Exploring New Product Concept Emergence Under Uncertainty in Medical Diagnostics

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EXPLORING NEW PRODUCT CONCEPT EMERGENCE UNDER UNCERTAINTY IN MEDICAL DIAGNOSTICS

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ABSTRACT

This paper explores how new product concepts emerge and how development teams adapt, modify these concepts that emerge in the context of uncertainty. Specifically, it studies how cross-functional product development teams elaborate and define new product concepts under uncertainty that are based on fundamentally new technologies within a globally operating In-Vitro Diagnostics corporation. An inductive single-case study design with two embedded cases within an In-Vitro Diagnostics Corporation is employed to study this phenomenon. A wide range of primary and secondary data was collected. Data collection and analysis within and across the embedded cases were informed by grounded theory methods and techniques. Data analysis led to the emergence of scoping as a core variable to explain the emergence of new product concepts under uncertainty. It builds on contextual and temporaling sub-core variables, each having two dimensions, respectively: resource efficacy and context interpreting efficacy, and exploring and normalizing.

Keywords*: new product concept development; new technology; scoping; shifting; uncertainty; medical diagnostics industry*

1. INTRODUCTION

This paper aims to explore how new product concepts emerge under uncertainty and how development teams adapt new, emerging products concepts in radical, novel technology contexts. The early development phase of new product development is of particular interest to practitioners, regulators and researchers (Gassmann & Schweitzer, 2014; Kim & Wilemon, 2002; Reinertsen, 1999). It is during this phase when the key concepts and features of a new product are defined and the strategic directions for the following development activities are set. The newness respectively novelty of a product or technology arises from within, internal or outside, external. Internal novelty refers to the technology that is new to the organization and external novelty means that the technology is new to the market/industry (R. G. Cooper, 2006; O'Connor, 1998).

Research to date has investigated among other things the definition of product concepts (Bacon, Beckman, Mowery, & Wilson, 1994; Crawford & Di Benedetto, 2010; Krieg, 2004), focusing on single sub-process steps such as the Fuzzy Front-End (Gassmann & Schweitzer, 2014; Koen et al., 2001; Reinertsen, 1999), the process nature of new product development (R. G. Cooper, 1990; R. G. Cooper & Kleinschmidt, 1991; Högman & Johannesson, 2013) or concept shifting, a model considering the changes of new product concepts after its initial definition (Seidel, 2007).

Yet, little is known about how product concepts emerge and how their radical characteristics change within the initial steps at the front end of innovation in the context of uncertainty (Herstatt, Verworn, & Nagahira, 2004; Zhang & Doll, 2001). To this, the extant body of knowledge needs further insights on development teams that try to ensure project progressions (Seidel, 2007). Development teams frequently struggle to properly define product concepts particularly when they emerge in radical innovation contexts such as applying novel technologies (R. Cooper, Edgett, & Kleinschmidt, 2001). Moreover, compared to incremental product development, radical innovation can pose considerable challenges to development teams (Reid & De Brentani, 2004) even though new product development was researched intensively in past decades (Brown & Eisenhardt, 1995; Eppinger & Ulrich, 2015; Ernst, 2002; Krishnan & Ulrich, 2001).

To achieve the above aim, an inductive single-case study design with two embedded cases within a globally operating In-Vitro Diagnostics (IVD) corporation is employed. A wide range of primary and secondary data was collected. Data collection and analysis within and across the embedded cases were informed by grounded theory methods and techniques (Glaser, 1978, 2005; Glaser & Strauss, 2010). The analysis led to the emergence of scoping as a core variable that explains the emergence of new product concepts under uncertainty.

2. THEORETICAL AND EMPIRICAL BACKGROUND AND RELEVANCE

New product development has been subject to many research studies and a great number of successful practices have been identified (Eppinger & Ulrich, 2015; Krishnan & Ulrich, 2001). Most product development models have either focused on its process-nature (Cooper, 1988, 2006; Medina, Kremer, & Wysk, 2013), the role of project management approaches, the composition and interaction of cross-functional teams or the role of customers throughout this process (Moenaert, De Meyer, Souder, & Deschoolmeester, 1995; Van Kleef, van Trijp, & Luning, 2005).

The process-nature of new product development has also been investigated intensively (Cooper & Kleinschmidt, 1998; Crawford, M., & Di Benedetto, A., 2010). Specific attention was paid to the sub-process steps at the front-end of innovation as during this phase the key concepts including features of the new product are defined and the strategic directions for the following development activities are set (Eling & Herstatt, 2017; Koen et al., 2001).

In the context of front-end innovation, the extant research investigates the emergence of various characteristics of a product concept and its definition from different research streams. In marketing, research focuses on the business perspective of product concept features (Kotler, Keller, & Bliemel, 2007). In engineering, the focus is rather on the specification of product requirements as part of engineering tasks that shall be fulfilled by the future product (International Institute of Business Analysis, 2015) as well as on dedicated techniques for product concept generation such as process sequencing of divergent and convergent steps that support defining the scope of a new product concept (Gordon, 1961; Krieg, 2004). In recent years the common understanding of product definition and its stage-models have been extended by agile development approaches that quickly iterate, frequently collect user feedback and if necessary go back to earlier stages to review and adapt the product concept (Eppinger & Ulrich, 2015).

Amongst the great variety of existing studies on new product development, different typologies of products are used such as incremental or radical products (Eling & Herstatt, 2017; Garcia & Calantone, 2002; Gassmann & Schweitzer, 2014). Radical product innovation, as described in this present study, triggered by new technology, has been described in different ways. For example, radical innovation (Garcia & Calantone, 2002) or discontinuous innovation (Reid & De Brentani, 2004; Veryzer Jr, 1998) have been used interchangeably for settings where new product concepts were new from an internal as well as external perspectives (Holahan, Sullivan & Markham, 2014; O'Connor, 1998). Internal novelty may refer to the technology that is new to the organization or corporation and external novelty means that the technology is new to the market or industry. Due to these aspects, novel, radical product concepts may be more complex and less structured (Holahan, Sullivan & Markham, 2014; Veryzer Jr, 1998) due to the combination of technological as well as market uncertainty.

To the above, extant research advanced our understanding about how product development is coordinated in radical contexts that are characterized by high degree of uncertainty. For example, formal processes and control mechanisms that are needed to be adapted for radical contexts have been investigated, including the associated uncertainty reflected in the research on the fuzzy front end of new product development (Frishammar, Dahlskog, Krumlinde, & Yazgan, 2016; Zhang & Doll, 2001).

Linear development approach to new product development dominates extant research, trying to understand how a primary product concept that is fixed early on in the process is generated and how it shall be kept stable throughout new product development (Cooper, 2006; Brown & Eisenhardt, 1995). Another stream of research suggests that product concepts that are based on fundamentally new technologies and that emerge in the context of uncertainty may be less complete and more changeable than their incremental counterparts (Seidel, 2007). Seidel (2007) introduced the concept *shifting* to appreciate that during the implementation of new product concepts, key concept components may change over time to ensure implementation and go-to-market product readiness. However, Seidel's concept of shifting focuses on risk mitigation during product development rather than on product definition in the context of uncertainty. In our research we aim to expand understanding of shifting by exploring the emergence of new product concept in the context of uncertainty.

At the same time, such contrasting approaches to new product concept emergence and shifting under risk and uncertain decision making settings suggest further investigations of how product development teams actually elaborate and define product concepts on the one hand and on the other how these concepts change over time particularly with regards to the radical nature of the product. Our research will shed light on sources of uncertainty in the early innovation phase (Brown, Dixon, Eatock, Meenan, & Young, 2008; Pietzsch & Paté-Cornell, 2008) by focusing on how development teams define and adapt new product concepts during their emergence in radical contexts.

3. RESEARCH OBJECTIVES / PROBLEM

This paper explores how new product concepts emerge under uncertainty and how development teams adapt, modify these new, emerging products concepts ensuring further project progression. It builds on recent calls for more research to understand the emergence of new product concepts that are based on fundamentally new technologies

and that emerge in the context of uncertainty (R. G. Cooper, 2006; Herstatt et al., 2004; Högman & Johannesson, 2013). The paper also addresses the need to learn more about the role development teams play in defining such new, radical product concepts (Edmondson & Nembhard, 2009). Specifically, it studies how cross-functional product development teams comprising of disciplines such as biology, medicine, software, electronics and hardware elaborate and define new product concepts under uncertainty.

4. RESEARCH DESIGN

We employed a single-case study design that builds on two embedded cases (Yin, 2013) within a globally operating IVD Corporation. To ensure comparability between the cases with regards to novelty of product concept and technology and to control for the effect of internal and external factors on the selected cases, we adopted a sampling strategy based on the following comparable sampling criteria: corporate/governance structures, project phase, project size and scope, as well as early stage in which a new product concept is emerging.

The first embedded case - Case A - covers the emergence of a new product concept that builds on a novel detection technology for near patient testing. This segment of IVD is also called point of care diagnostics as specimen are tested close to the patient e.g. in an intensive care or emergency room setting. The second embedded case - Case B - is making the emergence of a new lab technology its main subject of exploration. The new product concept is building on a novel technology that shall be made available to the IVD sector. This technology allows for new and more accurate diagnostic testing as it combines lower detection limits with a higher test specificity.

We collected a broad range of primary and secondary data for the purpose of data triangulation as well as identifying additional research participants. Primary data was collected via semi-structured face-to-face interviews and supplemented by artefacts such as emails, meeting minutes, use case-diagrams and photographs, and general project documentation such as progress reports (Bryman & Bell, 2011; Creswell, 2013). Ten participants per case were purposively selected for the interviews. The interviews lasted on average sixty minutes, were recorded, and transcribed verbatim within the next three to four days (Brinkmann & Kvale, 2015). Following Brinkmann and Kvale (2015) the interview style can be characterised as an interview traveler which expresses that a conversation started by asking open questions, motivating the interviewee to tell her individual stories, using her own terminology, instead of directing the course of the conversations by direct or leading questions. This also highlights the descriptive nature of interviews where research participants were encouraged to precisely describe what their experiences were and how they acted in the context of emerging product concepts. In this process, we aimed to discover critical events and incidents that contributed to the early innovation phase of new product development under uncertainty in the context of a globally operating IVD corporation. A total number of twenty-two interviews, including follow-ups were conducted (Table 1). For confidentiality reason, the respondents' names as well as the company's name are disguised throughout the paper.

Data collection and data analysis within and across the two cases was informed by grounded theory methods and tools (Glaser, 1978, 2005; Glaser & Strauss, 2010). Initially texts and artefacts were coded substantively, meaning that the substantive codes were emerging from the data and were developed spontaneously rather than a priori in the form

of critical events, activities, participations, issues as well as contextual aspects. The substantive codes formed the basis for a second cycle of theoretical pattern coding, leading to the discovery of potential influencing factors for the emergence of new theory. Constant iteration between within- and cross-case data, substantive and theoretical codes, and theory led to the discovery of the core-variable ***scoping*** that contribute to the explanation of the emergence of new product concepts under uncertainty.

#	Interviewee code	Functional role	Follow-up (yes/no)	Case
1	S5	Project Lead	yes	Case A
2	S3	R&D Instruments		Case A
3	S6	Marketing – Product Manager		Case A
4	M1	R&D Applications		Vase B
5	M5	Business Development	yes	Vase B
6	S9	International Liaison Manager	yes	Case A
7	S2	R&D Technology		Case A
8	S10	Requirements Engineering		Case A
9	S7	International Marketing		Case A
10	M9	Requirements Engineering	yes	Vase B
11	M10	Business Liaison Manager	yes	Vase B
12	M8	International Marketing		Vase B
13	S8	Marketing / Regional Sales		Case A
14	M2	Instrumental Analytics		Vase B
15	M7	International Marketing		Vase B
16	S1	Development Lead	yes	Case A
17	M4	Project Manager	yes	Vase B
18	S4	Software Development		Case A
19	M3	Development Lead	yes	Vase B
20	M6	Project Lead		Vase B

Table 1: Overview of the interview process

5. FINDINGS

The core-variable scoping that emerged as the key theoretical construct refers to the process of defining the key characteristics of a new product concept. It consists of contextual and temporaling sub-variables, concepts that also emerged from the data. The former has two emerged dimensions: *resource efficacy* and *context interpreting efficacy* (Figure 1); the latter also has two dimensions grounded in data: *exploring* and *normalizing* (Figure 2).

Resource efficacy is about perceived availability of knowledge and capabilities and the team's ability to acquire resources. It means a team can use resources effectively if it believes that it has the right internal and sometimes even external knowledge and capabilities available or when a team lacks the needed knowledge and capabilities but it believes there is 'plenty out there available for grasp' and that it can at the same time acquire necessary knowledge and capabilities. These are necessary conditions. If just one of these is met or fulfilled it won't be possible to explore the full radical potential of the technology and eventually expand the product scope. Indicators that have an impact on the perceived availability of knowledge and capabilities are for example the perceived ability to extend established or even build up totally new knowledge and capabilities in a certain field. Apart from the perceived availability, knowledge and capabilities can only be used effectively if the team manages to acquire sufficient resources. This acquisition

of resources comprises monetary aspects such as ensuring sufficient funding but also non-monetary, informal aspects allowing the team to access resources e.g. immediately and/or on a temporary basis.

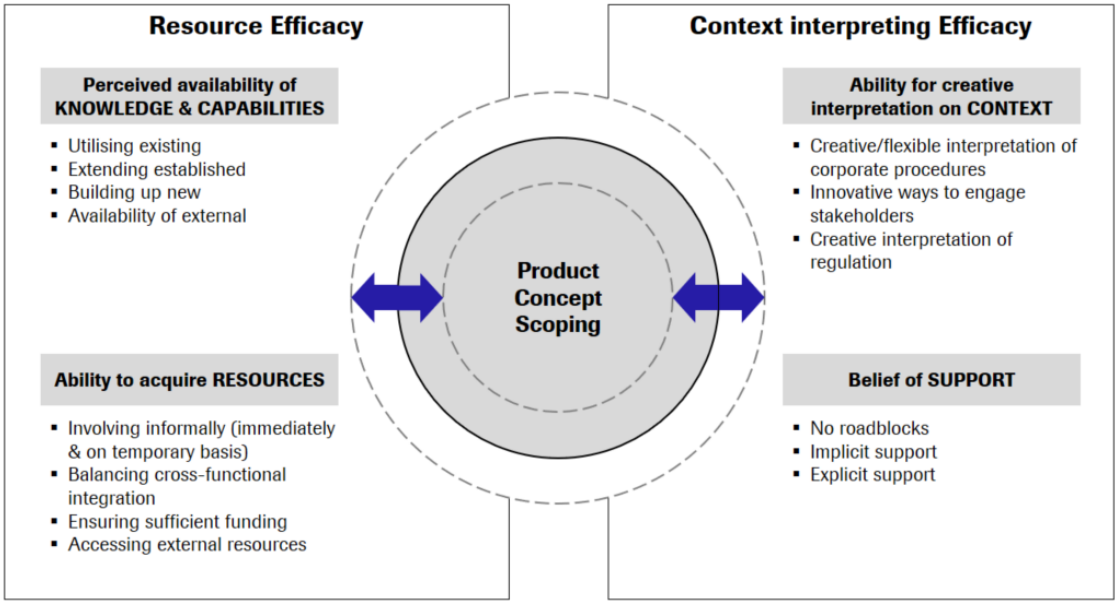

Figure 1: Contextual indicators of scoping

Context interpreting efficacy on the other hand is about the ability for a creative interpretation of the context as well the belief of support. Otherwise the expanding power of the creative interpretation piece will not come into force. For example, in the area of regulation, which marks an important element of the context, a creative interpretation of formal regulation allows to further exploit the radical potential of the product concept but it is just adequately followed-up if the team believes in a certain support of regulatory authorities. Such support may be expressed in manifold ways which range from explicit endorsement of a decision body to implicit support or the pure absence of hurdles or roadblocks.

The second set of indicators relates to a temporal change of the core-variable *scoping* when a product concept progresses throughout research and development; these indicators of temporal changes are: *exploring* and *normalizing*.

During the *exploring* (wide scoping) phase a new technology triggers by default a questioning of the status quo and its boundaries. That is, during this phase a radical potential of a new technology is exploited in several single steps such as technology assessments or technology enabling. This is feasible if the team manages to build up knowledge and capabilities as well as ensure sufficient resources. As a consequence of exploring, the product scope expands in areas such as new technological features but also business model aspects which may be new to the corporation.

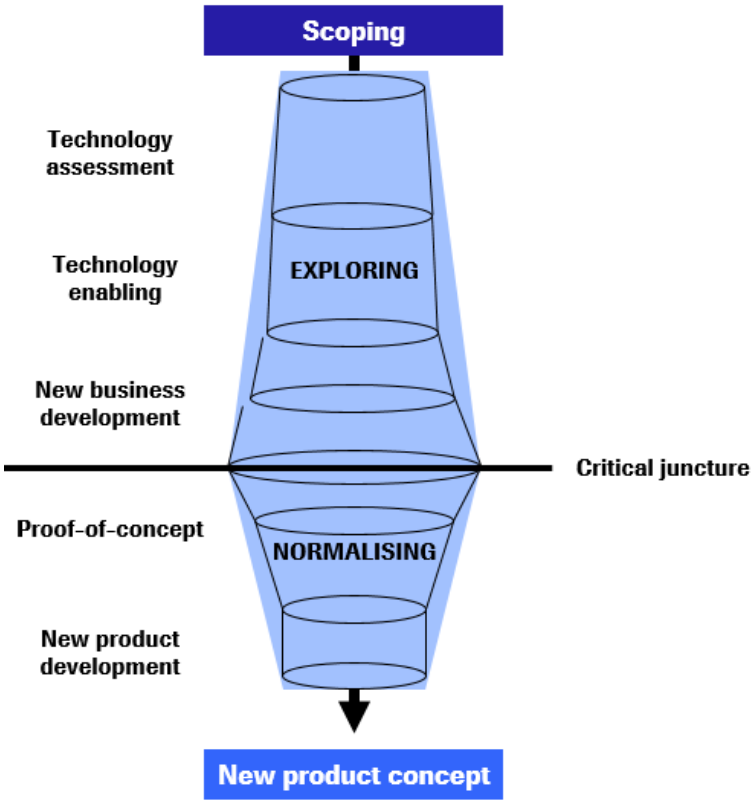

Figure 2: Temporaling indicators of scoping

Normalizing (narrow scoping) – in contrast to the *exploring* phase – was observed with an increasing maturity of the product concept starting with the initiation of a proof-of-concept. This point marks a critical juncture as from that time onwards the creative, future-oriented focus as part of dealing with the associated uncertainty is gradually shifting to a more formalized, backwards-looking second phase of normalizing. During that phase radical concept components were either removed or modified so that the product concept was less radical. This critical juncture is seen as a cutting point in the process of scoping that describes a transition from uncertain decision-making context, which is exploring, to a risk decision-making context, which is normalizing. As a consequence, development teams constantly adapted individual concept components and hence de-radicalised the product concept after initial generation. That way teams modified product concepts to enable project continuation and finally completion in a corporate setting.

The discovery of normalizing helped to identify critical steps in which the (perceived) level of radicalness might be maintained or decreased. On the one hand the perceived radicality declines based on the internal knowledge and capabilities that is built up and formerly unknown or new aspects are considered as known and established. On the other hand, the stepwise transition from product definition to product development revealed a gradual process of de-radicalization of the product concept. Indicators that have an impact on radicality include process elements such as tightened internal formal procedures that limit the ability for creative interpretation of the context. In addition, innovative elements of the product concept are diminished or eliminated. These include a review of customer segments that are addressed as well as a cancellation of radical product features for the sake of risk-mitigation. Furthermore, as part of business model design, new-to-the-market

revenue models options were for example eliminated and well known revenue models preferred. This way various types of uncertainties such as market adoption were mitigated.

6. DISCUSSION OF RESULTS

This study makes a number of contributions on how new product concepts are emerging under uncertainty and how they are adapted, modified by cross-disciplinary development teams over time to ensure project continuation and future implementation. It has identified scoping as the main concern of the teams involved in the process of defining product concepts that are based on fundamentally new technologies and of exploring more radical concept components to expand the scope of the future product. Scoping helps exemplify and visualize a product concept as a multidimensional space of solutions of a new product as well as describe the process of defining and bounding this space. This process is heavily vested in the individuals that define it. Individuals as well as groups of people create a shared understanding of a future product by attaching specific meaning to it. Overall, scoping offers the opportunity to extend and broaden our current conceptual and theoretical understanding of the emergence of product concepts under uncertainty (R. G. Cooper, 2006; Reid & De Brentani, 2004).

The success of scoping depends on four necessary *contextual* variables: resource efficacy and context interpreting efficacy and *temporaling* variables: exploring and normalizing. Depending on their ability to use resources effectively and to effectively interpret a respective context, the teams are able to explore multiple radical options for the product concepts. Such expansion of a radical product concept is common in the front-end of innovation (Reid & De Brentani, 2004) and in the impact of resource availability and knowledge (Edmondson & Nembhard, 2009; Goffin & Koners, 2011; O'Connor, 1998). The same applies for the creativity piece in early development that has been researched in specific phases of the front-end of innovation (Frishammar, Dahlskog, Krumlinde, & Yazgan, 2016; Gordon, 1961).

During exploring and normalizing, the progression is viewed as an elaboration and adaptation of concepts rather than as an iteration backwards to prior stages. This *resembles* shifting concept as suggested by (Seidel, 2007). According to Seidel (2007), shifting takes place in later phases of new product development when the product concept is defined; in other words, it manifests in risk decision making settings such as normalizing. In uncertain decision making settings, as per our findings, extensive changes to product concepts are observed in earlier phases and the impact of these changes are considered on the radical nature of the product concept. That is, our findings extend shifting concept suggesting that the concept components are being shifted earlier on in the process of exploring within uncertain decision making settings.

In addition, present findings suggest that development teams in larger organisations use shifts in concepts and de-radicalisation of concept components to facilitate a completion of a radical project. As per our findings in the face of uncertainty, which is inherent in radical innovation projects (Herstatt et al., 2004; Zhang & Doll, 2001), the ability to shift and adapt a product concept allows the development team to maintain the required momentum right from the start of a project. Our findings also point to the fact that with the right resource efficacy and context interpreting efficacy teams are able to explore the scope of a product concept and exploit at the same time the radical potential that might

for example be associated with a new technology component (Ernst, 2002; Holahan, Sullivan, & Markham, 2014; Krishnan & Ulrich, 2001).

7. CONCLUSION AND CONTRIBUTION TO THEORY/PRACTICE

Our findings contribute to the current debate on and inform further research to better understand the phenomena of the emergence of new product concepts under uncertainty and the role development teams play in adapting, modifying these emerging concepts. The core variable *scoping* that emerged grounded in data contributes to our understanding of shifting by suggesting two states of scoping (shifting): *exploring (wide scoping)* that allows enlarging the product space to explore the full radical potential that might come along with a new diagnostics technology and *normalizing* (*narrow scoping)* with a more restricted, bound space of the product concept. The former takes place within uncertain decision making contexts, whereas the latter – within risk decision making contexts. Future research is called for to study how development teams transition from one state to another in their attempt to *explore* and *normalize* the process of new product concept development that are based on fundamentally new technologies as well as the impact of *resource efficacy* and *context interpreting efficacy* on the subjective interpretation of the development context. In addition to its relevance, scoping is also a modifiable concept; hence future research is suggested to investigate the above phenomena across various types of organizations, based on diverse radical technologies, and involving different configurations of development teams – all aimed to enhance the relevance and value of scoping.

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