Towards a Framework of the Process of Open Innovation: Case of Acclarent in the Medical Device Industry

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Abstract:
Using a case study of Acclarent, a medical device company, this paper attempts to propose a framework to further illustrate the process of open innovation in the medical device industry. We examined five elements in the mechanism of the open innovation process. Our paper shows how the success of Acclarent—a medical device start-up—depends on effective management of the flow of knowledge to satisfy unmet needs, while integrating in-depth knowledge of FDA regulations and third-party payers’ reimbursement policies into the product innovation process.

Keywords: Open innovation; medical device company; Acclarent.
A framework of the process of open innovation

Introduction
The concept of open innovation manifests the importance of firms employing “external ideas as well as internal ideas, and internal and external paths to market” [Chesbrough (2003a)] as they progress with their technology development. The underlying assumption of open innovation is the “mobility of knowledge workers” and the availability of capital which enable the generation of innovative ideas outside of the “silos” of corporate research labs [Chesbrough (2003b)].

The power of open innovation lies in the fact that knowledge created through such an open mindset and corporate policy can be reused and it can lead to increasing returns [Arthur (1996)]. Moreover, both the breadth and depth of the collective knowledge can surpass the knowledge contribution of an individual provider [Chesbrough & Appleyard (2007)].

Although the idea of open innovation paves an alternative path to the advancement of technology, theoretical discussions are still insufficient to expound the mechanism of open innovation. Open innovation contributes to broadening the “realm” for knowledge creation by focusing on “different sources of external knowledge” and the balancing role of both external and internal sources of knowledge [van de Vrande et al. (2010)]. Nevertheless, the theory does not provide us with a clear guidance on how new knowledge, the core of innovation, is constructed. In this paper, using the case of Acclarent, we plan to contribute to existing theories through an in-depth examination on “how” knowledge is created or recreated through such a process.

Theoretical Background
West and Bogers [2011] conducted an extensive literature review on open innovation research and they developed a four-phase model for inbound open innovation to categorize prior studies in open innovation. These four phases include: “obtaining, integrating and commercializing external innovation, as well as work on nonreciprocal innovation flows.” For the purpose of this paper, we only allude literature related to the first phase in their model.

In terms of obtaining external innovation, studies have examined external stakeholders, e.g. [Li et al. (2010); Tether and Tajar (2008)], suppliers [Li and Vanhaverbeke (2009); Schiele (2010)], competitors [Lim et al. (2010)], or universities [Cassiman et al. (2010); Fabrizio (2009)], as well as market-feedback [Dodgson et al. (2006)], networks [Vanhaverbeke (2006); Zeng et al. (2010)], and communities [Stam (2009); Janzik (2010)] as source of external knowledge. In addition, Tortoriello and Krackhardt [2010] demonstrated that the nature of relationship between a firm and an external stakeholder may determine the effectiveness of the search for external innovation. Moreover, there is also an increasing amount of research scrutinizing the role of third party actors in enabling external innovation, e.g. [Jeppesen and Lakhani (2010); Mortara et al. (2010)].

In addition to studies on obtaining external innovation, other research investigating different aspects in open innovation includes: analyzing firms adopting an outside-in (versus an inside-out) approach of open innovation, e.g. [Lichtenthaler and Ernst (2007); Witzeman et al. (2006)], examining small and medium-sized enterprises (SMEs) rather than the traditionally large, multinational enterprises, e.g. [De Jong and Marsili (2006); Massa and Testa (2008); Ndou et al. (2011)], exploring firms’ cultural dimensions of implementing open innovation [Herzog and Leker (2010)], studying different types of alliance strategies to maximize startup firms’ innovation performance [Neyens et al. (2010)], and incorporating analysis of user innovation, customer interaction, online
A framework of the process of open innovation

community, and alliance networks in the existing literature, e.g. [Hienerth (2006); Lettl (2007); Spaeth et al. (2010), and Van Rijswijk et al. (2008), Weber et al. (2012)].

While existing research on open innovation has certainly expanded the scope of the original concept and enlightened us on various open channels of sources of ideas, there is still a lack of attention on the process of knowledge (re)creation, which is the underpinning of innovation.

Our proposed model in investigating how innovative knowledge is generated through interaction of both external and internal sources is meant to establish a framework of linking macro and micro levels of analysis regarding knowledge exchange and flow, thereby enhancing the value of the open innovation paradigm.

Using a case study of Acclarent, a medical device company, this paper attempts to illustrate how the process of open innovation is implemented in the medical device industry, which can shed some light to the mechanism of open innovation.

In our proposed framework, we focus on five essential elements to capture the mechanism of innovation in medical device businesses. These five elements include: sources of ideas, the interrelationship (quality of relationship) between innovators and the sources of ideas, types of knowledge, characteristics of knowledge, and path for knowledge acquisition. We first give a brief introduction of the case, then illustrate the five elements in the following sections. Data are obtained through both face-to-face interviews and secondary resources.

Research Method
Since previous studies examining open innovation in the medical device industry are scarce, we employed both primary and secondary research to obtain first-hand data as well as background information on medical device companies and the industry. The medical device companies we selected for interview are from the MDR Web site. We used locations, annual revenue, and patents as major criteria for determining medical companies in our sample. As a preliminary research, we employ a case study method in this paper to have an in-depth understanding of the phenomena. Our literature review on medical device industry indicated that many medical device companies center in the Silicon Valley area.

Acclarent was chosen because it was located in Menlo Park, a hub for many medical device companies in Silicon Valley. The company had 16 active patents in 2009. In our in-depth interview with Bill Facteau, CEO of the company, he provided us with ample data on the company’s innovation procedures and practices, and challenges the company faced in developing new products. In addition, we were able to find valuable secondary information from the book related to the process of innovating medical technologies, co-authored by Joshua Makower, founder of Acclarent, which offered us insightful details on how the idea of the Acclarent’s Balloon Sinuplasty devices was formed. The combined interviews, case studies, and archival research thus presented us a much more clear and affluent resource on the innovation of Acclarent’s Balloon Sinuplasty product as well as key issues concerning innovation in the medical device industry. The rich information we collected rendered Acclarent worthy for a case study.

The Case of Acclarent

Background
Acclarent Inc. is a medical device company dedicated to the development of innovative technologies to better meet the needs of ENT patients. By 2010, the company acquired 16 patents and there were 120 patent applications pending. The company typically has 3-4 new products every year, and the Balloon Sinuplasty, an instrument designed to improve quality of life for sinusitis patients, is their major product line. Approximately 50% of the balloon sinus patents are related to their key products. Acclarent’s revenue in 2009 was 95 million (Facteu) and it was acquired by Ethicon Inc., a Johnson & Johnson company in the same year.

Joshua Makower, Acclarent’s founder, is an entrepreneur in the medical device industry. He started a medical technology incubator named ExploraMed I in 1995, which spawned EndoMatrix and TransVascular. In 2003, Medtronic acquired TransVascular for a deal valued up to $90 million. The success sale of TransVascular leaves Makower in a position to decide what to do next [Zeniou et al. (2010)]. After a thorough assessment of what he would like to accomplish in his career and his strengths and weaknesses, he set out his next project acceptance criteria which he believes would have a reasonably high chance of success: (1) focus on real world problem (no more science experiments), (2) work on problems that affected a large number of people, and (3) devote to projects that would not involve any patient deaths. In order to accomplish his goal, he restarted ExploraMed II, which serves as a platform for launching two to three medical device businesses [Zeniou et al. (2010)]. After forming a trusted team and researching several clinical areas which met Makower’s project criteria, a company focuses on ear, nose, and throat (ENT), Acclarent, was established in 2004.

Sources of innovative ideas
Since innovation starts with idea generation and development, “understanding the sources of ideas is critical for innovation” [Desouza et al. (2008)]. Three subjective groups may play an important role in sources of innovative ideas in the medical device sector: physicians (customer), patients (user), and insurance companies (buyer). (see Figure 1)

![Fig. 1. Sources of ideas](image)

Physicians are the major customers for medical device manufacturers as they are usually the decision makers for the adoption of medical devices in the treatment process. Patients are the users who physically experience the effect and quality of the medical devices. It is therefore essential for medical device manufacturers to improve physicians and patients’ satisfaction with their apparatus when they invent a new product.

As a medical device company, one of Acclarent’s areas of innovation is in the Ear, Nose, and Throat (ENT) field. To better understand the problems in the ENT field in order to propose innovative solutions, Acclarent adopted an open innovation strategy. The
founder of Acclarent, Joshua Makower, asserts that, rather than starting with a solution, an existing invention, or ideas from academia, innovation of medical device starts with “focusing on a set process”, which evidences a thorough examination and in-depth understanding of an area of medicine [Stommen (2010)]. As a result, Makower, John Chang (Vice President of Acclarent), and engineers at the company collaborated closely with ENT physicians and their patients to identify clinical problems and uncover their unmet needs. That is where the invention starts. They observe life surgeries, identify clinical problems, find out physicians’ unmet needs, and then propose solutions. In the process of developing new concepts, Acclarent has a Science Advisory Board (SAB) where they obtain advices from physician consultants. The strong partnership with physicians allows Acclarent to develop thorough and profound knowledge of the medical problems which, in turn, drives the innovation.

In addition, insurance companies play an important role in the innovation process in medical device industry. The reimbursement from insurance companies for employing certain medical devices is a crucial source for funding medical device corporations’ on-going innovative projects. Consequently, it is critical for medical device firms’ to assure the acceptance of insurance company of their inventive product in order to obtain compensation. Because reimbursement criteria determine the success or failure of a new medical product in the market, medical device manufacturers must take into consideration these criteria and policies in their innovation process.

Relationship between innovators and sources
The Acclarent’s case also reveals that the relationships between innovators and the sources of ideas determine whether there is a flow of different knowledge for generating a new set of knowledge. In studying the relationship between an organization and its publics, Hon and Grunig [1999] mainly identified four indicators to measure relationship outcomes: trust, control mutuality, relationship commitment, and relationship satisfaction. Since the relationship between innovators and the sources of ideas is like that of between an organization and its various publics, we adopt three of the four indicators to examine the quality of relationship between innovators and their sources of ideas. Figure 2 provides an overview of the relationships between Acclarent and its external sources of ideas. Moreover, we attempt to investigate how such quality of relationship may affect different types of knowledge sharing in the innovation process.

Fig. 2. Relationship between Acclarent and its external sources of ideas

Innovators must build up trust with physicians in order to acquire practical clinical knowledge and to gain access to first hand information of surgical procedure. Trust, according to Hon and Grunig [1999], is “one party’s level of confidence in and willingness to open oneself to the other party (p.14). Gambetta [1988] also asserts that trust in an individual means “the probability that he [or she] will perform an action
that is beneficial or at least not detrimental to us is high enough for us to consider engaging in some form of cooperation with him [or her]." (217). If there is no trust between innovators and physicians, it is unlikely for the innovators to attain experiential knowledge from physicians.

According to Rastogi [2000], effective sharing of complex knowledge cannot be accomplished without trust and cooperation. Therefore, mutual trust between individuals is key to promote interpersonal complex knowledge sharing [Chowdhury (2005)].

In addition, innovators should have relationship satisfaction with patients (user) in order to solicit their feedback on any type of medical treatment. Relationship satisfaction is defined as “the extent to which one party feels favorably toward the other because positive expectations about the relationships are reinforced.” [Hon and Grunig (1999, p.14)]. Patients may not be willing to collaborate with innovators by sharing their feedback if they don’t believe the purpose of investing in such a relationship is to benefit themselves ultimately. In a study examining the effect of type of mentor and quality of relationship on employees work and career attitudes, Ragins, Cotton, and Miller [2000] discovered that satisfaction with a mentoring relationship exerted a stronger impact than the presence of a mentor on attitudes. In addition, Liao, Chang, Cheng, and Kuo [2004] contend that when employees have a good relationship with the firm, they would like to share working knowledge with coworkers voluntarily and unconditionally (p.33). It can thus be inferred that relationship satisfaction may serve as a crucial factor in influencing individuals’ attitudes and/or behaviors such as knowledge sharing.

Moreover, the relationship between innovators and insurance companies (buyer) can be characterized as “control mutuality”. Control mutuality refers to “the degree to which partners agree about which of them should decide relational goals and behavioral routines”, [Stafford and Canary (1991, p.224)]. Since the criteria for reimbursement from insurance companies are essential guidelines for medical device firms to obtain compensation for their product usage, these criteria thus affect the product innovation process as innovators must consider how their invention fits with existing rules so that they can secure financial returns.

Types of knowledge

Idea generation often derived from agitation of different types of knowledge. There are two types of knowledge: explicit knowledge and tacit knowledge, e.g. [Nonaka and Takeuchi (1995); Nonaka et al. (2000)].

Explicit knowledge: This type of knowledge can be found in documented information or materials such as reports, articles, manuals, patents, pictures, images, video, sound, and software etc. [Nonaka and Takeuchi (1995); Nonaka et al. (2000)].

Tacit knowledge: Tacit knowledge is personal knowledge derived from individual experience and is shared and exchanged through direct contact [Borghoff and Pareschi (1997)]. In Acclarent’s case, knowledge learned from physician’s personal clinical practice experience, for example, is considered tacit knowledge because such knowledge is mainly obtained through the accumulation of physicians’ personal know-how of medical operation.

Characteristics of knowledge

In addition to types of knowledge, knowledge can also be categorized in terms of its characteristics. Such categorization may provide a framework in steering innovators to search for needed or useful knowledge. Because various sources of ideas may possess different knowledge, in this study the knowledge categorization is developed pertaining to Acclarent’s circumstance. Based on its characteristics, knowledge can be classified
into: professional, process, operational, and discipline knowledge.

1. Professional knowledge: This type of knowledge refers to specific knowledge related to a particular professional field of interest. Professional knowledge can be obtained from interaction with professionals or from documented information such as books, journals, reports, and manuals etc. Therefore, it can be both tacit and explicit knowledge.

2. Process knowledge: The process knowledge in this study is different from the term used in process management, where process knowledge means "explicit, formalized knowledge about executing sequences of work activities" [Borghoff & Pareschi, (1997 p.838)]. In Acclarent’s case, process knowledge refers to information gathered through observing life surgeries, identifying clinical problems, discovering physicians’ unmet needs, and researching possible solutions. Since process knowledge can be acquired through information sharing and through documented materials, it can be both tacit and explicit knowledge.

3. Operational knowledge: Operational knowledge mainly includes knowledge of FDA regulations and insurance company’s reimbursement policies. Such type of knowledge may not be the core for idea generation, but it is still vital as it may serve to validate the feasibility of innovative ideas. In this study, operational knowledge is mainly explicit knowledge. However, the interpretation of FDA regulations and the discretion of reimbursement policies can be tacit knowledge.

4. Discipline knowledge: discipline knowledge comes from innovators’ own educational background and training. Sparkle innovative ideas may be generated from integration of discipline knowledge in related fields or in totally different fields. Discipline knowledge is mostly documented information, and thus explicit knowledge.

Path for knowledge acquisition

The path for knowledge acquisition refers to “means” for obtaining different types of knowledge in the idea generation process. Such means can be broadly classified into one way or two way communication based on the nature of relationship between innovators and sources of ideas. In this study, knowledge acquisition from physicians is mainly through two-way communication in that innovators need to interact with physicians to attain their experiential knowledge. However, knowledge can also be acquired via one-way communication by observing life surgeries.

The knowledge on patients (end user) can be collected through feedback solicitation (two-way communication) or through examining existing literature (one-way communication) related to patients’ response and recovery process pertaining to certain medical treatments.

For medical device manufacturer (innovators), comprehension of insurance company’s reimbursement policies primarily results from thorough investigation of their reimbursement criteria and the medical code system (one-way communication). Nevertheless, innovators can strive for maximizing their benefit in the classification of reimbursement criteria by seeking support from physician associations and by engaging in negotiation with insurance companies (two-way communication).

Table 1 summarizes the five components that we proposed as a framework to explain the mechanism of open innovation process in the medical device industry.

Table 1. Mechanism for the Open Innovation Process in Medical Device Industry

| Dimension | | |
A framework of the process of open innovation

<table>
<thead>
<tr>
<th>Sources of idea</th>
<th>Innovator (Manufacturer)</th>
<th>Physicians (customer)</th>
<th>Patients (user)</th>
<th>Insurance (buyer)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Quality of Relationship</td>
<td>Trust</td>
<td>Relationship satisfaction</td>
<td>Control mutuality</td>
<td></td>
</tr>
<tr>
<td>Types of knowledge</td>
<td>Mostly Explicit</td>
<td>Tacit/Explicit</td>
<td>Tacit/Explicit</td>
<td>Explicit/Tacit</td>
</tr>
<tr>
<td>Knowledge characteristics</td>
<td>Discipline knowledge</td>
<td>Professional knowledge</td>
<td>Process knowledge</td>
<td>Operational knowledge</td>
</tr>
<tr>
<td>Path for knowledge acquisition</td>
<td>1. One way communication (e.g. books)</td>
<td>1. Two-way communication (e.g. interaction)</td>
<td>1. Two-way communication (e.g. primary research)</td>
<td>1. One way communication (e.g. secondary research)</td>
</tr>
<tr>
<td></td>
<td>2. Two-way communication (e.g. interactive learning)</td>
<td>2. One way communication (e.g. observation)</td>
<td>2. One way communication (e.g. secondary research)</td>
<td>2. Two-way communication (e.g. negotiation)</td>
</tr>
</tbody>
</table>

How does knowledge contribute to innovation?
The ability to generate new knowledge and to create value is important to innovation. According to Carneiro [2000], the success of an innovative product is connected to research activities and changing orientation, which are dependent on the development of knowledge levels and the innovative efforts of knowledge workers.

In analyzing intraorganizational knowledge transfer on business innovation, Tsai [2001] also asserts that knowledge transfer among organizational units stimulates the creation of new knowledge, thus contributing to organizational units' ability to innovate [Tsai (2001); Kogut and Zander (1992); Tsai and Ghoshal (1998)]. In addition, Spencer [2003] contends that knowledge is viewed as a resource that accelerates technical progress (p.218). By acquiring technological knowledge from the innovation system such as research institutes, universities, and innovative corporations for the use of their own researchers, firms can increase their innovative performance (p.218). Therefore, knowledge sharing and exchanging can lead to the generation of new knowledge, which is an important driving force for innovation.

Nature of the innovative product--Disruptive innovation

Acclarent's main product may also be understood as disruptive innovation originating from the process of external knowledge transfer through interaction with other sources of innovation. Disruptive innovation is not a breakthrough innovation, rather, it is a process by which complicated, expensive products and services are transformed into simple, affordable ones [Christensen (2009, p.3)]. The innovation, therefore, should focus on understanding the “jobs” people need to do to maintain their health and how to make these jobs easier, more convenient, and more pleasant for them (p.13).

The innovative idea of Acclarent’s main product—Balloon Sinuplasty device—was derived from John Makower and his team’s clinical observations of how sinusitis patients underwent the standard form of sinus surgery called functional endoscopic sinus surgery (FESS) to treat severe cases of chronic sinusitis. FESS involves cutting and removing
Further look: the role of regulation and reimbursement in medical device innovation

As an external factor influencing the innovation actors, the role of FDA regulation and reimbursement system has been unique in the process of open innovation in the medical device industry.

FDA regulations exert a major impact on medical firms’ innovation. FDA regulations govern many activities that medical device companies perform, or activities performed on their behalf to ensure the safety and effectiveness of the medical devices distributed domestically or exported to other countries. FDA regulations play an important role in the economic success of small innovative firms due to the direct and indirect regulatory costs (especially delays in generating revenues) occurred in the commercialization of innovative products stage. In medical device industry, if product innovation is derived from compliance to the regulations, you need to involve clinical trials in the innovation process, which could cost millions of dollars, according to William Facteau, Acclarent’s CEO. Many venture capitals do not want to invest in medical device companies because it is too expensive and risky in terms of ROI, and because there is so much uncertainty involved due to the health care reform, stated Facteau. Such a trend may cause medical
device companies to select a path where clinical trials are not required in inventing new products. Consequently, further investigations of how FDA’s regulations facilitate or hinder innovation in the medical device industry (especially small firms) are called for.

For medical device companies, obtaining adequate coverage and reimbursement from third-party payers such as private health insurance companies, Medicare, and Medicaid for all or part of the costs and fees associated with using medical devices, is critical for medical device product acceptance and widespread adoption in the marketplace [Risk Factors]. Reimbursement constitutes part of the revenue of medical device companies and may be a crucial source of funding for continuous innovation in these companies. Acclarent claimed that approximately 15 third-party payers do not currently cover or reimburse sinus procedure performed with its Balloon Sinuplasty devices because they believe such devices is new and investigational [Risk Factors]. These private payers have generally required using a separate billing code that is unique for Balloon Sinuplasty [Risk Factors]. Nevertheless, the fact that the Balloon Sinuplasty instrument is considered a “tool” rather than a “procedure” allows Acclarent to get reimbursement from existing Category I Current Procedure Terminology, or CPT, codes relating to the various sinuses treated using FESS procedure. “These codes do not currently distinguish between FESS performed with Balloon Sinuplasty devices and traditional instruments” [Risk Factors]. In addition to the reimbursement from third-party payers, Acclarent had 6% of its revenue from international sales of its Balloon Sinuplasty devices by 2008 [Risk Factors].

Acclarent’s case suggests that the third-party reimbursement policies and the medical coding system may significantly impact the profits of medical device companies. As a result, the structure of the medical codes and payment guidelines can be vital affecting the medical device company’s innovation process. To determine if the Balloon Sinuplasty team should proceed further with the invention, Acclarent hired a professional reimbursement consulting firm to evaluate whether the use of their Balloon Sinuplasty devices could fit within the existing FESS codes. The team’s idea was able to be carried out due to the positive feedback they received from the consulting firm as well as a legal/reimbursement expert [Zenios et al. (2010)].

Acclarent’s case also reveals that there is complex knowledge regarding how to “categorize” the nature of an innovative device since different categorization could influence the pathway to innovation and the potential development of the end product. Future research should further investigate how reimbursement criteria, policies, and coding systems may have an effect on a medical device company’s innovation process.

Discussion and conclusion
Most of the existing literature in open innovation tends to focus on high tech companies when investigating factors related to open innovation, this paper adds to prior research in this field by extending the theory to the realm of medical industry. Acclarent’s case indicates that open innovation is one of the essential elements for medical device companies to explore the unmet needs in the market thereby sustaining its innovative capability in a highly competitive industry. We examined the five elements in the mechanism of the open innovation process. “Fulfilling the unmet needs” is necessary but not sufficient for an innovative product to be successful in its commercialization. Since medical device companies are regulated by FDA, familiarity with FDA’s regulations to obtain clearance for product pre-market approval is critical in determining whether the innovative product can be commercialized. In addition, revenue of medical device companies depends, to a large degree, on third-party payers’ reimbursement. Therefore, a thorough understanding of third-party payers’ reimbursement criteria and medical codes system is essential for medical device firms to be profitable.
A framework of the process of open innovation

A more important contribution of our study to the open innovation literature is the development of a framework in examining the mechanism of the core of the innovation process—knowledge exchange and flow. As West and Bogers [2011] argue: “accessing internal and external knowledge bases are key to the innovation process.” In fact, an innovation may be the result of fresh recombination of existing knowledge that creates new commercial value [Khilji et al. (2006)].

Previous literature on open innovation has investigated the role of different sources of ideas in facilitating innovation. However, a further investigation of how diverse knowledge is exchanged and integrated among various sources thereby sparking into innovation is lacking. With the case study of a medical device company, integrating theories from both the field of open innovation and the field of communications, our model (see figure 3) intends to close such a gap by linking macro and micro level of analysis in a hope to open a new path to expand and enrich the scope of open innovation research.

Fig. 3. A model of knowledge exchange and flow in the process of open innovation

The lesson learned from Acclarent’s case is that the success of a medical device start-up depends on how well the company can effectively manage the flow of knowledge to satisfy unmet needs, while integrating their in-depth knowledge of FDA regulations and third-party payers’ reimbursement policies into the product innovation process. Future empirical research is needed to investigate the complex interplay among the various actors in the open innovation process.
A framework of the process of open innovation

References


A framework of the process of open innovation


A framework of the process of open innovation


A framework of the process of open innovation


