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EARLY STAGES USER INVOLVEMENT AS A PRODUCT INNOVATION CAPABILITY IN THE MEDICAL TECHNOLOGY INDUSTRY – A LITERATURE STUDY

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Keywords: user involvement, product innovation capability, medical technology

1. Introduction

This article is a literature study related to user involvement in the early stages of the product innovation process. The article is focused on the medical technology industry and it is an initial publication in the action research project InnoPlant. The goal of InnoPlant is to develop new forms of innovation fostering collaboration between the medical technology industry and the public healthcare system in Sweden. InnoPlant is primarily focused on the collaboration between the industry and its users and purchasers in the early stages of the innovation process. The involvement of users in the early stages of the innovation process has been singled out by practitioners in InnoPlant as well as in previous literature [e.g. Biemans 1991, Lüthje and Herstatt 2004] as an important factor for successful medical technology innovation. However, there is research that contradicts its importance and even states that user involvement might be counterproductive for the innovation capability [e.g. Christense, 1997]. The aim of this article is provide a comprehensive overview of the phenomenon and to highlight certain capabilities related to early stages user involvement that can be further researched and developed within the scope of InnoPlant.

2. Research approach

The need for this literature study was initially addressed by representatives from the three medical technology companies that participate in the InnoPlant project. They asked for a document that they could use to benchmark their routines for user involvement. Thus, the goal of the study was to present a synthesis of previously published research that could provide guidance in the specification of future research in the companies. A list of 16 keywords and phrases was initially put together to establish the scope of the study.

Keywords and phrases: *Capabilities, Innovation, New product development, Innovation process, Innovation capability, Radical innovation, Incremental innovation, Early-stages user involvement, User driven innovation, User needs, User studies, User-centred, Medical technology, Healthcare, Medical devices*

2.1 SAMSÖK

The information seek was conducted in SAMSÖK (http://samsok.libris.kb.se), a search engine that enables cross search on eight data bases and provides access to full text articles. The data bases connected to SAMSÖK are presented below.

DOAJ/Directory of Open Access Journals, Highwire Press, New York Times Archive, ScienceDirect Science Magazine, Scopus, SpringerLink, Web of Science (ISI) with Conf Proc, Wiley InterScience

2.2 Information seeking strategy

The following strategy was applied in the seeking of information.

1. Search with above listed keywords and phrases in SAMSÖK.
2. Reading abstracts on the SAMSÖK site looking for keywords and interpreting the context in which they were used. In SAMSÖK there is a clustering function that categorizes the articles in general topics (e.g. new products) and subjects (e.g. engineering). This function permitted us to eliminate articles that were obviously of the topic. Approximately 30 abstracts were read per search round which gave a total number of about 500 read abstracts. Out of these 50 articles were selected for full paper review based on their relevance to the topic.
3. The full-paper review was performed in a grounded manner searching for streams of literature related to early stages user involvement. Five comprehensive streams related to the topic could be identified, organizational theory, strategic management, user-centered design, knowledge management, and learning theory. A framework of capabilities related to early stages user involvement was also developed during the full-paper review process. This framework of capabilities consisted of identification of users, acquiring, assimilation, and transformation of user knowledge as well as exploiting.
4. Subsequently with the full-paper review process 23 relevant articles and books in the references of the initial articles was tracked down through SAMSÖK, Google Scholars and the university library. These articles were scanned for contributions that related to the capabilities in the framework.

3. Product innovation capability

The product innovation process can be defined as the process from the initial idea to a commercially successful product [Koen et al. 2002]. The ability to continuously develop product innovations is fundamental for many knowledge-intensive companies as the ability is closely interlinked with sustainable competitive advantage. Sustainable competitive advantage is defined as the ultimate goal of a company and it depends on the company's' resources and capabilities [e.g. Penrose 1959, Wernerfelt 1984]. Companies with valuable, rare, inimitable and non-substitutable resources are more likely to perform well in the competition [Wernerfelt 1984]. However, to obtain sustainability a company constantly has to address the reconfiguration, renewal, and recreation of its resources and capabilities as a response to a changing environment [e.g. Wang and Ahmed 2007]. This adaption process has been conceptualized by several authors. Cohen and Levinthal (1990) introduced the term absorptive capacity which describes how companies are taking in external knowledge, combining it with internal knowledge, and apply it to commercial ends. Absorptive capacity also emphasizes that the ability to evaluate and utilize external knowledge is largely a function of the level of prior knowledge in a company. An extension of this concept is dynamic capabilities which emphasize absorption as a mean to address environmental changes. A fundamental component in these definitions is the individual and organizational ability of learning and re-learning. Product innovation capability has commonalities across industries, yet companies may develop their product innovation capabilities from their unique starting point and through their unique paths. This implies that the characteristics of a company's products and the market influences how the capability is developed (e.g. Eisenhardt and Martin 2000). Day (1994) suggests that the first steps in the development of capabilities in an organization are to make a diagnosis of the current capabilities and to anticipate future needs of

capabilities. Hence, to diagnose the capabilities related to early stages user involvement in the InnoPlant companies, we ought to develop our understanding of what these capabilities are.

4. Early stages user involvement

In the literature the early stages of the innovation process are described as the steps taken from the initial opportunity recognition and idea generation until a concept is defined. The early stages of the innovation process typically involve opportunity recognition, opportunity analysis, idea generation, idea selection, and concept development. The end of the early stages is the definition of a concept which is further developed in the new product development process and eventually it is taken to the market in the commercialization phase [Koen et al. 2002]. Cooper and Kleinschmidt (1994) displayed in an empirical study that the quality of execution in these early stages is decisive for the outcome in new product development projects. Olsson et al. (2009) displayed in a qualitative study of five medical technology companies that managers considers user involvement as a key aspect of developing new innovations. From their perspective it includes real understanding of the users´ environment and the problem that the new solutions are to address. The importance of this phenomenon in the industry is also supported by other well cited researchers. For instance, Teece (2007) states that the sensing and shaping of new opportunities is a fundamental activity for a company's innovation capability and it includes activities such as scanning, creation, learning and interpretation. However, previous research also indicates that early stages user involvement is not unequivocally positive. Cambell and Cooper (1999) argue that early stages user involvement consumes resources in terms of time, money and labor without providing any guarantees for success. Christensen (1997) argues in a similar line stating that users only may contribute to incremental innovation as they do not hold sufficient technological knowledge. Furthermore, Ulwick (2002) argues that the user cannot express what they want and that the involvement will only end-up in "me-too" ideas. A counter argument in the literature is that many companies are more knowledgeable in methods to measure user response to product ideas rather than methods to generate new ideas [Eliashberg et al. 1997]. However, it is conceded that even when they apply these generative methods the ideas from users are addressing current needs rather than future needs. An important aspect to reflect up on here is the difference between users in different markets. In the field of medical technology it has been displayed that users (medical doctors) contribute actively in the development of novel innovations consisting of complex technologies [Lettl 2007]. The bottom line of the reviewed literature suggests that the challenge is to identify the right users and involve them in the right manner early on in the product innovation process.

5. A Conceptual framework for capabilities in early stages user involvement

As the review process for this article was rather stochastic a structure for the article was developed along with the reviewing process. The applied framework was inspired by the work on absorptive capacity by Todorova and Durisin (2007) and comprised the focal capabilities that were frequently recurrent in the literature (see figure 1).

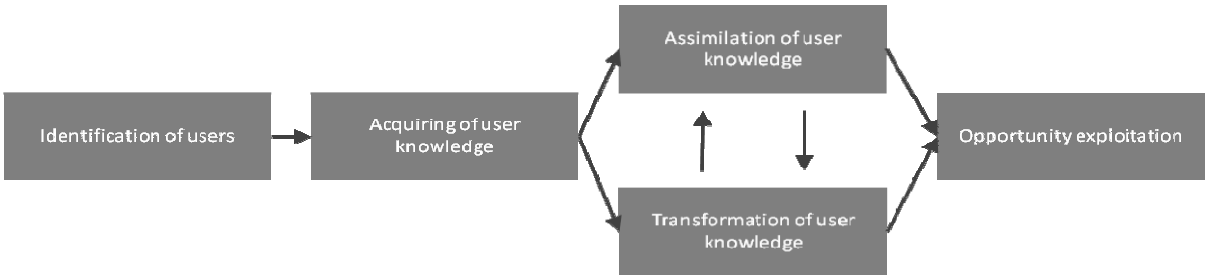

Figure 1. Subordinated capabilities in early stages user involvement (inspired by Todorova and Durisin, 2007)

4.1 Identification capability

One focal area in the literature is the ability to identify the right users to involve in the early stages of the innovation process. The user group in medical technology is described as highly heterogeneous composed by healthcare professionals, patients, careers, persons with disabilities, those with special needs, as well as professionals allied with healthcare, all with different needs and requirements [Shah and Robinson 2008]. The main issue that companies face according to the reviewed literature is to identify users in these groups that can really contribute to the initiation of innovation projects. The most dominating literature on this field is the lead-user methodology. Lead-users are those users who are more likely to contribute in innovation as they experience needs for an innovation earlier than the majority of the market and will probably gain much from a solution satisfying those needs [von Hippel 1976]. Furthermore can lead users be identified by their expertise and degree of knowledge in a certain products or their degree of dissatisfaction with current products [Lüthjes 2004]. A close definition to lead users is the definition of inventive users who may contribute actively in the initiation of novel innovations, especially in medical technology [Lettl 2007]. The main difference in the definition ought to be that the inventive user possess research resources and can distribute their time so that they can participate actively in the development of innovations. There are examples of positive effects from the involvement of lead users in medical technology. Lilien (2002) found out that medical technology concepts developed by lead users displayed a sales potential that had an average eight times higher than products using more traditional development processes. One technique that has been used successfully to identify these special users is so called pyramiding. Pyramiding is a search process that builds upon the idea that people with a strong interest in a topic or field tend to know people more expert than themselves. Von Hippel et al. (2009) demonstrated in an empirical study that pyramiding is an efficient method compared to for instance mass screening to find persons with certain qualities. In the early stages companies may experience a need to involve users in the evaluation and testing of novel ideas. In this case literature suggests that it is important to identify user with a certain attitude. They should preferably have openness towards new technologies, willingness to take risks, and willingness to experiment [Lettl 2007]. Moreover is it recommended to involve those who are supposed to benefit most from the radical innovation in the evaluation [Leifer, et al. 1992]. However, there might be a significant difference in the identification pattern for novel and incremental innovation. In incremental innovation it is suggested to rather involve users with a potentially high sales volume rather than certain knowledge or resources [Lettl 2007]. These statements are not empirically manifested. One literary field that seems to be relevant regarding the identification of users is the network effects. Empirical research indicates that successful medical technology innovations are frequently developed in networks of external stakeholders, amongst them users [Biemans 1991]. Thus, it can be argued that networking capabilities is an important ability to identify users to initiate collaborations with. Walter et al., (2006) defines networking capabilities as a company's ability to initiate, develop and utilize the relationships with different partners at different stages of the innovation process. He suggest that the capability of networking encompasses five dimension, 1) the ability to coordinate between collaborating partners, 2) knowledge of their partners, 3) relationship skills with other partners, 4) internal communication skills, and 5) building new relationships. It can be argued that a company that grows a networking capability also increases its abilities to get in contact with the right users.

4.2 Acquiring capability

The second focal area that was recognized in the reviewed literature is the acquirement of user knowledge in the early stages of the innovation process. This capability can be described as a company's ability to involve themselves with users so that they benefits from the experiences in terms of explicit and tacit user knowledge that contributes to product innovation. Tacit knowledge is the type of knowledge that is personal, non-articulated, silent, hidden, experience based and skill type bodied knowledge that needs to be transferred face-to-face. The opposite is explicit knowledge which is the type of knowledge that can be articulated, codified and stored in various media and easy to transmit to others. [e.g. Polanyi 1966, Nonaka 1994]. In a very general manner the reviewed literature suggests three streams of acquiring approaches. A company may design for the user, with the user or by the

user [e.g. Kaulio 1998]. *For* the user, implies that the manufacturer design on behalf of the user, utilizing data on users, general theories and models of users. Designing *with* the user means that the company is tuning the design with users throughout the innovation process. Finally a company may design *by* the user and actively involve the user in the development of new products. Gould and Lewis (1985) recommend bringing the design team into direct contact with potential users, as opposed to hearing or reading about them through human intermediaries, such as marketing, sales, and users' managers. Designers make several assumptions about users that affect their decisions, and such assumptions may be mistaken if the designers have not met the users. An alternative approach for companies that design *for* the user is to apply intermediary methods such as personas. Personas are defined as *"memorable representations of users that remain conspicuous in the minds of those who design and build products"* [Pruitt and Adlin 2006, p. 5]. However, persona methods are criticized for actually increasing the distance to real users and their needs. Chapman et al. [2008] displays that descriptions with more than a few attribute are likely to describe few, if any real users. Personas might also limit the acquirement of tacit user knowledge. If a company decides to work closely with their users they must develop an ability to initiate collaborations with users based on mutual trust, communication and commitment on an individual, group and organizational level [Blomquist and Levy 2004]. Habermeier (1990) argues that this is particularly important in the development of complex and specialized equipment such as in many medical technology applications. A fundamental issue in user involvement is the recognition of needs. A need may be defined as a psychological feature that arouses a person to action toward a desired goal or simply the reason for the action. There is an abundance of psychological theories on motivation and human needs. However in the engineering literature the Kano model is frequently referred to as an applicable approach for need recognition. According to the Kano model user needs can be divided into basic needs, expected needs, and excitement needs. Basic needs are those needs that the user will not mention as they are too obvious and taken for granted. Expected needs are those needs that a user will probably mention when acquiring an artifact. The excitement needs are those needs that are difficult to discover in the interaction with the user. However, if excitement needs are acquired and satisfied a company has the opportunity to differentiate themselves from its competitors. One important aspect of the Kano model is that the characteristics of the needs change over time, e.g. excitement needs will become expected needs, and expected needs will become basic needs. Thus, a company must have the ability to continuously acquire and monitor the needs of the user [Ullman 1997].

4.3 Assimilation capability

Assimilation is a focal capability in early stages user involvement and refers to a company's ability to understand, analyze and interpret user knowledge. Certainly the assimilation capability is closely interlinked with individual and organizational learning. Considering an organizational perspective the key issue tends to be the ability of individuals to question the values, assumptions and policies that led user's to certain actions in the first place. If individuals in a company are able to view and modify those actions then learning occurs. These ideas were first introduced by Argyris and Schön in their work on double-loop learning in organizations. Also educational theorist such as Kolb [1984] argues that the concrete experience (for instance a user problem), reflection, conceptualization of ideas and testing of ideas are fundamental for learning. According to this, a company that wants to learn about their users must have the ability to assert resources to realize activities that stimulates these knowledge generating activities. O´Reilly & Pfeffer [2002] adds to this by emphasizing on the ability of a company to capture the generated knowledge. Regarding the spreading of user knowledge there are some controversies. Nonaka [1994] argues that continuous knowledge sharing in a company is crucial to convert tacit knowledge into explicit concepts. Hendriks [1999] suggests that time and space is the most prominent barriers for this knowledge sharing but he also highlights social distance, culture and language as factors contributing to failure. Furthermore, it is argued that ignorance is a barrier for knowledge transferring. These barriers can potentially hinder communication with users as well as with colleagues. Especially in large organizations, employees do not know who possesses certain knowledge that might be valuable to their work, or about other employees' needs of their knowledge [O'Dell and Grayson 1998]. Burt [1992] introduce a different perspective on how innovation occurs in

an organization with his structural hole theory. Structural holes are defined as individuals bridging between different groups of people who are not related in any other way. In research on managers network position it was displayed that those managers who were in a structural hole positions were more likely to express ideas, less likely to have ideas dismissed and more likely to have ideas evaluated as valuable [Burt, 2004]. In the context of early stages user involvement this suggests that employees should have many external, company unique, contacts and in the same time have a proficient internal knowledge sharing for innovation.

4.4 Transformation capability

The transformation capability in early stages user involvement refers to a company's ability to embody explicit and tacit user knowledge in innovative ideas, prototypes, and concepts. This ability exists in a close interplay with the assimilation capability, as the embodiment of knowledge seems to be a bulk of iterative learning cycles. There is an abundance of technical and organizational approaches, tools and methods to embody the user knowledge. However, for this framework we focus on two focal abilities frequently mentioned in the literature, the ability of providing a creative organizational climate and the ability of prototyping. Previous research on organizational creative climate tells us that there are certain key areas that companies can develop in which people are not only creative, but also motivated to develop ideas into value-adding contributions. Ekvall [1996] defines the following ten dimensions for creative organizational climate:

- Challenge
- Freedom
- Idea-support
- Trust
- Dynamism
- Playfulness
- Debates
- Conflicts
- Risk-taking
- Idea-time

According to Ekvall (2008) [from Olsson et al. 2009] risk-taking and idea-time are the most contributing factors. Thus, in innovative organizations decisions and actions are rapid and immediate and experimentation occurs frequently. To the contrary, risk avoiding organizations in which committees, investigations and analyses precede every decision, are often governed by a hesitant and cautious mentality. The idea-time dimension refers to the time available within an organization for people to elaborate on new ideas that are not related to existing projects. Impulses can be tested and discussed in organizations with idea time, while in organizations with no idea-time all working time is specified and occupied by operational matters [Ekvall 2008 from Olsson et al. 2009]. However, to be able to embody new user knowledge the ability of prototyping is almost self evident [Schrage 1999]. According to Floyd (1984) a prototype can be seen as a learning vehicle, providing more precise ideas about what a product should be like. Prototypes comprise embodiments from simple paper models to complex computer models. In early stages user involvement, employees must be able to:

- adjust the type of prototype to the audience [Erikson 1995]
- use prototypes to explore what role an artifact will have in the users life [Houde and Hill 1997]
- use prototypes to explore the users attitudes towards its looks and feel [Houde and Hill 1997]
- use prototypes to explore what type of techniques an artifact must possess in order to fulfill its function [Houde and Hill 1997]
- decide the degree of fidelity for a prototype depending on the user and the purpose of the prototype [Walker et al. 2002]
- use prototypes to estimate the relevance of a proposed solution before large investments [Floyd 1984]

4.5 Exploiting capability

The exploiting capability is the ability of a company to utilize their new invention to achieve a return on investments. Thus, the exploitation is something that takes place in the commercialization phase. However, the literature reveals that the exploitation capability is highly influenced by user involvement activities in the early stages, such as researching potential customer demand [Chrisman

and McMullan 2000], developing and testing of technologies [Manning et al. 1989] and generating stakeholder support [Rice 2002]. Thus, these activities will prepare the way for manufacturers as they reduce uncertainty and generate user support which allows the company to maximize the innovation lead-time. Innovation lead time refers to the period of monopoly of the first entrant, prior to competitors entering the industry. Thus, the exploiting capability is dependent on the preceding capabilities in early stages user involvement.

5. Discussion and conclusions

This article provides a comprehensive framework describing the capabilities that medical technology companies may possess in order to arrange, drive and benefit from user involvement in the early stages of the innovation process; and thereby increase their product innovation capability. The framework is constructed by converging knowledge from various research fields such as organizational theory, strategic management, user-centered design, knowledge management, and learning theory. The validity of the five overall capabilities in the framework is supported by previously published literature dealing with absorptive capacity (e.g. Cohen and Levinthal 1990, Todorova and Durisin 2007). However, it can be discussed whether these capabilities are described at a sufficient abstraction level and whether they include the most relevant subordinated activities. As the framework is intended to be used as a tool in an action research project, it seems to be more expedient to describe the capabilities in a general yet tangible manner rather than just listing specific tools or approaches. One important conclusion could be that there is a close interplay and connection between the five capabilities and that a company's attitude towards learning seems to be the least common denominator. This attitude towards learning include the continuous learning about users and user specific needs, ways to acquire this knowledge, and how it can be assimilated, transformed and exploited.

6. Limitations and future research

The term "capability" facilitates the quest for new knowledge as it provides us with freedom to look beyond explicit activities such as processes and more tacit activities like for instance risk taking. However, such an all embracing term is difficult to handle as its theoretical definitions tend to be too general or too simplified, or it might just exclude component factors important in practice. This is certainly also the case concerning the framework in this article, due to the limited number of keywords, the number of articles read and possibly a partially correct interpretation of the contents of the articles. How can we then further approach the exploration and understanding of the capabilities in early stages user involvement? By applying an action research approach we seize the opportunity and challenge to explore what these capabilities comprise and how they are developed and managed in an applied situation. Action research appears to be a suitable research approach as it normally produces relevant knowledge by combining practical and theoretical contributions. In the realization of the action research project this article may provide a benchmarking tool for the companies in the diagnosis of current capabilities and the anticipation of future needs of capabilities. Due to the involvement of both employees (from the medical technology industry) and users (from the county councils) in this action research project, we intend to develop a more robust knowledge considering the capabilities in early stages user involvement. The researchers' role in this setting is to facilitate the interaction between the manufacturers and the users and to support and contribute in the reflective learning process concerning the diagnosis and development of the capabilities. From a practical perspective, the goal of these new attuned forms of interaction is to uncover hidden needs, to discover more incremental and radical product opportunities and better means to tune and predict innovative product ideas. This in turn will provide the companies and the public healthcare system with the means to face a rapidly changing environment.

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