, noting that the "architecture is the organizational structure and control that supports the activities that allow the company to make its value proposition to the marketplace and embed the human and social capital that, with other resources, add value to those activities." Not only does the BM architecture make the value proposition available to customers (e.g., by linking factors of production with intermediate inputs and outputs to final outcomes), but it may also contribute significantly to value creation and appropriation by unlocking important

complementarities between different BM elements and the organization of the firm. For example, UCB implemented a new communication platform alongside a new performance management system, which, among other things, led to improved coordination, knowledge sharing and incentives for people to work toward patient centricity. In contrast, despite LEO's emphasis on patient centricity, top management did not change the reward and performance measure systems to reflect the increased service content and importance of the end customer, and thus failed to facilitate sustained value creation. Besides realizing complementarities, relinking allows firms to open up their organizational boundaries and tap into important sources of knowledge. LEO, for example, would have been unable (both legally and technically) to develop and launch its global patient support program without third-party participation.

Overall, it seems reasonable to conclude that changes related to reactivating and relinking contribute more to value creation and appropriation than repartitioning and relocating. These parts of the BM are harder to imitate because, as Simon (1962: 468) reminds us, they "interact in a non-simple way." In particular, it is more difficult to replicate the value proposition when its development relies on a complex set of interrelated (complementary) processes, structures and resources. By contrast, it is very straightforward to offshore or outsource similar activities, which would arguably lead to less differentiation in relation to the value proposition.

Type, extent and degree of BM changes. The evidence analyzed across the cases suggests that all three companies were leaning toward an increasingly service- or customer-oriented BM (commonly referred to as patient centricity). More specifically, the companies augmented their incumbent models by adding a range of services (such as patient support programs and training of HCPs)—with the aim of improving differentiation and building stronger customer relationships. Aside from the value proposition, this trend was also evident in other parts of the BM. LEO and particularly UCB designed many parts of the organization around the end customer and servitization. For example, LEO's Innovation Lab was introduced for the sole purpose of developing and testing digital solutions and services. In other words, the types of BM changes reflected the increasing importance of servitization.

An interesting finding was that BM change appeared to be systemic in all the cases examined. In other words, a change in one part of the BM usually needed to be accompanied by appropriate changes elsewhere. Novo Nordisk's dedication toward patients, HCPs and sustainability (e.g., through offering a wide product portfolio and the DAWN program) was accompanied by a new organizational unit (Global Stakeholder Engagement), and a new management and performance model (Triple Bottom Line). LEO's patient support program (QualityCareTM) would never have been completed without changes to the value network (e.g., partnering up with digital agencies) and BM architecture (e.g., the establishment of GPE). Similarly, UCB's transformation into a biopharmaceutical company and later development into a solution provider could not have been achieved without changes to the value proposition (e.g., divesture of the film and chemical division), BM architecture (e.g., centers of excellence and multidisciplinary teams) and value network (e.g., partnering up with OXO and PatientsLikeMe). Although some of the BMI literature (e.g., Abdelkafi et al., 2013; Schneider and Spieth, 2014) argues that an individual change to a particular BM element can constitute BMI, in practice, such a change will set in motion a sequence of changes to adjacent BM elements. However, in the cases, the way in which the sequence of changes was arranged differed markedly. In some instances it was architectural, including establishing design rules so that certain sub-elements would form a coherent whole, while in others it was more modular, where elements were partitioned rather than changed according to a monolithic structure. For instance, the extent of LEO's BM changes resembled that of a modular form. Although LEO's BMI unit (GPE) resided in the global sales and marketing department, it had its own distinct goals, structures, processes and capabilities. In other words, the unit was not designed to fit into the existing organization or vice versa. Later, the LEO Innovation Lab was implemented in a similar manner, so as not to interfere with the value creating and appropriating mechanisms of the incumbent BM. Novo Nordisk and especially UCB opted for more architectural features, such as integrating new organizational units into existing management and organizational practices, and vice versa, by implementing new management and performance measures that complemented the new strategic orientation of the companies.

The reason for these differences may be due in part to the varying degrees of innovation desired. Novo Nordisk focused on incremental improvements and modifications to their incumbent BM. Thus, most of the changes were implemented with the intent of increasing efficiency and effectiveness across the company's entire range of operations. Accordingly, it made sense to incorporate elements with architectural features that would contribute to the entire system design. Similarly, but within a different context, UCB also went for changes with architectural features.

Given that UCB was attempting to fundamentally transform its incumbent BM, top management was tasked with changing the overall architecture of the company by re-wiring several elements of the BM. Meanwhile, the top management team at LEO favored an "in-between" configuration, where incumbent elements (such as the overall architecture) were largely preserved, while newer and more radical elements were added. Due to the radical nature of these elements, and the lack of changes to the existing architecture, top management resorted to more modular and autonomous changes confined to specific areas within the organization. Looking at the level of novelty, it is fair to say that none of the companies produced BMI that was new to the world. In fact, companies such as Rolls-Royce, Xerox, Coca-Cola, IBM, and the banking industry in general were already focusing on servitization in the '90s. That said, introducing patient support services (such as QualityCareTM and Parkinson's Well-Being MapTM) and restructuring the entire organization around the patient (as was done at UCB) was indeed new to the pharmaceutical industry. Although Novo Nordisk was one of the first companies to adopt patient centricity, they are still to a large extent leveraging the advantages of the traditional "blockbuster" model, but to a degree far greater than many other pharmaceutical companies.

Organizational design changes

The purpose of redesign efforts is to improve organizational efficiency and effectiveness, problem solving, as well as the ability to cope with organizational and environmental change. In the following I discuss the changes made to each company's organizational design with regard to structure, coordination needs, information processing requirements, performance measures and complementarities.

Organizational structure. While the role of organizational structure and hierarchy in shaping BMI efforts has received surprisingly little attention in the extant BMI literature, the cases have demonstrated that they are indeed intimately linked. By far the most extreme example is that of UCB. Top management decided to dissolve the company's functional and product division structure because, although it was ideally configured to deal with the large-scale production of stable products, deficiencies emerged in environments demanding innovation (particularly integrated solutions) and change. As argued by Zenger (2002), the low-powered incentives, rules, guidelines, and proscribed behaviors offered by traditional hierarchies tend to discourage innovation and

flexibility. Instead, top management introduced the "patient solution teams"—called so in order to stress the company's aim of providing integrated solutions that go beyond the drug. The team-based structure not only facilitated speedy integration between various bodies of knowledge so that more complex customer needs could potentially be met, but it also infused market-like controls. In particular, each team was granted decision rights to self-organize, including its own processes through which to fulfill its new patient-centered mission. In other words, the teams were responsible for their complete output, processes and activities (Peters, 1992; Hammer and Champy, 1993; Mohrman, Cohen, and Mohrman, 1995). This resembled the high-powered, flexible and entrepreneurial spirit found in start-up firms. Without this team-based structure, UCB would have been unable to transform from a product provider into a full-blown solution provider.

The redesign efforts at Novo Nordisk differed in several respects from those at UCB. In contrast to UCB and LEO, Novo Nordisk focused on exploiting its existing capabilities and dominant market position in drug development and sales, as opposed to creating new services for the end customers. In that sense, the value proposition has remained relatively unchanged over the past decade, and for that reason, the traditional functional configuration sufficed. Strictly speaking, when a new drug candidate has been identified, it goes through the same sequence of stages and is evaluated using existing criteria, maximizing the repetition of tasks. This structure enables the development of functional expertise in performing tasks and allows for the development of explicit rules and procedures to guide behavior (Scott, 1981). As a result, Novo Nordisk is able to mass produce a stable set of high quality products. This is not to say that Novo Nordisk does not work cross-functionally, but, unlike UCB, they have not structured their entire organization for that specific purpose.

While UCB and Novo Nordisk each emerged at the extreme ends of the continuum, LEO's redesign choices resulted in a hybrid configuration with a mix of both market-like and hierarchical features. Much like UCB, LEO made efforts to become a solution provider, with products and services developed to meet more complex customer needs. Initially, GPE was introduced for that specific development purpose, and featured a highly autonomous and informal structure. However, similarly to Novo Nordisk, top management wanted to keep the functional hierarchy relatively intact to maintain stable production and delivery of products. As a consequence, GPE and the previously existing functions were never properly integrated, even though GPE relied heavily on

the other functions and subsidiaries. Thus, unlike UCB's "solution teams," GPE never had complete control over the process nor output. As noted by Zenger (2002: 90), "significant changes to a core element of hierarchy unleash complementary pressures to either alter other elements or to abandon the original change." As a result of the suboptimal hybrid structure, top management decided to spin off of those activities that could not be effectively dealt with within the existing functional configuration. However, of the three cases examined in this thesis, LEO was the only one to attempt to create a dedicated department and unit with an explicit focus on BMI.

The implication of these findings is that organizational structure may exert powerful influences on the implementation of BM changes, and on the extent to which the structure itself is established, redesigned, or replaced as BM changes unfold. Thus, depending on the type, scope and degree of BMI, the structural modes can vary in their applicability. For example, a service-based BM consisting of radical and architectural features calls for a different structure than a product-based BM consisting of incremental and architectural features.

Coordination needs in a changing task environment. Turbulent environments usually force companies to make substantial changes to their internal task structure (Tushman, 1979) in order to enhance the ability to create and capture value in the marketplace. This in turn leads to new coordination challenges and capability needs. Despite significant changes occurring in the pharmaceutical industry, Novo Nordisk only made minor adjustments to its internal task structure. In contrast to many other firms, Novo Nordisk's traditional BM still seemed to work well enough. Aside from the divestment of its enzyme business, the organization did not face coordination problems to the degree encountered by LEO and UCB. Unlike UCB's and LEO's novel BM activities, Novo Nordisk's core activities constituted routine tasks that were easily coordinated by means of supervisory control, reliance on formalization, and centralized communication. However, the ease of coordination was partly achieved by the implementation of The Triple Bottom Line. In general, it can be argued that, rather than replacing or adding new tasks, Novo Nordisk shifted the focus within its existing task structure. For example, marketing-related tasks (particularly market access) became more important than others. Therefore, in addition to the new management and performance systems, rearrangements in the top management hierarchy were made to reflect the growing importance of marketing.

A Cross-case Comparison: Key Findings

Meanwhile, LEO made substantial changes to its internal task structure. Specifically, a new disease area was included (actinic keratosis, Picato®), while expanding the current value proposition to include services (QualityCareTM and Columbus) and devices (Daivobet® gel Applicator and Enstilar® Foam). This led to a number of non-routine tasks involving both a high level of task variety and a low level of task analyzability. While high variety implies that organizational members cannot usually predict problems or activities in advance, the lack of analyzability implies that organizational members do not know exactly how to respond (Daft and Macintosh, 1981). For example, in the development of QualityCareTM, LEO did not expect to face that many technical and partner-related issues. When such a situation is coupled with the complexity associated with such a service, and a general lack of experience, it becomes increasingly difficult to respond in a timely and appropriate manner. Moreover, top management failed to take into account the interdependencies between the new non-routine tasks and the existing routine tasks, resulting in further internal coordination issues. However, such interdependencies may not seem readily apparent when the task characteristics are difficult to analyze ex ante and vary considerably. Despite these issues, LEO managed to build new capabilities by combining various organizational design mechanisms. The modular implementation of GPE (and, later the LEO Innovation Lab) provided the necessary room and resources for capabilities to grow. In addition, the formalization of patient centricity or BMI helped attract people with experience and skills in services.

In a similar fashion, UCB extended its current value proposition beyond products to include services. But, in contrast to LEO, UCB managed to mitigate many of the coordination difficulties associated with a changing task environment. More specifically, top management was able to recognize the deeply embedded interdependencies between the old and new tasks. This allowed them to identify potential complementarities and subsequently redesign the organization to create the conditions under which such complementarities could arise. For example, there was an explicit logic of complementarity in the development of the patient solution team structure. The teams consisted of people from the most important functions, such as market access, new product development, compliance, pricing, etc. This allowed UCB to not only speed up the time to market but also to address emerging needs from the most important stakeholders (patients, payers and physicians). Part of the reason why UCB managed to limit coordination costs and get the

complementarities right was that they viewed the change process from a total organizational perspective rather than a subunit perspective, as was the case with LEO. In other words, while LEO wanted to keep its existing functional structure intact, everything was up for grabs at UCB. Another reason relates to the numerous restructuring efforts at UCB, which made the organization more accustomed to change, while LEO was hesitant and risk averse. Overall, even though UCB's task structure was fundamentally changed several times, they always seemed to limit coordination issues and avoid irreversible commitments by "getting the complementarities right."

Despite these differences, the cases share important characteristics in that they all seemed to undertake coordination efforts that moved decision-making closer to the customer. This was not only illustrated by the increased number of services, but also by the strengthened focus on the marketing organization. Put differently, all three companies attempted to increase the value added by reversing (i.e., changing the internal task structure of) the traditional value chain from upstream to downstream activities.

Information processing requirements. As noted above, BMI often involves undertaking new tasks and/or enhancing the functionality of current ones. This results in new coordination needs, which in turn lead to different information processing requirements. To address the growing processing requirements, UCB adopted a number of integrating mechanisms that increased its information processing capabilities. With the addition of new products and (particularly) services, an increasing number of decisions were referred upward. However, one notable limitation of hierarchy is its finite and relatively restricted capacity for processing information (Daft, 2006). As a result, the top management team of UCB experienced information overload. To deal with this problem, top management delegated extensive decision rights to the "patient solution teams." Not only did this preserve top managers' scarce mental resources, but it also led to more effective resource utilization, because decision rights were granted to those who held the relevant local knowledge to guide the decisions (Jensen and Meckling, 1992).

In conjunction with the success of the "patient solution teams," the projects grew in scale and scope to the extent that the again required intervention from top management. To cope with the increasing complexity, it was found necessary to increase the size of the top management team. Thus, the "patient solution teams" transformed into the so-called "patient value units," with each unit head included in the top management team. In addition, strategic marketing also became part of

top management. As a result, the top management team increased both in size and diversity, which enhanced its problem-solving capabilities. This was done by (1) increasing the amount of knowledge and information that could be absorbed and recalled, (2) increasing the number of critical judgments available to correct errors in decision-making, (3) increasing the number of potential solution strategies, and (4) increasing the variety of perspectives brought to bear on specific problems (Harrison, 1975; Hoffman and Maier, 1961; Shull, Delbecq, and Cummings, 1970). Moreover, to further strengthen information processing capabilities, UCB introduced another complementary practice. The ability to source and process important customer data and transform it into insights (i.e., useful and meaningful pieces of digested information), which could then be incorporated into new services, products, or activities, required that UCB improve its internal communication flows, particularly along the horizontal dimension. All of this was achieved with the implementation of a new web-based intranet platform (UCB Plaza). In addition to allowing multiple organizational members to contribute ideas, the platform improved the identification of knowledge resources within the organization. An equally important feature of the UCB Plaza is its ability to aggregate information and knowledge from dispersed individuals, which could lead to improved organizational decision making under uncertainty (cf. Deutsch and Madow, 1961). As argued by Felin and Zenger (2011: 4), "even naive and biased information aggregation can do better than expert or managerial judgment."

In contrast, although LEO also made substantial changes to its internal task structure, it seemed to place less emphasis on the relationship between information processing and the new task activities. Top management were convinced that by delegating decision rights to GPE, they would be able to economize on the vertical knowledge transfer costs (Jensen and Meckling, 1992) resulting from the increased service content. However, due to limited hierarchical authority, GPE was largely unable to exercise those rights. As a consequence, problems and conflicts were commonly escalated to the top management level and forced project delays and increased coordination costs. Information processing was further hampered by the lack of liaison positions. As mentioned earlier, GPE relied on participation and input from other functional areas, but there was rarely a common point of contact, which resulted in additional coordination problems. In spite of these accumulated difficulties, the delegated decision-making power enabled GPE to judge, absorb, and pass on the relevant input from the end customers. Similarly to UCB's Plaza, LEO

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introduced an intranet platform (Pulse) with the aim of improving horizontal knowledge flow within the organization. The platform had limited success, however, partly because of low userfriendliness and partly due to organizational members' preference for informal communication channels. As an additional knowledge sharing practice, GPE hosted a range of workshops for employees involved in Columbus and QualityCareTM. These were somewhat useful in identifying synergies across the different projects. Concurrently with the launch of QualityCareTM, GPE designed a launch excellence framework for the subsidiaries, highlighting the (generic) steps and challenges associated with the implementation of QualityCareTM. Nevertheless, despite these efforts to improve the company's information processing capabilities, considerable coordination costs were still incurred. One could even argue that the efforts were counterproductive, in the sense that they exacerbated information overload. The reason for this, I suggest, is that LEO treated information processing from a unit perspective rather than an organizational perspective, as UCB did. In the end, as a consequence of the escalating information processing burden, it was decided to enlarge the size of the top management team.

Throughout the fifteen years studied, Novo Nordisk's task environment remained relatively stable, with low uncertainty and high predictability. Accordingly, the organization did not face fundamentally different information processing requirements. Put differently, new problems did not emerge at a sufficient frequency to require a significant increase in information processing capabilities (Daft and Lengel, 1986). Rather, most issues were well understood, which meant that lengthy discussions were rarely needed to resolve them. Instead, coordination and information exchange were sought by means of formalization and standardization efforts, including the reliance on rules, standards, procedures, policies and precedents. These practices represented information filters that would allow the organization to immediately identify the most crucial pieces of information in the information stream (Arrow, 1974; Daft and Weick, 1984). The Triple Bottom Line and the accompanying balanced scorecard system were implemented for that specific purpose of disseminating and sourcing the right pieces of information pertaining to Novo Nordisk's strategic priorities. Like many other companies at the time, Novo Nordisk was being constantly bombarded with information about digitalization and patient support programs. However, the filters ensured that efforts and information activities would be directed toward refining and reinforcing the existing BM, rather than radically altering the way Novo Nordisk did business. Occasionally, however, the

organization did suffer problems and coordination breakdowns. The way that Novo Nordisk identified and responded to such issues was through a unique organizational practice—namely, the actions of so-called "facilitators." Each year, the group of facilitators would visit a select number of strategically important departments and subsidiaries to ensure that inefficiencies and implementation errors were being kept to a minimum. If errors were identified, or if processes appeared to be inadequate or incompletely described, the facilitators would help implement corrective actions. If the focal unit or subsidiary then neglected to take the corrective actions, the problem would be escalated to the top management level. Besides serving as a control mechanism, the facilitators were instrumental in the sharing of best practices. Although UCB and LEO faced far greater information processing requirements than Novo Nordisk, the recent FDA rejection of Tresiba® led top management to reconsider some aspects of its information processing orientation. As a result, global marketing and medical affairs became part of the top management team to ensure that effective interventions could be made in advance of potential future rejections.

An interesting finding from all three cases was that the size and/or composition of the top management team changed markedly during the fifteen years under study, and that these changes were made to improve information processing. This, I suggest, is due in large part to the inherently systemic nature of BMI. As noted by Stieglitz and Foss (2015: 105), "it is well known from the literature on coordination in complex systems that system elements may stand in different relations of specificity and complementarity to each other (Lachmann, 1956; Milgrom and Roberts, 1990; Williamson, 1996; Levinthal, 1997)." However, the lower levels of the hierarchy are rarely in a position to identify such relations. Instead, due to their global perspective, the top management team is better positioned to take actions according to those relations. Perhaps not surprisingly, it was also evident that, depending on the type and scope of BM changes, the companies faced different information processing requirements.

Performance measures. As shown in previous sections, the implementation of BMI rests on the firm's ability to align or match its structures, tasks, and information processing to its intended BM change(s). Performance measurement systems play a critical role in this regard because they are used to control and influence behavior in the organization and guide the strategic reorientation process (Wouters, 2009). Such systems usually consist of a balance between internal and external measures, and between quantitative and qualitative measures (Keegan, Eiler, and Jones, 1989). In

general, all three firms seemed to stick with the performance measures traditionally associated with pharmaceutical firms—notably, measurement related to number of unit sales, number of physician visits, and time to market. Since the vast majority of pharmaceutical revenues are still generated from drug sales, this is hardly surprising.

In the case of LEO, despite the increasing service content and coordination failures, top management were reluctant to incorporate new KPIs, as they would interfere with the day-to-day running of LEO. Although the new BMI unit (GPE) had new task-specific KPIs (such as customer satisfaction and number of enrolled customers), it did not matter much, since the existing organization was strongly preoccupied with reaching sales and budget targets. As succinctly explained by Kindström and Kowalkowski (2015: 202), "despite the common opinion that 'what gets measured gets done,' to the frustration of service managers, incentive systems and metrics are frequently still product-centric." This lack of alignment was problematic due to the interdependent relationship between GPE and the other organizational units. Interestingly, while top management's intention was to minimize coordination failures and conflicts of interest, the reluctance to include service objectives as part of the overall performance measurement system ended up causing even more coordination failures and conflicts of interest.

In contrast, while Novo Nordisk also relied greatly on its existing product-centric performance measures, the new Triple Bottom Line reporting system took into account the new strategic priorities. A list of 19 performance targets was compiled to reflect various aspects of social and environmental responsibility. For example, one target included the implementation of sustainable BMs in developing countries, measured by (1) the number of least developed countries in which Novo Nordisk is operating, and (2) the number of least developed countries that have chosen to buy insulin under the best possible pricing scheme. While the former constituted a proxy for access to essential medicines, the latter addressed the expected affordability of essential medicines. Since the new performance measures represented an extension of the firm's current operations (rather than a radical departure from established practices), they resulted in positive spillover, as the extent to which fulfillment of one target enhances the quality or achievement of other targets.

Meanwhile, UCB also rolled out new performance measures, but they were designed specifically for the more radical step of developing and delivering customer-tailored solutions. In

particular, organizational units were measured on their ability to prioritize capability renewal by means of, for example, job rotation and coaching. In a similar study, Rasmussen and Foss (2015: 260) found that, UCB's sales and marketing subsidiaries "had to submit regular reports about their budget allocation, [where the objective function was to spend] at least 30 percent of the budget [on] non-traditional marketing activities." Besides that, individual contributions and achievements were encouraged by new, high-powered incentives such as variable remuneration. In other words, UCB's new measures were intended to promote the risk-taking and entrepreneurial behavior that is associated with more radical BMI efforts. In contrast to LEO, the top management team at UCB viewed BM change in terms of a monolithic process, or as an organization-wide phenomenon. For that reason, they recognized the importance of incorporating the BMI into the overall performance measurement system. Even though UCB's organizational units were also measured based on product-centric performance indicators, the autonomy enjoyed by the "patient solution teams" allowed them to effectively balance concurrent and dissimilar tasks.

One interesting finding here is that all three companies seemed to add new measures to existing ones, rather than removing or replacing the existing ones. As argued by Gunasekaran, Patel, and McGaughey (2004: 335), many firms "fail to realise that performance assessment can be better addressed using a trivial few-they are not really trivial, but instead those few areas are most critical to success." Neves, Carole, James, Wolf, and Benton (1986: 141) conclude that "managers lack time or simply find it too difficult to try to identify good signals from the mass of numbers." Thus, the proliferation of performance measures may have slowed down the BM change process (somewhat) in all three cases. Why then, one might ask, are top managers reluctant to remove or replace existing performance measures? Besides the obvious reason that the vast majority of revenues are still generated from drug sales, I speculate that performance measures are particularly sensitive to organizational resistance. While changes in the organizational structure do not directly force organizational units or individuals to change their behavior or develop new skills, appropriate performance measures are more indicative of how of much effort they have exerted. Moreover, top managers' compensation packages are usually tied to short-term performance variables, such as profitability, market share, productivity, patents and firm growth. In other words, managers are more inclined to preserve performance measures that are favorable for them but not necessarily for the long-term outcome.

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Complementarities. Milgrom and Roberts (1990) broadly define complementarities as existing among organizational elements if the benefits from doing organizational activities jointly are higher than the sum of the benefits gained from doing the activities separately. Thus, as argued by Stieglitz and Foss (2015: 110), "if the changes involve design decision relating to fixing the levels of a set of variables (say, x and y), complementarity is obtained when choosing a higher level of x raises the returns of choosing a higher level of y, and vice versa." On the one hand, due to the synergistic feature of complementarities, they might enable managers to realize additional value creation from their BMI efforts. On the other hand, complementarities are by no means readily apparent to the decision maker; instead, they are usually revealed through deliberate search processes (Levinthal, 1997; Gavetti and Levinthal, 2000; Stieglitz and Hein, 2007). However, such a search may reveal that some organizational elements are inconsistent with the complementarity logic and therefore create misfits (Siggelkow, 2002). The problem is that

different change initiatives are often crafted by different groups of employees and managers. Compensation initiatives may stem from human resource department, re-engineering from line management, and quality initiatives from a separate quality function. The separation of these decisions increases the probability that non-complementary design choices will be selected (Zenger, 2002: 91-92).

The findings from the cases in this study show that the complementarity logic (or lack thereof) plays a critical role in redesigning the organization for BMI. This logic is perhaps best illustrated by the case of UCB. UCB's process of BMI from 2000 to 2015 exhibited several stages in which complementarity dynamics arose. The acquisition of Schwarz Pharma, for example, enabled UCB to address unmet patient needs within the CNS segment, while significantly improving the BM of neurologists by supplying them with a wider set of treatment options. This might in in turn influence sales force productivity, as additional products can be marketed to the individual neurologists. In addition, with Schwarz Pharma, UCB gained access to new markets in Eastern Europe and China, where Schwarz Pharma was already operating very productively. This meant that UCB would be able to market their other products without first setting up subsidiaries. The change in the rights structure of UCB was such that decision rights changed in a way that was complementary to the change in strategy; specifically, delegating extensive decision rights to the

"patient solution teams" (and later "patient value units") enabled UCB to get closer to the customers, where decisions can be made based upon the latest detailed information. The delegation of decision rights was accompanied by variable remuneration, which increased the power of the pay incentive. The UCB Plaza was complementary to rights delegation in terms of sourcing and building knowledge because it helped foster the knowledge exchange that gave rise to new ideas for patient solutions. Top management's strong emphasis on redesigning the entire organization around the "patient value unit" structure and specific patient missions created unity and homogeneity that in turn mitigated some of the coordination issues associated with delegation. The complementary aspects of these organizational elements and activities also explain the speed and decisiveness with which top management orchestrated the BM transformation.

Conversely, LEO's process of BMI revealed a number of "anti-complementarities" or misfits between organizational elements. Most notably, several strategic changes were introduced between 2009 and 2015 to support patient centricity. However, these changes were not followed by corresponding changes in the overall organizational design. For example, except for the new BMI unit, all the existing units were still guided by product-centric incentives and performance requirements, which were not complementary to LEO's new strategic orientation. Moreover, even though the new unit was given extensive design rights, the new regional structure conferred even more powerful decision authority to the product-oriented regional heads. Consequently, as noted by Brynjolfsson and Milgrom (2013: 4), "when there is a large number of complementarities among practices within an existing system, but [there are] conflicts between practices from the old system and practices from the new system, then it is likely that the transition will be difficult," particularly when goals are not aligned and decision-making is decentralized. Thus, due to the "anticomplementary" nature of changing only one organizational element or a small subset of elements, overall implementation efforts are likely to be less successful. LEO's top management should have instead changed all of the elements in the system simultaneously or not introduced new elements in a piecemeal fashion. This is because, consistent with the literature on complementarities, significant changes to a core organizational element will set in motion complementary pressures to either change other elements or to abandon the original change (Zenger, 2002). As a result, LEO decided to somewhat abandon its original strategy by spinning off the "anti-complementary" activities into a new, independent unit (LEO Innovation Lab). The reason that LEO did not manage to "get the

complementarities right" is partly due to top management's misperception of the "interaction effects among choices that interact with each other in different ways" (Siggelkow, 2002: 900). Moreover, LEO also had to deal with significant organizational resistance, while having scarce resources and capabilities. In other words, they may have lacked the needed capacity to do everything at once, instead opting for a seemingly less risky piecemeal approach.

Given that Novo Nordisk adopted an incremental approach to BMI, they were not confronted with the same level of internal inconsistencies as LEO and UCB. In other words, Novo Nordisk's organization already constituted a complementary system of organizational elements. Thus, decisions with regard to organizational design were made to reinforce existing complementarities across the organization without violating the internal fit among existing choices. For example, the new Global Stakeholder Engagement unit allowed Novo Nordisk to extend its capabilities beyond its original scope. More specifically, the unit enabled the company to enter the bottom-of-thepyramid markets, which synergized well with the company's growing insulin portfolio. Furthermore, the training and education of HCPs could potentially lead to increased prescribing rates and brand loyalty for Novo Nordisk products. This was also supported by new performance measures that ensured alignment with existing organizational units. These changes were implemented with relative ease because they were made to fit the existing complementary logic.

At the same time, however, top management's emphasis on such a tight fit made Novo Nordisk more vulnerable to environmental change. As mentioned earlier, the FDA's rejection of Tresiba® was surprising to many in the company. It is likely that the tight coupling between activities filtered out important external information that would have been fit destroying. Nevertheless, to cope with the increasing pressures from payers and regulators, top management shifted their focus toward the marketing organization by, for example, making them part of the top management team. In hindsight, I speculate whether this action was sufficient, because tight coupling usually requires a firm to change many organizational elements simultaneously (Nadler, Shaw, and Walton, 1995). Yet, as exemplified in the case of LEO, doing so is an inherently difficult task.

Complementarities seemed to play a significant role in all three companies' BMI implementation process. Interestingly, while both LEO and UCB made similar changes to their BMs in terms of increasing the service content, the implementation process varied considerably due

to the perception (or misperception) of complementarities. This shows that even if complementarities are obtained among BM elements, underestimating the interaction effects among the underlying organizational elements can lead to poor implementation or inadequacies in decision-making.

Stage 3: Outcomes

Realized BMI

All three companies made changes to their BMs and organizational design; however, UCB went much further than the other companies in this regard. UCB underwent a dramatic transformation, in which the underlying logic of the change was a shift in emphasis from products to services, while opening up to new and unusual external partners to make firm boundaries more permeable. However, the most remarkable aspect of this transformation relates to the scope and speed with which UCB managed to redesign the formal organization to accommodate the new BM.

The changes at Novo Nordisk seem less dramatic, as the objective was to refine and reinforce existing BM activities rather than radically transform them. Although customer centricity was a central component of Novo Nordisk's BM, this focus did not materialize into new and radical service offerings, as in the cases of UCB and LEO. Instead, top management was convinced that customer centricity could be better achieved by improving the quality and availability of drugs. Thus, in contrast to many other pharmaceutical companies, Novo Nordisk has managed to mitigate external pressures to an extent that its traditional BM has remained viable. Part of the explanation for this may lie in the fact that Novo Nordisk operates within a very narrow therapeutic range, and is therefore able to devote more resources and attention, rather than spreading them thin across several therapy areas. As a result, it is likely that Novo Nordisk's concerted efforts paid off because more refined and reliable structures and processes were in place—which allowed the firm to leverage its existing BM activities more efficiently and effectively than other pharmaceutical firms.

In sum, UCB and Novo Nordisk resided at opposite ends of the BMI continuum. Between these two extremes, LEO adopted an "in-between" configuration, with the objective of shifting toward more radical BM activities while introducing minimum distortion to the existing ones. This approach seems appealing in its attempt to reconcile the benefits of both extremes, and is therefore

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easy to sell to top management. However, as illustrated in the LEO case, it is possibly the most challenging form of BMI to implement because decision makers will face difficulties in differentiating the organizational design to accommodate both stable and dynamic areas of BM change. As a consequence, it becomes increasingly difficult to "get the complementarities right."

The Multiple Roles of Organizational Design

In the next subsections I analyze the different roles played by the firm's organizational design in the process of BMI (see Figure 9.2). As shown in the previous section, all three companies went through different yet similar stages of organizational redesign to support the BMI process. In particular, I attempt to specify and discuss the possible causal linkages between the firms' organizational designs and BM changes.

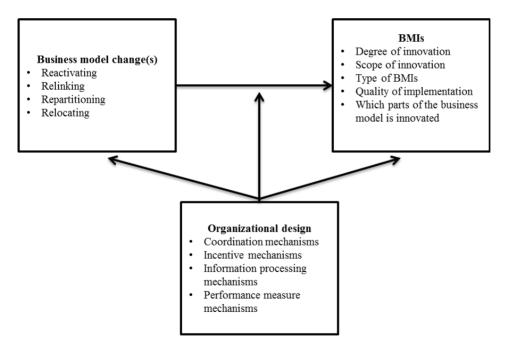


Figure 9.2 Proposed research model

Organizational Design as a Driver of BMI

The evidence from the cases seems to suggest that the choice of organizational design is an important driver of the scope and degree of BMI. With regard to scope, centralized decision making is likely to trigger system-wide BM changes with architectural characteristics. In particular, centralized decision makers are uniquely positioned to (1) integrate diverse bodies of knowledge, (2) assess complementarities, or the lack thereof, and (3) make simultaneous changes to the system. Therefore, firms that initially rely on centralized coordination are more likely to engage in architectural BM change. In the case of UCB, several BM and organizational elements were changed in a coherent fashion (e.g., the acquisitions of Celltech and Schwarz Pharma, and SHAPE) each time top management altered the strategic direction of the company. The magnitude, speed and coherence with which UCB transformed its BM would not have been possible without centralized direction. On the other hand, firms that initially rely on decentralized decision making are more likely to engage in modular BM change. Specifically, although decentralization allows use of what Havek (1945: 519) called "knowledge of particular circumstances of time and place," it impedes coordination, resource redistribution, communication and accountability. For that reason, the nature of BM changes are more likely to be isolated and confined to specific areas of the organization, rather than contributing to a coherent and internally consistent whole. For example, the majority of LEO's BM changes were largely driven by the new BMI unit (GPE), while other parts of the organization remained unchanged. However, as mentioned in the previous section, the existing organization was somewhat affected by GPE and vice versa. This may be attributed to the way top management perceives (or misperceives) interaction effects among new and old elements. In the case of LEO, top management misperceived the interaction effects, which led them to implement BM changes in a modular fashion despite their architectural properties. Thus, whether firms engage in modular or architectural BM change, they need to develop architectural knowledge so that the appropriate decisions can be taken to support the chosen approach.

Meanwhile, organizational design choices are also likely to influence the degree of BMI undertaken. UCB introduced performance and reward structures that encouraged risk-taking and innovation, while Novo Nordisk relied more heavily on "hard" performance criteria such as sales and productivity. Not surprisingly, this led Novo Nordisk to institute short-term and incremental BM changes, while UCB implemented radical changes by exploring fundamentally different

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opportunities. Similarly, the level of delegation can also influence the degree of BMI. For example, LEO's new BMI unit (GPE) had extensive decision rights, which enabled them to cooperate more closely with the end customers. Not only did this allow LEO to better sense the need for changes in the BM, but it also provided access to potential *lead users* who could be a crucial source of new radical ideas with commercial benefits (e.g., Matthing, Kristensson, Gustafsson, and Parasuraman, 2006; Luthje, Herstatt, and Von Hippel, 2005). As noted by Von Hippel (1986: 791), "lead users [are those] whose present strong needs will become general in a market place months or years in the future. Since lead users are familiar with conditions which lie in the future for most others, they can serve as a need-forecasting laboratory for marketing research."

BMI Challenges resulting from Organizational Design

While organizational design may be an important driver of BMI, it may also significantly limit or hinder such efforts. Among other things, the organizational design determines the allocation of resources and decision rights, the types of people recruited, and the kinds of behaviors that are rewarded. Thus, existing organizational members have a strong incentive to maintain the status quo, since changes may render some capabilities less valuable than they were previously and, at the same time, shift the power structure within the organization. As illustrated in the case of LEO, the existing organization design greatly slowed down the progress on BMI and reduced the impact of the new BMI unit (GPE). Relatedly, before UCB restructured the organization in 2008, the line management functions had considerable power in terms of resources and decision-making authority. As a consequence, project managers were forced to beg for resources and attention in order for their projects to progress. Moreover, firms that engage in either architectural or radical BMI, or both, are more likely to face challenges arising from the existing design. This is because such types of BMI not only influence many parts of the organization but may also require fundamentally different organizational design features.

The main advantage of BMI comes from its highly systemic features that promote the valueenhancing effect across a system of interdependent activities (i.e., complementarities). However, although BMI may appear systemic on paper, this is rarely the case in the real world, where diverse interests, cultures, structures, processes, and so on, compete for the power to shape the BM. In order to solve such coordination problems, managers may resort to principles of organizational design. Nevertheless, changing or not changing organizational design may present its own unique challenges with regard to complementarities. For example, the strong forces of inertia at Novo Nordisk caused by the existing set of complementary organizational design and BM elements led management to disregard external factors, such as the increasing price pressure from health care payers and regulators. UCB's complete BM transformation meant that the organization had to break up existing complementarities while establishing an entirely new system of complementary activities. Due to the inherent complexity of having several interacting elements and activities, it becomes challenging to discern ex ante the true performance implications of internal changes (Rivkin, 2000). For that reason, although many simultaneous changes were made each time UCB's BM changed, it had to undergo several major transformations before assuming its current form. This challenge was compounded by the radical nature of UCB's value proposition. In particular, radical changes are usually associated with a sharp departure from what is known about the BM, taking the designer into new and unexplored territory (Levinthal and March, 1993). As part of the "SHAPE Program," top management at UCB decided to reduce the total workforce by 2,000 positions.

Organizational Design Facilitators of BMI

BMI poses considerable managerial challenges, as indicated above and in the previous section. Due to the systemic nature of BMs, such challenges are usually ubiquitous—they arise between headquarters and subsidiaries, and within and across units and departments. Moreover, different types of BMI are associated with different challenges and thus require different organizational designs to achieve success. To deal with these challenges, each case company developed its own set of organizational design facilitators to enhance the effect of the drivers discussed earlier. In the case of Novo Nordisk, while the hard and quantifiable performance measures led the organization to focus on short-term and incremental improvements, it was the use of a functional structure with formal rules and procedures that facilitated the incremental addition of new products and the refinement of old marketing and pricing practices (e.g., DAWN and the differential pricing policy). Zollo and Winter (2002) argue that such design choices facilitate the development of proposals for improving existing routines. In contrast, UCB's use of autonomous cross-functional teams (patient solution teams), with an emphasis on digital collaborative learning (UCB Plaza), facilitated the

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development of completely new ways to work. For example, instead of organizing work around short-term and quantifiable performance measures, each patient solution team aimed to fulfill specific patient missions, such as improving the life of young people suffering from epilepsy. Although LEO was less successful than UCB and Novo Nordisk in regard to BMI implementation, they were the only company that introduced a dedicated BMI unit (GPE). Besides being instrumental in the development of an entirely new value proposition, GPE facilitated experimentation and learning that later let to the LEO Innovation Lab spin-off.

The Role of Time

An interesting finding with respect to BMI and the accompanying organizational design changes was the role of time or temporal shifts. For example, during the early stages of the BMI process at UCB, centralized decision making proved useful in triggering the organization-wide changes that were needed. These temporal shifts not only served to reconnect disparate organizational units and create a synchronized readiness for change, but also ensured faster integration between UCB and Celltech employees, along with reducing the time spent in a suboptimal configuration. Conversely, LEO adopted a decentralized decision structure during the implementation of the new BM. As a result, LEO was unable to foster the same level of synchronized readiness for BM change. Instead, the decentralized decision process served as barrier to rallying organizational members around the new strategic priorities. In the mid-to-late stages of UCB's BMI process, extensive decision-making power was delegated to the patient solution teams. Based on the evidence, time appears to be an important factor that can either positively or negatively affect the impact of organizational design choices during BMI. All three companies went through periods of stability and continuity, which allowed time for the change to better manifest itself and mesh together with the larger organization. This was particularly important because BMI complementarities are rarely apparent at the time of a new BM's introduction. Rather, identifying complementarities requires a deliberate search and experimentation, which take time to carry out.

The Locus of BMI

The question of where in the firm BMI is carried out is important because having the answer represents a first step toward understanding the sources of BMI and the mechanisms by which it is

brought forth (or implemented). While technological innovations are usually carried out by the internal R&D unit or New Product Development, the locus of BMI within the company is more ambiguous. The reason for this, I suggest, is that, technological innovations are largely comprised of discrete knowledge bundles that can be made explicit, since they consist of some tangible elements and can therefore be located more easily within a distinct unit. BMI, on the other hand, is more holistic and tacit in nature and is therefore more likely to be an organization-wide and boundary spanning activity. In the cases of Novo Nordisk and UCB, the location of BMI activities was distributed across several organizational units. In LEO's case, BMI was carried out by the newly established BMI unit (GPE), but after a few years it became apparent that the BMI must be either anchored within the larger organization or spun off. This is not say that a dedicated BMI unit is not important, but rather that it must be linked in a coherent manner to the existing organization. Of all three companies, UCB was the most successful at accommodating the tacit dimension of BMI. More specifically, designing the entire organization around the team-based structure provided the colocation of expertise needed to deal with high levels of tacit process knowledge.

Although BMI appeared to be an organization-wide process in the cases, it tended to cluster around downstream activities such as marketing, sales and corporate communication. For example, the majority of Novo Nordisk's BM improvements were driven by the newly established Global Stakeholder Engagement unit, while LEO's new BMI unit (GPE) resided within the Global Sales and Marketing department. The basic reason BMI's downstream locus is that it a customer-oriented process that includes all the activities needed to create additional customer value. Thus, BMI activities are more likely to be structured around units with more ready access to pertinent customer information. This was reflected in the type of strategic partnerships and value propositions that each firm engaged in.

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Concluding Discussion

Guided by the overarching research question—What is the role of organizational design in the unfold, but has looked at the different roles played by the organizational designer, as well as at the locus of the activity itself. To do so, a multiple-case study of three select players in the pharmaceutical industry over the course of fifteen years (from 2000 to 2015) was conducted. An overarching theme of the thesis is that BMs are complex systems of elements and activities that may relate to one another with different levels of specificity, interdependence, and complementarity. Any changes to such a system (i.e., BMI) are likely to cascade in ways that are difficult to predict ex ante, especially when human actions are involved. Consequently, BMI is a complex and uncertain process that shifts over time and requires the coordination and integration of new and old system elements into a coherent whole. This directs attention toward organizational design, which determines the "sum of the total ways in which a firm divides its labor into distinct tasks and then achieves coordination among them" (Mintzberg, 1979: 2). Unless the complexity of coordinating BMI efforts is properly managed and designed, the firm's ability to change its BM become attenuated and the likelihood of poor implementation increases. For these reasons, BMI is conceptualized as the reconfiguration of the designable parts of an organization. By affecting the ability to coordinate and synchronize activities, information, and tasks between organizational members and units, organizational design is likely to have an impact on the firm's ability to dynamically adjust to, and take advantage of, BM opportunities that are central to firm survival and growth in the presence of environmental change.

This thesis contributes to the recent debate in the literature regarding the nature of BMI and its causal mechanisms (with a focus on organizational design), as well as to research on organizational complementarities. In this regard, I developed a new framework that encompasses the processes through which BMI comes about and have shed light on the multiple roles of organizational design. Moreover, the thesis also supplies much needed detail on how organizational complementarities are created or lost in the process of finding the right fit.

Theoretical Contributions

This thesis contributes to the literature by (1) conceptualizing BMI as an organizational redesign process; (2) explicating the possible causal linkages between the firm's organizational design and BM change; and (3) advancing our understanding of organizational complementarities by providing ample detail on how the search for value-enhancing effects can either promote or hinder BMI efforts.

Conceptualizing BMI. The conceptualization of BMI through an organizational design lens shows that design choices related to structure, information processing, performance measures, and tasks and responsibilities are an integral part of conducting BM change. Such design elements therefore need to be recognized and incorporated into the analysis of BMI. Without concurrent or subsequent change(s) made to the underlying organizational design, it becomes increasingly difficult to effectuate the proposed BM change(s). This is because the organizational design represents a formal means of implementation, since managers can operationalize BMI by altering the allocation of resources and decision-making competencies. In this way, BMI is transformed into something that can be acted upon. While the extant research has contributed immensely to a general understanding of what BMI is (e.g., Santos et al., 2009; Teece, 2010; Zott and Amit, 2012), why firms engage in it (e.g., De Reuver, Bouwman, and MacInnes, 2009; Lee et al., 2012; Miller et al., 2014; Sabatier, Craig-Kennard, and Mangematin, 2012; Wirtz et al., 2010), and what its characteristics are (e.g., Velamuri et al., 2015; Frankenberger et al., 2013; Dunford et al., 2010; McGrath, 2010; Smith et al., 2010; Sosna et al., 2010) and its performance implications (e.g., Amit and Zott, 2007; Bock et al., 2012; Giesen et al., 2007), relatively little attention has been devoted to the organizational design of BMI. One notable exception is Foss and Saebi's (2015) Business Model Innovation: The Organizational Dimension. The book encompasses different contributions from leading scholars within the field that specifically deal with the organizational dimension of BMI, including organizational design considerations. This thesis adds to the debate by proposing a

framework that sheds new light on the BMI process and organizational design choices needed to coordinate different types of BMI efforts. In particular, the framework points toward the importance and challenges of managing fit between BM elements (new and old ones), with regard to value creation, value appropriation, value chain organization, the value network, and the array of organizational design choices available to managers. For example, at UCB, the BMI was architectural and led to specific design rules for subsequent BM changes in order to form a coherent system, while in the case of LEO, the BMI was modular and changes were partitioned rather than combined into an overarching system. UCB relied heavily on centralized decision making in order integrate the various functional activities and obtain the necessary complementarities to drive the value-enhancing effects, whereas LEO placed a high value on decentralized decision making in order to confine BM changes to specific areas of the organization so as to avoid interfering with the day-to-day operations.

More generally, it was evident that all three companies made organizational design changes to support BMI regardless of the type, scope and degree of BM changes. For example, even though Novo Nordisk adopted the least radical form of BMI, the company still introduced new performance measures, a new unit, and changed the roles and responsibilities of the top management team. Hence, by studying the transition from an "old" BM to a new model in three related but different companies, the findings of this thesis may contribute to research on organizational design in complex systems (Fleming, 2001; Levinthal, 1997; Nadler and Tushman, 1997; Simon, 1962). Most notably, the thesis argues that the process of BMI may challenge the ability of traditional organizational designs to facilitate and implement BM change. BMI is more systemic than more conventional types of innovation (e.g., product and process innovation), and therefore requires fundamentally different coordination mechanisms to accommodate for the added complexity involved in managing such innovations. More specifically, BMI is not just about what firms do (e.g., the bundle of products and services they offer to satisfy specific market segments), but also about how they do it (e.g., how they link factor and product markets to produce and deliver their bundle at a profit) (cf. Santos et al., 2009). As such, BMI requires a complex set of interactions involving multiple organizational units and levels, and often spanning firm boundaries. Due to these complex interactions, competitors may have a hard time identifying and replicating them within their own organizational context, which in turn helps differentiate the innovating firm's offering and ultimately leads to a competitive advantage. As such, I argue that BMI may serve as valuable empirical research context in which to investigate larger organizational questions relating to organizational change, design, integration, and survival. In the case of UCB, for example, the change brought through BMI forced the company to undertake multiple rounds of organizational restructuring in order to accommodate the new BM.

Extending the causal relation between BMI and organizational design. The findings of this thesis contribute to our understanding of the causal web in which BMI is embedded. Given the nascent stage of BMI research, the causal mechanisms are still poorly understood and largely speculative. Nevertheless, recent studies have pointed to the roles of dynamic capabilities (Leih et al., 2015), the corporate center (Santos et al., 2015; Casadesus-Masanell, Ricart, and Tarjizán, 2015), the top management team (Stieglitz and Foss, 2015), and organizational design (Colombo, Mohammadi, and Rossi-Lamastra, 2015; Kindström and Kowalkowski, 2015) in explaining BMI. Although those contributions provide valuable insight into the underlying causal structure of BMI, they remain largely anecdotal and conceptual rather than empirical. The findings presented in this thesis thus contribute to the research by theoretically and empirically showing how organizational design can act as either a driver or barrier, or as an important facilitator of BMI, and how these roles may shift over time. For example, the formation of new organizational units and the removal of old ones seemed to drive a significant part of the BM changes in all three companies. To illustrate, Novo Nordisk's new Global Stakeholder Engagement unit used its influencing power to establish important partnerships that extended Novo Nordisk's capabilities well beyond its original scope, thereby paying the way for the DAWN program and the differential pricing policy. With regard to challenges, LEO's existing organizational design proved to be a significant hindrance to the progress of BMI, and ultimately led to the spin-off of the more radical BM activities. At the same time, organizational design was shown to be a crucial facilitator of BMI implementation. This was perhaps best exemplified by the case of UCB, in which the entire organization was frequently redesigned to fit the planned or emergent BM changes. Specifically, the use of autonomous crossfunctional teams and an emphasis on digital collaborative learning facilitated the development of completely new ways to work (i.e., relinking). For example, instead of structuring tasks around short-term and hard performance measures, each team developed its own distinct patient mission. This thesis argues for the importance of organizational design in the BMI process. Since BMI

implies changes to the formal organization, firms need to develop architectural knowledge on how on such changes affect the interdependencies and complementarities in the organizational system in order to make appropriate design decisions. Thus, in addition to developing capabilities related to experimentation, agility, and leadership (Achtenhagen et al., 2013; Doz and Kosonen, 2010; Demil and Lecqoc, 2010; Gambardella and McGahan, 2010) in order to change the BM, the findings suggest that firms also need to accumulate knowledge about the overall organizational design in order to avoid misfits between organizational design and BM elements.

Another important finding related to BMI and organizational design was the role of time or temporal shifts. Despite the dynamic nature of BMI, previous research seems to have disregarded the temporal dimension of BMI, instead focusing on other characteristics, such as type, scope and degree of change (e.g., Santos et al., 2009; Abdelkafi et al., 2013; Demil and Lecocq, 2010; Stieglitz and Foss, 2015). However, the findings presented here suggest that time may be an important factor in explaining the interaction between organizational design choices and BM changes during different periods. For example, highly centralized decision-making structures that can reconnect diverse organizational units and foster a synchronized readiness for change are likely to be important in the early stages of BMI. But as time goes by and the hierarchy becomes increasingly overloaded with information, decentralization may be needed to improve the organization's information processing capabilities. In addition, to unlock the value-enhancing effects of BMI, top managers must allow for periods of stability and continuity so that the preceding change can better manifest itself and mesh together within the wider organization. I particularly emphasize that BMI complementarities are seldom apparent at the time of the creation of a new BM. Instead, complementarities are achieved through deliberate search and experimentation, which takes time to carry out. For these reasons, it is difficult to map out the causal web of BMI, as some mechanisms may prove effective at one point in time during BMI, but less so at another.

Where in the firm does BMI activity mainly takes place? Another interesting finding of this thesis relates to the locus of BMI. The extant research is not clear about where BMI occurs within the organization. Specifically, there is little clarity about whether it is located at the organizational level (or BM level), as most studies suggest (e.g.. George and Bock, 2011; Zott and Amit, 2008), or at lower levels, particularly at the managerial level, as some recent work has indicated (e.g., Chesbrough, 2010; Stieglitz and Foss, 2015). This thesis similarly shows that the locus of BMI is at

the organizational and managerial levels. The evidence also indicates that BMI is located at the strategic business unit level, particularly within the marketing organization. For example, many of Novo Nordisk's BM refinements were driven by the newly established Global Stakeholder Engagement unit, while LEO's new BMI unit (GPE) resided within the Global Sales and Marketing department. Meanwhile, UCB structured their activities around the patient solution teams. The reasons for this, I suggest, is that BMI is a customer-oriented process that encompasses all the activities required to create additional customer value. Thus, BMI activities are more likely to be situated within units having closer access to the end customers.

Improving the understanding of complementarities. This research contributes to the ongoing research on organizational complementarities (e.g., Milgrom and Roberts, 1995; Levinthal, 1997; Rivkin and Siggelkow, 2003). As noted by Ennen and Richter (2010: 12) in their extensive review of empirical papers in this field, most extant studies "take a cross-sectional perspective on complementarities, using static measures of performance (e.g., productivity) or performance changes over relatively short periods of time." As a consequence, there is little evidence on the role of complementarities in the cases of organizational change and transformation. Such a lack has also inhibited scholars from providing sufficient detail on how organization-specific factors (e.g., industry, strategy and BM) influence the role of complementarities. However, a notable exception is Siggelkow's (2001) qualitative study of Liz Claiborne, which offers great detail on how factors such as as product design, marketing, production, distribution, etc., relate to one another, without neglecting the overall organizational configuration of the firm at two different periods in time. The findings presented in this thesis follow this example by providing ample detail on how organizational complementarities emerge, disappear, and re-emerge in the process of innovating incumbent BMs. For example, the case of UCB illustrates several of such complementarity dynamics. With the acquisition of Schwarz Pharma, UCB was able address new patient needs within the CNS segment, while creating more value for the neurologists (who are an important part of the firm's value network) by supplying them with a more diverse range of treatments. In effect, such added value may increase sales force productivity, since more products can be marketed to the individual neurologists. The Schwarz Pharma acquisition also allowed UCB to access new markets in Eastern Europe and China that hitherto had been overlooked. Through this move, UCB would be able market its existing product portfolio without first setting up fully fledged sales and marketing

subsidiaries. Prior to 2008, although UCB worked cross-functionally, the line management functions still had significant power in terms of resource allocations and decision-making authority. As a consequence, projects were often slowed or halted, since project managers had constantly beg for resources and attention in order for their projects to move projects. With the formation of the "patient solution teams," top management made a change in the rights structure of the organization such that decision-making authority was changed in a way that was complementary to the change in strategy; particularly by delegating extensive decision rights to the "patient solution teams" (and later, the "patient value units"), permitting UCB to get closer to the end customers. The added responsibility and independence was complemented by making incentives more high powered through variable remuneration. The company's new internal communication platform (UCB Plaza) was complementary to rights delegation with regard to sourcing and developing knowledge because it supported the knowledge exchange that gave rise to new ideas for patient solutions. Perhaps most importantly, top management's emphasis on structuring the entire organization around the team, as well as around specific customer missions, led to added unity and homogeneity, which in turn alleviated some of the coordination issues associated with autonomous organizational structures. Top management's understanding of the complementary aspects of BMI was further exemplified by the speed and decisiveness with which they orchestrated the company's BM transformation.

Managerial Implications

Together, these findings have important managerial implications for firms that decide to engage in BMI. The argument outlined in this thesis suggests that organizational design plays multiple roles in the process of BMI, and can therefore affect the firm's ability to change its BM in a variety of ways. For example, in some situations, a centralized decision-making structure with formal rules and procedures and functional specialization may be needed, while in others, flatter and more autonomous structures accompanied by specific customer missions may be more appropriate. Thus, managers need to base their choice of BM change on a number of contingencies, such as the dimensions and features of the existing organizational design, BM elements, strategy and environmental conditions. Based on these contingencies, I specify broad roles (e.g., drivers, barriers and facilitators) of organizational design that arise during the coordination and integration of different types of BMI, as it relates to mobilizing structures, processes, organizational resources and

capabilities when a BM change takes place. Specifically, the insights can help managers determine the optimal organizational design configuration for a given BMI, and how different organizational design variables may act during different stages of the BMI process. Armed with such insights, managers will have a greater chance of succeeding with their BMI implementation efforts. Moreover, in contrast to the extant literature (e.g., Doz and Kosonen, 2010; Demil and Lecqoc, 2010; Gambardella and McGahan, 2010), the findings imply that firms may not need to directly develop BMI-specific capabilities. Rather, firms may indirectly influence and build such capabilities by introducing specific organizational design mechanisms to elicit certain behaviors among employees (cf. Foss et al., 2011). For example, UCB and LEO designed their organizational boundaries.

In addition to pinpointing the role of organizational design during BMI (see Figure 9.2), I believe that the insights can provide a helpful perspective on organizational complementarities. While managers usually point to the importance of change agents in bringing about organizational change, this thesis argues for the critical role of complementarities. Without sufficient knowledge about how to interpret complementarities, decision makers might be unable to realize the value-enhancing effects associated with BMI. For instance, the choice of a new BM is usually tied to many other choices than merely ensuring alignment between the various BM elements. In the case of LEO, a number of BM changes were proposed to support a more customer-oriented approach. However, even though changes were made to the value proposition, value network, and value chain, they were not accompanied by corresponding changes to the overall organizational design. As a consequence, the firm experienced greater misfits and tensions between the new BM elements and the established organization. Thus, despite the efforts made by several change agents, LEO had to abandon its original strategy by spinning off the "anti-complementary" BM activities into a new independent business unit (LEO Innovation Lab). This could potentially have been avoided if decision makers understood more about the complexities of organizational complementarities.

More generally, it is hoped that the framework (Figure 9.1) presented herein can help managers better understand and manage the BMI process. Notably, the framework outlines three critical stages of the BMI process: (1) motivation; (2) implementation; and (3) outcome. In contrast to other BMI frameworks (e.g., Cavalcante et al., 2011; Frankenberger et al., 2013), this one

incorporates a complementarity logic by illustrating potential areas of fit or misfit. Such a logic can help managers anticipate some of the complex interrelationships surrounding BM change, and thus make choices that better reflect the holistic nature of BMI. Further, to my knowledge, this is the first framework to shed light on the organizational redesign process of BMI. As such, it may help managers think of organizational design in a *proactive* way, rather than seeing it more *reactively* as either a barrier to or necessary facilitator of BMI (cf. Foss et al., 2012). The framework also points to important areas in the BM from which BMI may begin. For instance, the findings from the cases show that changes to the value proposition (reactivating) and the architecture (relinking) of the BM are the most common types of BMI adopted, while repartitioning and relocating are used to a lesser extent in the BMI process. The reason for this, I suggest, is that the former types of BMI may have greater overall implications for value creation and appropriation vis-à-vis offshoring/onshoring or outsourcing/insourcing selected BM activities. Thus, the framework offers practical guidance for managers seeking to embark on BMI by providing a useful starting point from which an incumbent BM can be innovated. Similarly, the thesis improves our understanding of the role of time and where BMI is located within the larger organization. Equipped with such insights, managers and decision makers are in better position to knowledgably engage in BMI, and use time to their advantage to modify (or remove) BM elements in a synchronized manner.

Limitations and Future Research

The goal of this thesis was to outline a new framework that could shed light on the processes underlying BMI, including, most notably, the role of organizational design, using an in-depth multiple-case analysis for illustration. Since this thesis relied on qualitative research methods to investigate the role of organizational design in the process of BMI, it is not suitable for addressing the questions of size, extent, performance, effectiveness, efficiency, or cost, as they relate to BMI, or for establishing whether a specific cause results in a pre-specified effect. Future studies could therefore use quantitative research designs to study the effects of various BM and organizational design configurations on performance. Relatedly, it is a limitation of this thesis that the performance implications of BMI were not studied. Ostensibly, BMI is undertaken for its adaptive or disruptive value, thus implying that increased firm survival rates and performance can be expected from such innovation. For example, while Zott and Amit (2007) found that novelty-

centered BMs coupled with specific product market strategies can improve firm performance, Brea-Solís, Casadesus-Masanell, and Grifell-Tatjé (2015) used micro-founded methods to quantify BM performance during three distinct stages in the evolution of Wal-Mart. Apart from these studies, however, the beneficial outcomes of BMI remain underdeveloped in the literature. In a highly conceptual manner, BMI may be understood as finding novel ways to create and capture value in concert with a plethora of different stakeholders. This can include new ways of bundling products and services together to generate more value (e.g., Kastalli and Van Looy, 2013), new ways of reorganizing activities to reduce transaction costs (e.g., Amit and Zott, 2012), new ways of collaborating and coordinating across firm boundaries (e.g., Tsvetkova, Gustafsson and Wikström, 2014), new ways of organizing (e.g., Foss and Saebi, 2015), new ways of retaining business stakeholders such as customers (e.g., Amit and Zott, 2012), new ways of managing open innovation (e.g., Saebi and Foss, 2015), and so on. Arguably, a number of beneficial effects may be derived from such forms of BMI, including positive complementarities, increased innovativeness, improved cost-effectiveness and reduced coordination costs. Even when BMI fails to generate and appropriate adequate value, it may still be 'symbolic[ally] efficient'; "An [organizational design] that makes an organization appear innovative or ethical, for instance, may help it either to raise capital from other organizations or to attract customers" (Abrahamson, 1991: 608). Beyond this highly conceptual level, our knowledge about the performance consequences of BMI remains rudimentary. Thus, future research could endeavor to develop a systematic mapping of the various performance outcomes that are likely to stem from different types of BMI. In addition, future work could investigate the relative contribution to competitive advantage of BMI versus other types of innovation.

The findings of this thesis generally point to the role of organizational design in BM choices. However, I have also uncovered some implicit evidence that seems to stress the importance of managerial intentionality and power (Hutzschenreuter, Pedersen, and Volberda, 2007; Pfeffer, 1992). For example, LEO's BMI process was partly slowed by the new BMI unit's (GPE's) inability to gain the required commitment from the existing organization. As nicely put by Pfeffer (1992: 38), "when interdependence exists, our ability to get things done requires us to develop power and the capacity to influence those on whom we depend." Furthermore, over the years, the marketing organization appeared to play an increasingly significant role in all three companies.

Although it seems logical to assume that BMI would naturally gravitate toward marketing due to marketing's customer focus, the relationship is perhaps more nuanced than that. More specifically, while R&D was king in the past, the ability to gain patient outcome data, negotiate with payers to secure reasonable payments, and influence prescriber and patient behaviors are probably more important in the current health care context. As a consequence, the marketing organization is in an ideal position to accumulate power that could in turn influence BM choices. As such, the complexity and interdependence entailed in BMI might result in added uncertainty, opening up for political processes in decision making. Under such circumstances, organizational members may seek to exert influence by emphasizing decisions that serve their own interests while discounting the significance of others (Eisenhardt and Bourgeois, 1988). In addition, the characteristics of BMI may also influence the power positions within the organization. Specifically, BMI that is more radical and broad in scope is more likely to alter the internal power structure than BMI with the opposite characteristics (Pfeffer and Fong, 2005). Thus, it would be worthwhile for future studies to look into how intentionality and power evolve, influence, facilitate or even redirect the BMI process. For instance, is there evidence that decision makers intentionally reject some BM choices while accepting others? What challenges and opportunities does this pose for the organizational designer?

Although the thesis provides some evidence for why particular areas of the BM are more open to innovation than others, I believe an attention-based view would be useful in gaining a deeper understanding of why this is the case. As a consequence of the complex and systemic nature of BMIs, managers are subjected to a considerable number of choices regarding, for example, the type and extent of BMI; resource, capability and information requirements; integration between new and established BM elements; the scope of available alternatives; and so on. However, due to their limited capacity to process information, decision makers can only devote attention to a limited number of choices and issues (Simon, 1945; Ocasio, 1997). Future research should therefore investigate more specifically how key elements of attention-based theory contribute to the formulation and implementation of BMI. For example, it was clear that the radical and modular characteristics of LEO's BMI required more managerial attention than Novo Nordisk's incremental and architectural BMI. Meanwhile, UCB's radical and architectural BMI also demanded considerable managerial attention. Therefore, future studies should explore in greater depth how different types of BMI may affect managerial attention. Moreover, by taking an attention-based view of the post-BMI process, scholars would be able to distinguish between the stated intentions of engaging in BMI and what managers actually pay attention to in the BMI implementation process. Such insights could enable the organizational designer to set up structures and processes to ensure that attention is paid to the most appropriate and relevant BM choices and issues.

The main focus of the thesis was an investigation of the role of organizational design in the process of BMI, thus leaving out an important discussion on leadership. As noted by Stieglitz and Foss (2015: 104),

BMIs are far from homogenous. Some may involve relatively minor connected changes in, for example, the customer segments that are addressed and the revenue model in a business unit. Other BMIs may be massive corporate-wide processes that involve basically all employees and all processes and activities.

For example, at UCB, four massive restructurings accompanied their new BM, while Novo Nordisk for the most part made minor adjustments and continued what appeared to be a fine-tuning of their existing BM. Such differences are likely to pose fundamentally different leadership challenges, and therefore require different leadership competencies. Stieglitz and Foss (2015) have developed a useful typology that combines the key dimensions of BMI with the role of top management. However, it has not been tested empirically. Hence, future empirical studies are needed to determine the extent to which different leadership styles directly o indirectly influence specific forms of BMI. Furthermore, all three companies initiated the BMI process after appointing a new CEO. In other words, it seems that CEO succession may be a fundamental lever that triggers BM change—it would therefore constitute an interesting topic for future research on BMI.

Final Remarks

Throughout the thesis, I have argued that the relatively new and underdeveloped field of BMI can increase the importance of its holistic approach by seeking cross-fertilization with the more established and decades-old field of organizational design. Doing so would not only enrich our understanding of the BMI process and where it takes place, but would also give us a better sense of how organizational complementarities are obtained or dissolved. As such, there is much to learn from combining insights from both fields in new and previously underappreciated ways. This thesis has made the synergies between the two fields more apparent, so that the theory in both fields, particularly BMI, can be extended.

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