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Internationalization of an Academic invention through successive science-business networks: The Case of TAVI

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Abstract

This paper explores and discusses the internationalization of a new medical technology that emerged out of a Danish university hospital. While the particular invention took place in the periphery of the international medical network, the new venture circulated to the most competent and influential international science-business networks in order to mobilize the resources and competencies required to develop the technology and make a breakthrough into the market. The study demonstrates that such an innovation process evolves through phases that call for very different resources and capabilities. It thereby becomes an opportunity to actors, networks and companies that control such capabilities to move in to take control and pull the venture through the next phase.

We argue that the new international venture and born global literature tend to overemphasize the roles of the entrepreneurial founders in international new venture processes. This study indicates that technology-based Born Globals and international new ventures are able to expand and scale very rapidly. This process is not a long distance run directed by the founding entrepreneurs, but more similar to a relay race where different, experienced entrepreneurs and firms successively take control and move the venture through the next phase. This radically reduces the need to learn as the new venture expands and scales. The process may require several such handovers. Our study also confirms that the inception period may be long and that networking activities in this period are important. However, we also argue that there are multiple inception periods along the innovation process. Each of these associates with entrepreneurial drivers that take control in later stages.

Keywords: network, academic entrepreneurship, medical technology, interaction, internationalization, life science industry, process study

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Introduction

This article is an empirically oriented paper addressing interactions and activities in the processes that brought a radically new medical technology from invention to international medical markets. As such, the case describes a typical Born Global (BG) invention and business development process. It addresses the roles of academic, institutional and business networks through the innovation process, emphasizing how the venture moved across different science-business networks over time, and transformed along the way. The study applies a networked interaction oriented perspective on new international ventures, such as represented by Johanson and Mattsson (1986), Johanson and Vahlne (2003), Etemad (2004a); Etemad (2004b), Evers (2010) and (Chandra et al. 2012). Our study also pulls from other process and network approaches to studies of innovation in business networks (Ciabuschi et al. 2012; Hoholm 2011; Håkansson and Waluszewski 2007; Van de Ven et al. 1999).

There is a considerable research interest in new international ventures (INVs) and born BGs (Moen and Servais 2002; Oviatt and McDougall 1994). In the early literature on firms' internationalization associated with the Uppsala model, it was seen as a gradual process from local to national and then to international markets over time. At the core of this early theory was the understanding that internationalization critically depended on learning and networking processes that take considerable time and effort (Johanson and Vahlne, 1977; 1990). However, an emerging feature of the recent global economy is that firms, even small new ventures, may internationalize from their very inception or shortly after the establishment of the organization, and may expand and scale at a fast pace (Oviatt and McDougall 1994). These INVs and BGs have been in focus in a wave of international business entrepreneurship research (Knight and Cavusgil 2004; McDougall and Oviatt 2000; Zahra 2005). Intensive R&D investments usually makes the home market insufficient for these most often technology-based ventures, and pressures them to cross national borders early or even at the very start of the venturing process (Almor 2000; Coviello and Munro 1995; McDougall et al. 1994; Rasmussen and Madsen 2002). There are also several recent calls for studies to assess factors that can either facilitate or inhibit the development of academic entrepreneurship into successful international businesses and to explore such approaches to explain it (Peiris et al. 2012; Siegel and Wright 2015).

We perceive that the core issue raised by the emergence of rapidly internationalizing and scaling of the business is to understand how they apparently circumvent the time and capacity building constraints of the learning dependent process that is core to the early internationalization theory. How can these small firms internationalize so fast if they do not possess the capabilities required? There has accordingly been a pressing need to examine how new ventures learn and what they learn (Zahra 2005).

Recently scholars have contended the phenomena of rapid internationalization by studying BGs beyond the lifespan of the legal entity. Several studies have claimed that the pre-founding process is significantly extended, therefore, increase the period without international activities (Hewerdine and Welch 2013; Laurell et al. 2013). At the same time, scholars emphasize the role of the pre-founding period of newly established firms where the entrepreneurs build their skills and experiences and build professional/personal networks. Some studies have in particular pointed at the networking activities in pre-founding periods as a critical factor (Andersson et al. 2013; Coviello 2006; Madsen and Servais 1997; Zahra 2005). However, there is still the question of how, after obtaining such pre-expansion capacity, founders of technology-based INVs/BGs manage to govern, coordinate

and control their companies through much more demanding and expansionary processes into highly challenging and variable global markets.

Researchers have generally taken the entrepreneurial firm as the primary unit of analysis when studying internationalization processes, where the firm and its entrepreneurs are seen as the primary drivers of the "entrepreneurial process". This study observes a critical discrepancy between explanations focusing on the founders and the firm, and reasonable interpretations of the process. We argue that INVs and BGs may be able to internationalize and scale at a rapid pace because they are using a development and scaling model that radically reduces their need to learn. Rather than a long distance run, it appears as a 'relay race' where the relay baton passes to those who are more capable to do the successive runs. In such a process, established science-business networked actors who already have the resources, competencies and experiences required at a particular stage in the overall process, move in to acquire ownership and pull the new venture forward - until they may hand it over to others.

This paper builds on data collected in a study of the emergence of a new medical technology called Trans-Aortic Valve Implantation/Replacement (TAVI/TAVR) from its invention at a university hospital in Denmark to its use around the world nearly 20 years later. Recent research on internationalization has drawn attention to the process-oriented, evolutionary character of internationalization in which path dependency and history are important (Chandra et al. 2012; Evers and O'Gorman 2011). We study the internationalization process from the early invention of the technology in 1988/89 to the first regulatory breakthrough in the form of a European Conformity (CE) approval in 2007, focusing on one of the two dominant technology companies in the TAVI market at the time; the US-based company Edwards Lifesciences.

Literature and Theory

Traditionally, internationalization has been understood as a long, time-consuming process. Small and medium sized enterprises (SMEs) have often proved unable to sustain international activities due to limited resources and lack of knowledge. Indeed, withdrawal from international activities was observed in a large group of SMEs (Freeman 2007). This traditional view concluded that internationalization depended on large firms, while small firms were home market oriented (Laine and Kock 2000). The wave of INVs and BGs since the 1980s has dramatically changed this view.

There are two main views on internationalization processes in the more recent literature (Rialp et al. 2005). The first is a process-oriented theory (PTI) associated with the Uppsala model (Johanson and Vahlne 1977). It describes internationalization as a gradual and incremental process in which business relationships are seen as channels for learning and aligning of relevant information and capabilities (Selnes and Sallis 2003). This stage-change model provides a self-reinforcing and path dependent pattern of international expansion where foreign market selection and modes of entry are based on network relationships (Johanson and Vahlne 2009; Kiss and Danis 2008).

The second view is represented by the international new venture theory (INV). It focuses on factors enabling early and rapid internationalization of in particular BGs (Autio 2005). Several studies have confirmed that many

small firms internationalize rapidly and do not seem to follow the gradual expansion process suggested by the Uppsala model (McDougall et al. 1994; Rennie 1993). Researchers in this school study companies that perform international activities from their inception (Oviatt and McDougall 1994). High-technology industries tend to internationalize at an early stage (Coviello and Jones 2004; Crick and Jones 2000; Jones 1999; Peiris et al. 2012). In this literature, the role of strategy is more significant, since both the focus and the pace of internationalization depend on the competitive characteristics of the market and the ability of the firms to move in them (Chetty and Campbell-Hunt 2004). However, it has also been argued that even though entrepreneurial start-ups may quickly internationalize, this does not necessarily imply that their actions are thoroughly planned. In particular, Crick and Spence (2005) claimed that actions of entrepreneurs may happen due to serendipity or, as Coviello and Munro (1995) and Ellis and Pecotich (2001) see them, random and somewhat irrational.

The learning process

The learning through experience is a critical part of the early Uppsala model (Johanson and Vahlne 2009). Hence, the emergence of INVs and BGs have caused researchers to raise questions about how they are actually able to expand and scale so rapidly. How can they learn so quickly and perform so successfully if the time to learn is limited and the development and scaling processes is so demanding? This problem has induced researchers to focus on the pre-organization phase of INVs and BGs. Hewerdine and Welch (2013) discuss whether 'new' is an appropriate description of entrepreneurial start-ups, considering their extended pre-organizational evolvement. In many studies, pre-organizational history and events are limited to the founders' careers and experiences (Madsen and Servais 1997); however, it is important to include early activites of entrepereneurs into understanding of the internationalization processes after the launch of the firm. Hence, 'organizational emergence' has been the subject of sustained interest from entrepreneurship researchers (Keupp and Gassmann 2009). Evers and O'Gorman (2011) - building on Venkataraman (1997) and Shane (2000) - argues that the internationalization process is strongly influenced by the entrepreneurs' prior knowledge and prior social and business ties. By incorporating the full process of inception, researchers have tried to capture the start of the internationalization process in order to understand the entire learning and networking processes (Madsen and Servais 1997; Sharma and Blomstermo 2003). In the medical technology industry, time lags between invention and commercial product are very common, but they can be considerably shortened if research has been conducted at a university prior to the founding of the firm (Gassmann and Keupp 2007).

Academic entrepreneurship and science-business networks

It has been acknowledged that research-based academic environments, including universities, government research centers and non-profit research institutes, develop knowledge for technological innovations and entrepreneurial start-ups (Audretsch et al. 2005; Cooper 1973). Centers with substantial knowledge concentrations generate more entrepreneurial opportunities than less concentrated ones (Audretsch and Keilbach 2007). Moreover, what has been identified as 'centers of expertise' typically create opportunities for breakthrough innovations through experimenting with emerging radical concepts (Ahuja and Lampert 2001; Venkataraman 1997). However, the realization of opportunities requires additional investments, knowledge and actions typically involving significant interaction with business partners.

In academic entrepreneurship literature, a few studies describe the process of the transfer of the concept or technology from an academic institution into a company identifying various phases (Djokovic and Souitaris

2008). However, they are not addressing the issue of internationalization of research results. At the same time, scholars emphasize the challenge of interactive communication between universities and companies in the process of commercialization of research (Markman et al. 2008).

Established research has emphasized the lack of commercial skills of technical entrepreneurs within public institutions and the lack of funding to commercialize the projects. Recent studies have also found that the owner-managers of young technology-based firms have limited experience of specific business functions, such as marketing, finance and personnel management. Additionally, in the case of university spin-offs, limited financial resources and limited access to business networks through personal relationships are particularly challenging.

There is a trend in innovation policy and strategy to help build more extensive research and development networks to deal with technological and market complexity and attract investors, resources, activities and actors to help foster high growth companies. University or research center environments represent attractive opportunities for investors and global companies to create innovation-oriented business networks. Research has suggested that such 'complementary relationships' give local entrepreneurs opportunities to link up with external resources and complementary knowledge (Roper et al. 2008).

There are many examples in the literature in which academic spinoffs have established the early foundation for the development of specific industries (Druilhe and Garnsey 2004; Müller 2010). The wave of INVs and BGs signifies something more than that - a different and more effective way to move a lot more such spin-offs to global markets. It signifies a different and more effective scaling model.

The significance of networks

Many scholars have studied networks and network relationships in order to explain the rapid internationalization of companies (Andersson et al. 2013; Ojala 2009; Ruzzier et al. 2006; Zain and Ng 2006). In this view, personal as well as international networks are seen as supporters of the venturing processes controlled and directed by the firm and – usually – its founding entrepreneurs (Zahra 2005). However, questions still persist as to how these entrepreneurs obtain the capacity to actually govern, coordinate and control these rapid expansion and scaling processes. How do they acquire the managerial skills to direct activities while internationalizing so rapidly into markets where they have limited or no experience at all?

In international entrepreneurship literature, a key consideration has been to understand how networks may enable BGs to acquire and mobilize resources for early internationalization (Coviello and Cox 2006). While the literature has tended to focus on the existing networks of firms, there is growing evidence that INVs actually have to build new networks. Nevertheless, since there are many pre-existing networks, the new business can be also seen as modifying existing business networks (Aaboen et al. 2011; Andersson et al. 2011; Cantu and Corsaro 2011).

The business network approach sees interaction as a fundamental aspect of new business development (Håkansson and Snehota 1989). It embraces the idea that interaction processes are effective ways to handle uncertainties, motion, variability and lack of knowledge on both sides of the relationship. The key strategy for network creation is related to the business context itself. The concept of 'strategic identity' introduced by Håkansson and Johanson (1988) suggests that relevance in the market is obtained through establishing and

maintaining relationships with other actors in the process to make it fit. Network positioning is essential and can shift over time. At the same time, actors in the network have a bargaining position – a capacity to influence the behaviors of related actors (Håkansson and Snehota 2006). However, unlike transacting objects (products or services) that are known to both partners, relationships tend to be perplexing in that their content is in a continuous state of alteration. Thus, interactions in business relationships entail additional costs and organizational adjustments related to aligning or organizing activities on both sides. The fact that continuous interaction occurs in various dimensions makes the process collective and costly for all of the actors involved. Based on this, it is not obvious that building and managing a network would be a rapid way to build and expand a given BG. The problem with the network explanation of the rapid process is that all of these network-building activities seem to align with the assumptions of the early Uppsala School rather than with the observation of rapid expansion and scaling of INV and BG processes.

Different entrepreneurial sources and opportunities in the venturing process

Johanson and Vahlne (2006; 2009) define opportunity as socially constructed market knowledge, where international opportunities are created in interaction with others. Interaction between different actors creates information flows where new opportunities are developed based on special knowledge, different roles and opportunities held by the different actors. When the idea is gradually shaped and shared in networks, it is more likely that the actors will identify the opportunities for them and commit the resources necessary to realize the opportunity (Dubini and Aldrich 1991). Styles and Seymour (2006) advocate going beyond the legal entity of the focal firm to focus on multiple firms, actors, and resources, as well as processes, history, networks and context in order to have a more holistic view of events and processes. In line with this approach, Styles and Seymour (2006, p.134) define international entrepreneurship (IE) as "the behavioral processes associated with the creation and exchange of value through the identification and exploitation of opportunities that cross national borders".

Chandra et al. (2012) suggested using opportunity as a unit of analysis instead of concentrating on the legal entity of the firm. Elaborating on this topic, they included the involvement of various actors, organizations and networks, and pulled from different definitions of the internationalization of entrepreneurship. They thereby obtain a perspective where many different actors represented entrepreneurial interest and capacity. In this study, we use this broader understanding of entrepreneurial sources to focus on the roles of different kinds of actors and the opportunities that are relevant to them in relation to the venturing process.

Rather than opportunity, however, which is something actors perceive of, we suggest to move the activities that build a new business around a new technology to the center of this investigation. Dramatic changes in the business developing activities over the course of the process are at the core of this investigation of how the needs of the venturing activities themselves relate to the different actors involved. This throws a spotlight on the understanding of the dynamics of interactions and confrontations, changes in roles and power, the dynamics of actor alignments and stakeholder negotiations during the internationalization process.

A knowledge and industrial capability based view

International entrepreneurship (IE) scholars have identified knowledge as the most important resource. Yli-Renko et al. (2002) claim that there is a positive relation between knowledge intensity and international sales. However, others have claimed that there is a lack of understanding of how knowledge is obtained

(Weerawardena et al. 2007) or developed (Freeman et al. 2010) and how it influences the process of internationalization (Kuivalainen et al. 2010; Mejri and Umemoto 2010).

INVs and BGs have to learn effectively and efficiently in order to accelerate the process of internationalization. However, we conclude from the literature, that neither prior learning by founders nor their building of networks can convincingly explain the wave of technology-based INVs and BGs and their rapid expansion and scaling processes. Rather, it suggests that the very need for extended processes of learning are reduced. Rapid internationalization cannot be explained by a sudden increased capacity of entrepreneurial start-up. Instead, this study focuses on the different ways that the new global venturing processes are organized and structured in an industrial perspective. The very scale of the phenomena of INVs and BGs suggests that it has to do with the capacity of a structured and highly experienced 'new business venturing' industry rather than with the enhanced capabilities of entrepreneurs and their networks.

Accordingly, the primary question for this study is: How can the rapid internationalization and scaling processes be explained in light of the knowledge, experience, resource and capability requirements needed to succeed?

This research approach in this article is to explore into these matters by means of conducting a single case study that follows the emergence of an INV/BG through its main processes and turning points from the conceptual idea to global market breakthrough.

Research context and methods

This study is part of a larger study of the emergence and adoption of the new medical technology; TAVI, at different heart clinics in Norway, Sweden and Denmark between 2012 and 2016. At the beginning of the research study, TAVI had been implemented in several countries around the world. An opportunity to research internationalization as a complex process has presented itself (Welch and Paavilainen-Mäntymäki 2014). Jones and Khanna (2006), as well as Welch and Paavilainen-Mäntymäki (2014), call for research that brings history and process back into international business studies to explore how history matters. These studies showed that a process-oriented research approach remains largely untapped and underdeveloped.

While there is still a dominant variance approach to explanations within IE, Hurmerinta-Peltomäki (2003) and Sharma and Blomstermo (2003) suggest making time and process more central to theorizing in internationalization process studies. It is necessary in some cases to reduce the importance of 'comparative statistics' in order to understand the phenomena in depth. While it has been widely agreed upon that process approaches are required, they have remained rare (McAuley 2010). Process research is concerned with understanding how things evolve over time and why they have evolved in a particular way (Van de Ven and Huber 1990). This is done by concentrating on sequences of events in order to explain change (Langley 1999; Miles and Huberman 1994). One important aspect of process research is that the data enables the incorporation of time and the capture of temporal evolution (Dawson 1997). Even though time is ubiquitous in process research, the inclusion of the time variable is very important to our efforts to explain the phenomena.

The case study method has been chosen since it is the more appropriate research approach when "how" and "why" questions are being posed and when the researcher has little control over the events (Ghauri et al. 2002;

Gummesson 2003). A case study is a history of the past and current phenomenon drawn from multiple sources of evidence (Leonard-Barton 1990) that allows researchers to trace processes in their natural context (Pettigrew et al. 1992; Halinen et al. 2012). In the life science industry (medical technology, biopharmaceuticals and pharmaceuticals), the orientation towards the global market has become a necessary condition for business development efforts. This investigation has essentially followed the development of two different competing suppliers of TAVI medical device technology: Edwards Lifesciences and Medtronic-CoreValve. However, this paper focuses on the Edwards case, since Edwards' valve was the first to be implanted in humans, later becoming the first TAVI valve to obtain FDA approval and thereby becoming commercially available in the US market.

We assume that several aspects of the context have shaped the internationalization process in the case we studied. Laurell et al. (2013) emphasize that international entrepreneurship in the life science industry is unique due to industry specificity, and should be studied separately from other high-tech start-ups. The life science industry in general, and medical technology in particular, is heavily regulated at the trans-national level, and strict regulations and bureaucracy can impede the process of internationalization. Additionally, export of the final product is restricted by different national standards and approval procedures (Stremersch and Van Dyck 2009).

This case will provide some answers to the overall research question. Our approach has partly been deductive and partly inductive, so that we use concepts that have already been described in the literature, and at the same time, gain inspiration from the data (Orton 1997).

Data collection

Process data are messy (Langley 1999). Process research requires high dedication over a long period of time and can be difficult for a single researcher to fulfill. However, it is not necessary to be present in the field during the whole process, since the analysis should not necessarily be based on the real-time data collection. Collected historical data can extend the time span of the process studied.

This particular research journey began when we became aware that the TAVI technology had been invented in one of the Danish university hospitals. We obtained general information about the technology's history and its development during an interview with a representative from Edwards Lifesciences in Oslo in the autumn of 2013. The next step was to investigate the early history of TAVI. Therefore, we made interviews at Århus University Hospital in Skejby, Denmark. The interview with the inventor, Henning Rud Andersen, was conducted in June 2014. Additionally, we interviewed various colleagues of the entrepreneur that worked at the hospital at the time of the invention.

We framed each interview around a series of topics: the background of the respondent, the history of TAVI development and how TAVI was introduced in Århus University Hospital, as well as the current status of the technology's implementation. Most of the interview was devoted to the process of TAVI's invention and development where the respondent identified critical events related to TAVI development and internationalization. We focused on "the "what", "why" and "how" questions concerning critical events, activities and choices that happened over time (Pettigrew 1997). This interpretation of the process gave us key events, names and dates that served as a skeleton for further investigation. The interviews were semi-structured,

and each of them lasted around one hour. All interviews were recorded and transcribed. In total, we conducted four interviews with practitioners at the hospital, including the inventor and one interview with the Edwards representative.

We further supplemented the interview data with other primary and secondary data sources. The secondary data collection included minutes from meetings, field notes from seminars with TAVI vendors' representatives and informal observations during annual conferences of TAVI's implementation involving current practitioners and suppliers in the field. The 'big three' of qualitative research include observations (participant or non-participant), interviewing (retrospective or real-time), and archival documents (internal or external) (Langley 2009). Use of secondary data allows researchers to examine temporally evolving phenomena in richer details. Comprehensive information about early TAVI development was obtained from the publications of various studies in the medical journals (Cribier 2012; Cribier 2014; Cribier et al. 2006; Cribier et al. 2004; Webb and Binder 2012). Other sources were health authorities' reports, news releases from TAVI suppliers, industry reports and news from Internet sources (among others, www.pharmamedtechbi.com and www.cxvascular.com), corporate fact sheets and brochures obtained during seminars and conferences. These documents enabled data triangulation across the written documents and the interviews to complement the picture and minimize the retrospective bias of respondents.

By studying internationalization as a change process, it becomes possible to combine different levels of activities and to look at the actions, reactions and interactions of multiple stakeholders as they sought to move from one state to another (Pettigrew 1987). In this study, we traced the history of the TAVI technology's development from two perspectives: the inventor and his engagement with the TAVI technology since the late 1980s, and Edwards Lifesciences and their activities in relation to the TAVI technology from the early 2000s.

Data analysis

We reconstructed the interdependent chain of events leading from the idea to commercial products available on the global market, in the order in which they occurred. One of the biggest challenges of data analysis in processual studies is "moving from a shapeless data spaghetti towards some kind of theoretical understanding that does not betray the richness, dynamism, and complexity of the data" (Langley 1999, p.694). The complexity and ambiguity of the data make it challenging to understand where to start. The ability to track the events along the time line can facilitate the detection of common surface patterns and the development of plausible explanations for temporal dynamics (Langley 2009). We used temporal sequences of events as the basis for tracing how and why the change occurred (Dawson 1994). We started analyzing the data with a visual mapping, a graphical data analysis that allowed us to present a large quantity of information in a small space (Miles and Huberman 1994). This type of data analysis serves as "an intermediary step between the raw data and abstract conceptualization" (Langley 1999, p.702), but at the same time, facilitates data reduction and synthesis. However, this type of analysis provides a rather mechanical quality (Langley 1999); therefore, visual mapping was supported by other approaches of data analysis in order to reach for deeper generalization. Further analysis involved a search for patterns or common sequences of events (Langley and Truax 1994) to proceed to middle-range theoretical explanations (Miles and Huberman 1994).

Following the process of technology development, we identified that there were several transfers of legal ownership. Therefore, we broke down sequential events into time periods using temporal bracketing data analysis (Langley 1999) We identified that within the flow of events, the change of the actors in charge of the technology development triggered natural periods of continuity in the activities pursued. Deconstructing the process into phases allowed us to have manageable pieces for analysis that facilitated the examination of how events in one phase changed the context that influences the events in the next phase (Denis et al. 2001). Analyzing the case retrospectively has enabled us to describe the roles of the new actors coming in. Each one shifted the trajectory of the new technology by pulling resources and knowledge from their networks that greatly affected the internationalization process. However, using this method, we are unable to uncover the actors' hardships in assessing and deciding on their opportunities along the way.

On this basis, we present the case by first providing the general background, and then focusing on each of the major turning points that marked the beginning and the end of each phase of the international innovation process. By doing this, we aim at focusing the punctuated process and the most important formative events that characterized the innovation process. This also highlights the science-business networks that acted upon it, as well as the critical factors and events that eventually transformed the innovation into an expanding new niche in the minimal invasive medical technology market in the area of severe heart diseases and care.

Background of TAVI technology

Before presenting the case study, we will briefly present the TAVI technology and the medical procedure that are the material substances of the innovation we have studied.

The TAVI technology and medical procedure offer a new treatment for people who suffer from severe aortic stenosis - which is a narrowing of the heart valve between the left ventricle and the aorta. This substantially reduces the capacity of the heart to pump blood through the body, causing blood to back up in the heart. The condition is life threatening and mostly concerns the elderly (Lindroos et al. 1993). More than 250,000 people around the world have severe, symptomatic aortic stenosis. Patients with these symptoms have very low survival rates unless they go through an aortic valve replacement procedure (Otto 2000). TAVI is a minimally invasive procedure in which an artificial valve can be implanted using a wire passing through blood vessels instead of having to do open-heart surgery.

TAVI, as a technology and medical procedure, has emerged and spread globally since 2002. The first CE approval of the technology was granted in Europe in 2007, and the Food and Drug Administration (FDA) approval in the US was given in 2011 for the first generation of TAVI valves (Dvir et al. 2012). In 2007, the aggregated number of TAVI procedures conducted across the world was approximately 1000. Two years later, the number had grown to 10.000, and by early 2014, it had risen to 100.000, in particular due to the rapid growth in Germany since 2007 and in the US since 2011.

The study: The emergence of Edwards' TAVI technology

In the following, we will present the case study by separating it into the four major phases of the process. These are separated by major shifts in ownership and control over the commercial rights to exploit the early invention. We will first present the early invention part of the story with a focus on the inventor, Henning Rud Andersen, highlighting the events that eventually moved the technology to California through an exclusive license agreement. Then, we will shift focus to the different sections of the process that followed, in which three different companies successively acquired and held the exclusive license. These three were Stanford Surgical Technologies in Silicon Valley, California, Percutaneous Valves Technologies in New Jersey and Edwards Lifesciences in Irvine, California. Table 1 illustrates the main phases of development of the TAVI technology.

Table 1 The four phases of the TAVI development process

Time span	Form of legal ownership	Actor in focus	Type of actor	Main activity
1988-1993	Patents	Henning Rud Andersen	Academic entrepreneur	Concept development
1993-2000	Exclusive license to the patents	Stanford Surgical Technologies (SST)/Heartport	New venture	No activities
2000-2004	Exclusive license to the patents	Percutaneous Valves Technologies (PVT)	New venture	Product development, experimental use
2004 until present	Exclusive license to the patents	Edwards Lifesciences	Global med tech company	Further development, production, marketing and sales

The inventor Henning Rud Andersen and the early emergence of TAVI

The concept of placing a heart valve on a catheter was first introduced in 1965, and an early catalyst of TAVI development was the first investigation of the concept of a balloon-expandable aortic valve on animals (Kodali et al. 2011). Our story starts in a Scandinavian university hospital heart center in 1988. Henning Rud Andersen, a cardiologist at Århus University Hospital, returned home from a cardiology congress in Phoenix, Arizona, with an idea to extend the new and successful stent technology at the time, to place a heart valve within it that could fit a human heart valve and be delivered through the blood vessels. This idea seemed crazy to most of his colleagues at the time, but his mentor, Professor Jørgen Fabricius, in Odense, was supportive to developing the idea further. Andersen then started constructing prototypes and did experimental implantations on pigs in the hospital's operation room. He sewed valves into an expandable stent using heart valve tissue from pig hearts he obtained from the local butcher shop. He then used a delivery device developed by Med. Doc. Alain Cribier in France in the 1980s for the balloon aortic valvuloplasty procedure (BAV) (Cribier et al. 1986).

Andersen and his team, after ten weeks of intensive work, performed the first in-animal implantation of a balloon expandable valve. On May 1st 1989, the first pig survived with a new heart valve. Andersen went on to file several patents on his idea, assuming the invention could have substantial commercial potential. After performing 15 operations on pigs, he filed the first patent application, and obtained his first TAVI patent in 1991, while continuing to build a patent portfolio to protect his intellectual property rights (IPR).

Andersen struggled to publish the results of these experiments. The major international medical journals were skeptical about the idea of implanting heart valves in unorthodox way as suggested by a completely unknown, young cardiologist from a small Scandinavian heart center. The rejection from the publishers was devastating. However, his is paper was eventually accepted by the newly established "European Heart Journal", which clearly had a low ranking back in 1992 (Andersen et al. 1992).

After publishing, Andersen sought to present his research at international conferences, but he only got accepted for poster sessions where he struggled to reach a bigger audience and attract attention from companies with sufficient resources to further research and develop the idea.

> "Nobody believed us. Neither the journals nor the conference reviewers nor the companies that produced heart valves and similar medical equipment. It sounded too crazy." (Informant 1)

Neither Århus University Hospital nor the Danish Technology Institute, which got involved in the patent filing activities, had sufficient funds to develop the technology further. Neither could they find relevant business partners for the project in Denmark.

> "Would you license it? You should know that if you have to do an investment, you have to put 200 million Danish or Norwegian kroner into the research program, which nobody believed in. And, I do understand the companies that showed no interest in the technology. If you go to a chief technical officer and ask: "Should I really put 10 engineers on this project and use 200 million kroner of research budget on such an idea?" No way!" (Informant 1)

At that point, Andersen started actively searching for global companies in the international heart valve business that would be interested in licensing and further developing his technology. He contacted the main players in the industry across Europe, and in particular in the US, including the companies Medtronic International (Minneapolis) and Baxter International; the global leaders in the cardiovascular heart disease industry. Neither of these companies responded positively to Andersen's offer.

The start-up company Stanford Surgical Technologies (later named Heartport)

In 1992, a representative of a small company called Stanford Surgical Technologies (SST) approached him at his poster stand at an international conference. This company had been established to commercialize minimally invasive heart surgery technologies out of Stanford University School of Medicine. This was the only company that came back to him with a keen interest in entering a license agreement to exploit the commercial potential of the patents. With the help of patent experts at the Danish Technology Institute, Andersen finally managed to sign a license agreement in 1993 with SST that gave the company the exclusive right to commercially exploit his patents worldwide. This was done in exchange for a modest yearly up-front payment and a license fee per item sold. Figure 1 illustrates the critical events in the opportunity-framing phase.

SST in charge of further TAVI development

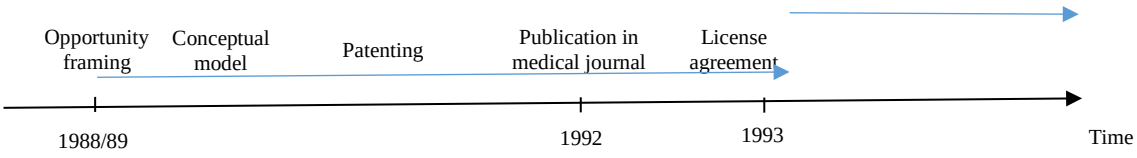


Fig. 1 Critical events in the moving of TAVI from Denmark to Silicon Valley

Two graduates from Stanford Medical School; Wes Sterman and John Stevens, founded Stanford Surgical Technologies (SST). It later changed its name to Heartport. It was a cardiovascular device start-up company developing products to perform coronary-artery bypass surgery and experimenting with minimally invasive approaches. In 1991, they had tried to do coronary-bypass and valve surgery without splitting the patient's chest. Based on the early success of this new approach, and with financial investments from two major venture capital firms in Silicon valley, they went on to build the company that came to represent a very early minimally invasive approach to this domain of medicine.

At that time, Andersen's concept fitted the general strategy of SST to work with related approaches to minimally invasive treatment of severe heart diseases. However, TAVI was also a separate domain that would require focus and substantial investments to be able to move from idea to product. Even though TAVI was an attractive investment given the growing external interest in the minimally invasive cardiology approaches at the time, SST ended up not giving priority to developing Andersen's idea, and merely added it to its portfolio of potentially interesting technologies.

The TAVI start-up company Percutaneous Valves Technologies

When Andersen realized that SST was not putting resources behind his invention to develop it, he approached and tried to convince other medical equipment producers to acquire the license or the entire company. The person he finally managed to get interested was a man named Stanton Rowe. Rowe worked with marketing of coronary stents at Johnson and Johnson (J&J) at that time, and Andersen finally convinced him to bring forward a proposal for the board of J&J to acquire SST (Heartport). However, the proposal was rejected at the time, and nothing seemed to happen for quite a few years. Stanton Rowe, together with his close colleague at J&J, Stanley Rabinovich, moved on to work for Datascope Corp., a company manufacturing and selling intra-aortic heart pumps and vascular closure devices. Regardless, they continued to pursue the idea to develop minimally invasive approaches to treat aortic heart valves.

J&J eventually acquired Heartport in April 2001 for USD 81 million in stocks, which it then moved to become a part of Ethicon, Inc. - a global leader in developing and marketing products for surgery. However, in December 2000, a small start-up company called Percutaneous Valve Technologies (PVT) had acquired the Andersen exclusive license from Heartport. PVT had been established in 1999 and was owned by Rowe and Rabinovich along with Professor Alan Cribier from France and Professor Martin Leon at Columbia University Hospital. In this start-up, Rowe had created an international cross-disciplinary team with world leading interventional cardiologists and bioengineers committed to creating a functional prototype valve to exploit the Andersen license.

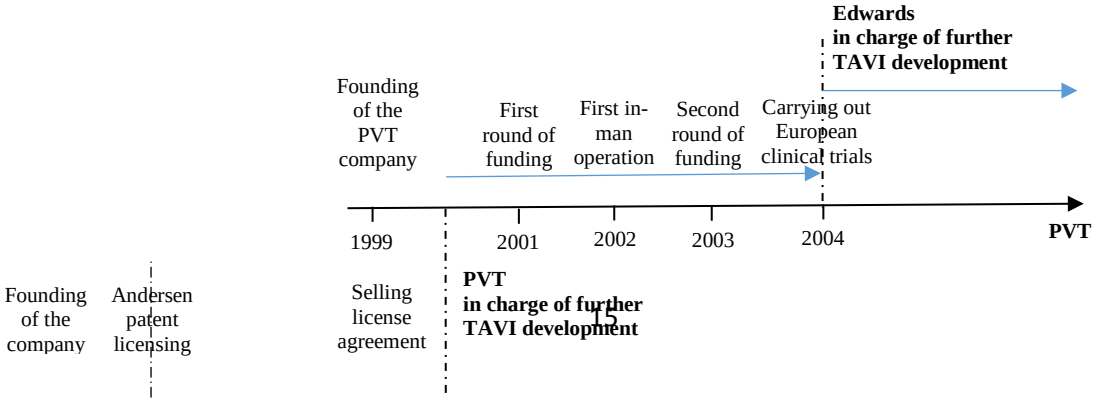
While PVT was raising financing in the equity market, major players in the field were skeptical, if not outright aggressively against it. The experts in the field of heart diseases, the thorax surgeons, generally rejected the concept of delivering a folded-up valve through a blood vessel by using a catheter, fearing that interventional cardiologists would take over yet another major area of patient treatment from the surgeons. Hence, it was a challenge for PVT to introduce the new product without support from the key experts in the area of cardiac surgery.

Meanwhile, PVT accelerated product development and started performing animal trials with the first prototype in September 2000. They aimed at developing a balloon expandable trans-catheter heart valve (Cribier 2012). PVT searched for resources and managed to interest two Israeli venture capital companies (Medical Venture Partners and Oxford Bioscience Partners). Finally, they invested 5.5 million dollars in the first round of funding in 2001. The intensive work on the TAVI technology resulted in the first in-man operation, which was performed on April 16, 2002 by Alain Cribier at the University of Rouen, France (Cribier et al. 2002). This event was a crucial breakthrough for PVT, demonstrating the feasibility of the new technology, which received substantial attention in the industry.

The PVT start-up, located in New Jersey, USA, Israel and also with a strong presence in Paris, managed to turn around much of the global medical society's attitude towards minimally invasive treatment of aortic valve malfunction. After the successful operation, several major players in the field showed interest and participated in the second round of funding where Boston Scientific Corporation, Medical Venture Partners, Medtronic Inc., and Oxford Bioscience Partners invested, altogether, 14 million dollars in the company.

Clinical trials, as a part of the approval procedure necessary for medical technology to become commercially viable, started shortly after the first in-man operation. Cribier and his team obtained permission from the French Administration to start feasibility studies at the University of Rouen shortly after the first in-man operation (Cribier et al. 2004). The team worked hard to refine the technique and assess the short- and long-term outcomes. Despite serious challenges, including the early deaths of several patients, these early experiences confirmed that a trans-catheter valve implantation was indeed feasible for patients with end-stage life-threatening calcific aortic stenosis. These studies were also the first steps to gaining market acceptance from the international opinion leaders.

In the wake of these early achievements, PVT, less than five years after its inception in 1999, was acquired by Edwards Lifesciences, Irvine, USA in January 2004. This moved the new technology into the hands of an established market player in the global heart valve market, starting a new era for the TAVI technology. Figure 2 presents the two attempts to launch the business to develop TAVI technology.



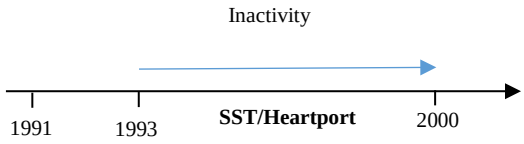


Fig. 2 Critical events in moving of TAVI from Silicon Valley to New Jersey, Israel and France

Edwards Lifesciences and the establishing of a dominant role in the TAVI market

Edwards Lifesciences Corp.,Irvine, California, acquired the PVT company but there were several critical events leading to the acquisition. Edwards was established in the year 2000 as a publicly listed spin-off from Baxter International Inc. The company specialized in heart diseases and was a dominant actor in the surgical heart valves market. The newly established spin-off company was looking for new opportunities to grow, since it had experienced slower growth within its core markets for heart surgery products. At the time, the company explored several areas outside its established domains, with no particular focus on the new PVT heart valve technology.

In 2001, Edwards launched an internal R&D trans-catheter heart valve development project called "PATRIOT". The project resulted in a design of their own TAVI prototype successfully used in animal trials, but the project did not receive particular attention at the strategic level until Cribier's first in-man TAVI procedure in 2002. This event led the company to reconsider its search for growth areas outside its traditional domain, to focus on the potential for expanding its established leadership in surgical tissue heart valves into a potentially emerging rapid growth area for trans-catheter aortic valves. Those valves were very attractive to Edwards because they would not replace the traditional surgical valves in their current surgical markets, but rather enlarge the total market by including previously non-treatable patients.

Edwards acquired PVT by placing an attractive bid on the entire company. Other industrial competitors were waiting for the technology to mature. Edwards, in this way, managed to acquire the company, including Andersen's exclusive license agreement, in front of the others for USD 125 million, plus up to USD 30 million in payments upon the achievement of key milestones. It also moved resources to prioritize the internal catheter-based valve project while simultaneously reducing investments in other non-core technologies, and by acquiring other start-ups in the interventional cardiology domain.

The company decided to enter the new market aggressively, while also seeking to maintain and grow its traditional surgical markets. They included PVT as a rather separated, clearly focused part of the large company, with major activities being conducted as far away as Israel. Stanton Rowe became the leader of Edwards' TAVI activities, assuring direct continuity from the PVT activities. The whole team of the PVT company joined a separate newly-established division focusing only on minimally invasive catheter-based technologies. The PVT acquisition triggered substantial debate within Edwards, as several of Edwards's officials argued that their own technology was better than that of PVT. However, PVT was at least one year ahead, since the first in-man operation and two rounds of feasibility studies had already been performed. Prior to the acquisition, Edwards did not have any in-house competence on interventional cardiology, and thereby acquired world-leading competence with extended global professional networks. This induced Edwards to mobilize its resources behind PVT's technology and thereby obtain a first mover advantage. The potentially disruptive character of the innovation

was deliberately and systematically turned into a complementary and collaborative strategy to advance both across the surgeon – cardiology divide.

Edwards took the results of PVT product development and embarked on bringing TAVI technology to the next level in order to gain the acceptance of the global cardiovascular community. For instance, Edwards focused on new specialized delivery systems for the valve by finding new access points and delivery routes (transapical and transfemoral). Led by cardiologists, PVT's breakthrough was solely designed for interventional cardiology. There was no role for surgeons. Therefore, Edwards realized that apart from the trans-femoral approach that is familiar to interventional cardiologists, it was critical to develop the trans-apical approach that requires a surgeon's skills to access the heart. Since the entire customer base of Edwards at the time was surgeons, it was critically important that the valve could be used by both surgeons and cardiologists. Hence, the trans-apical procedure became a cornerstone in the company's effort to build a partnership between cardiologists and surgeons.

Edwards was also able to quickly and significantly improve the quality of the valve itself, by taking the first 'Cribier-Edwards' valve further to what became the first generation of Edwards trans-catheter valves. These accelerated activities of Edwards resulted in the continuation of the CE marking clinical trial program in the European Union and in the launching of the FDA approval process in the United States for its first balloon expandable valve (Min et al. 2013).

According to FDA regulation procedures, assessment of basic safety and potential for effectiveness is made based on evidence from feasibility and pivotal studies. Edwards had enough resources to carry out studies to obtain primary clinical support for a marketing application. The first study, REVIVAL I, was approved by the FDA on January 26, 2005. Unfortunately, the results of the first feasibility study were very poor. As a result, the study was suspended until further modifications of the delivery system were done.

Edwards, as the only company with sufficient knowledge about the new treatment, also had to take responsibility for providing training for practitioners. The device was significantly improved, and the second feasibility study, REVIVAL II, was approved for both delivery systems; therefore, the interests of both professional groups were balanced. After two feasibility studies, Edwards got FDA approval to launch clinical trials for the trans-femoral approach in March and the trans-apical in December 2007.

At the same time, French investigators were able to assess TAVI after several European feasibility studies (REVIVE, PARTNER and TRAVERSE trials) were finished. As a result, in September 2007, the Edwards SAPIEN trans-catheter aortic heart valve technology with the trans-femoral delivery system received a CE mark. As soon as Edwards received the CE mark, it initiated a broad marketing campaign from its European headquarters in Nyon, Switzerland, in order to get ahead of its rival, CoreValve. In December 2007, Edwards announced the CE mark approval for European sales of its Edwards SAPIEN trans-catheter aortic heart valve with the trans-apical delivery system. Both versions of TAVI became commercially available in 2008 (Walther et al. 2012).

After getting CE-marking, up to 30 hospitals were interested in performing TAVIs with the new device in Europe. The results of various studies across the world substantially supported the increased interest in trans-

catheter valves at the core medical conferences. Figure 3 illustrates the critical events in the phase of commercialization and scaling up.

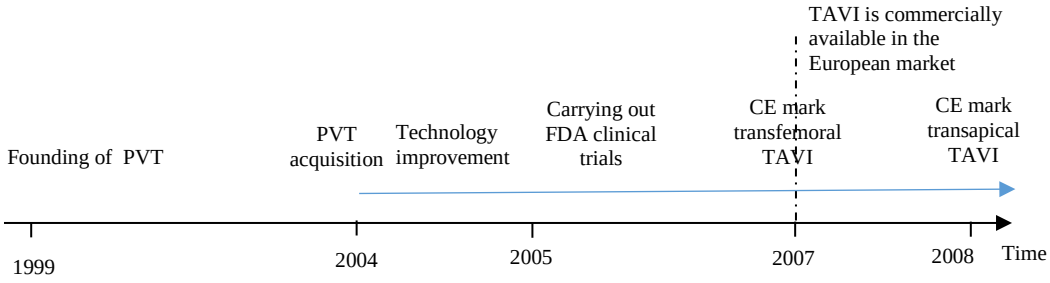


Fig. 3 *Critical events in the phase of commercialization and scaling up*

Case findings and analysis

The data suggest that the development of a business opportunity such as TAVI evolves through various phases. The transition between phases is associated with the transfer of legal ownership and the change of entrepreneurship in charge of the development. The case illustrates how control over the invention and the innovation process moved from firm to firm through license agreements, financial investments and acquisitions. These shifts are important because they indicate the points where lack of knowledge, resources or networks to others hindered further rapid development of the venture. Not only did the actor in charge shift, but also qualitatively different international networks were mobilized in order to perform the various activities necessary in the different stages of the innovation process. Importantly, a transition period overlap between two neighboring phases where pre-inception periods occurred in the beginning of each consecutive phase. These concerned the entrance of additional entrepreneurs at later stages in the process.

We accordingly analyze this case by emphasizing the sequence of phases that lead through three radical re-configurations and re-combinations in two successive international start-ups and a major incumbent medical technology company, each with particular, extended networks of resources, activities and actors. Figure 4 presents a graphic illustration of the process of TAVI technology development.

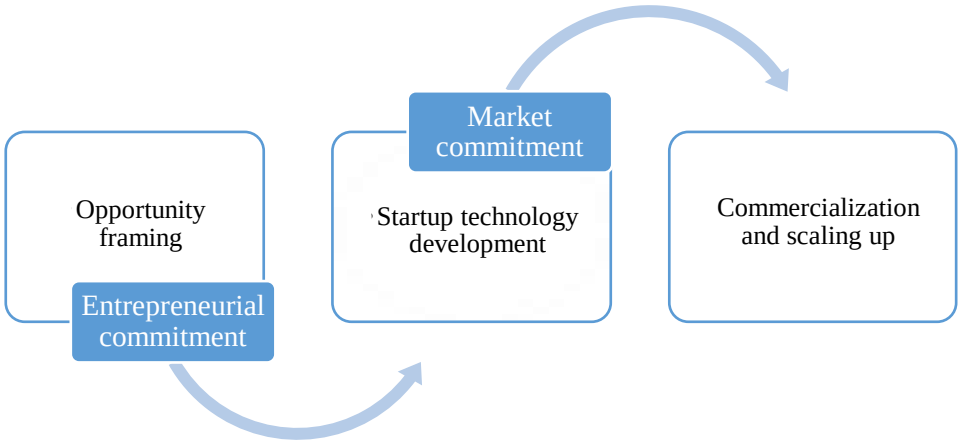


Fig. 4 *A basic model of the development of TAVI as an international new business*

Opportunity recognition and framing from research

The early idea was clearly based on knowledge developed among many experts in the cardiovascular field, as it emerged out of the dynamic, new area of medical stent technology in the late 1980s. The sticky knowledge (Elwyn et al. 2007; Szulanski 1996) accumulated by physicians through many years of practice, served as a foundation for opportunity discovery (Shane and Venkataraman 2000), which is usually shared during meetings and conferences. Therefore, the knowledge circulates in the international society of physicians, linking experts from leading research university hospitals.

The 'eureka moment' happened during a medical conference on this topic in Phoenix, Arizona. It was mostly the creative work of building the first prototypes, doing early experiments and filing early patents, that took place in Århus, Denmark. In other respects, the idea from the very beginning was associated with a particular international medical environment. Different prestigious medical hospitals, such as Stanford, Columbia and Rouen in Paris all got involved into the unfolding events. These medical hospitals with their vast networks of international leading experts in the field, played more important roles in the later rapid internationalization of the technology process than did Århus University Hospital. Therefore, TAVI was truly a born global technology start-up venture (Oviatt and McDougall 1994).

Having a proven patented concept, the founding entrepreneur realized that leveraging his local networks would not at all be sufficient to source, develop the technology and build a company to become a success in the international medical device market. Local actors such as Århus University Hospital and the Danish Technology Institute, held little importance for the internationalization process since they could not pull together the funds and experts necessary to launch a new venture and exploit the opportunity further (Andersson et al. 2013).

Uncertainty regarding the technology and lack of ability to make the connection between specific knowledge and a commercial opportunity (Venkataraman 1997), forced the entrepreneur to cooperate with existing medical device suppliers. By accessing global actors in the industry, he aimed at mobilizing international networks to accelerate the internationalization process at the inception. However, due to limited data proving the concept and strong opposition from dominant actors in the market (i.e. the surgeons), established medical technology companies considered the technology unproven and immature.

Launching a new venture to develop minimal invasive heart decease technologies

The transfer of legal rights to another entrepreneurial start-up located in the medical technology hub at the center of Silicon Valley, potentially provided access to venture capital and international networks. SST (Heartport) was located at the center of the Silicon Valley and had close associations with Stanford University. The leaders of the company were already proven innovators in the area of minimally invasive medical procedures. Investment opportunities in this industry are most prevalent in North America and the UK in the venture-rich medical technology hubs such as Silicon Valley, San Diego, Boston and London. Given Andersen's lack of attractive alternatives, SST had the most powerful negotiating position represented by its potential for mobilizing the resources needed to bring the invention to the next step. However, limited by resource constraints set by the investors in line with their exit-oriented strategy and faces with several other business development opportunities, SST did not have the entrepreneurial commitment necessary to move the technology to the next stage. Hence, in order to overcome the 'critical juncture' (Vohora et al. 2004), somebody else would have to take

the initiative. At this stage, TAVI was still in the pre-inception phase, since there was no working business plan and no operational activities (Hewerdine and Welch 2013).

The development of the concept did not progress until the entrepreneur pursued opportunities to move the license to a different venture by using his personal network. With increased interest in minimally invasive solutions in the market, the entrepreneur managed to involve an actor with access to the competencies, the critical IPRs, the financial resources and the most prestigious actors in the core areas of expertise. This process took several years, extending the pre-founding phase (Laurell et al. 2013). Or rather, it represented another pre-founding phase up to the establishing of PVT in 1999.

As a highly experienced business manager from within large medical technology companies, Stanton Rowe built an operational start-up company with the potential to bring the technology forward with sufficient speed. Through entrepreneurial networking processes, a number of critical interrelated deals were done to gather the two critical IPR elements. Cribier's balloon technology and the exclusive Andersen license, needed to mobilize the financial network (Pettersen and Tobiassen 2012). Stanton Rowe was a boundary spanner who could communicate the idea with both medical technology markets and experts working on technology development, bioengineers and cardiologists (Markman et al. 2008). The fact that he was able to pull together the resources, competencies and partners needed, brought the innovation to the next phase of building an operational business. Substantial technological, organizational and operational progress by the new start-up company spurred interest in the new technology from both financial and industrial investors, however, the entrepreneurial team did not have sufficient competence and resources to move the technology fast through regulatory systems and provide marketing operations to a large number of hospitals all over the world.

Commercialization and scaling up the business

Pulling a new medical technology successfully through various regulatory processes and radically scaling the operation, requires very different resources, capabilities and experiences than building an operational start-up company. The technical, operational and regulatory challenges faced by the studied start-up company were tremendous, and the economic window of opportunity narrowed in time since the time to expiration of the core patents shorted. Edwards was the company that eventually took the initiative to acquire the legal ownership of PVT, including the license, the technology, the management and its entire business- and professional networks. This move brought the TAVI venture into a production and market organization with the capacity to pull the new technology through the challenging processes of fitting the technology into the market and scaling up the business. An actor capable of bringing the new technology into sustainable international business that came from further down the value chain.

With Edwards' PVT acquisition, the interventional cardiology networks collected in PVT merged with a company dominated by cardiac surgery networks and markets. This new combination of resources and competencies was essentially driven by market knowledge (Styles and Seymour 2006). This substantially shaped the overall strategy of how Edwards moved TAVI further based on the collaborative partnership idea. Finally, the user-oriented activities, like development of new delivery systems and training programs, contributed to the influential entrepreneurial force that once again transformed the new technology and medical procedure. These

activities served as a base for the further establishment of a relationship commitment between suppliers and users with the aim of developing knowledge related to the TAVI technology (Johanson and Vahlne 2006).

Discussion

The history of what emerged to become Edwards' engagement in TAVI, clearly illustrates that in taking advantage of a new technology in highly internationalized industries, the market eventually clearly favors incumbents. Such a company already has an established market position with extended and long lasting relationships with the users of the products. It also has vast resources, broad in-house competencies and experienced management with a deep understanding of the particularities on the customer, the regulatory and the user sides of the market. It clearly also illustrates how an international new venture may be able to develop and scale rapidly when it is successively handed over to companies and networks with the adequate resources and capabilities to carry out the next development phase. What takes time, in this case, is when the INV is controlled by someone not willing to or able to mobilize such resources and capabilities.

The case provides an illuminating image of the diverse challenges involved in moving a new, untested technology through the many development, upgrading and validation processes required to bring it to safe, proven and efficient use in heart clinics around the world. There were several setbacks, turf battles between professional user groups, difficult strategic options and challenges, etc. that needed dedicated market commitment and experienced leadership at the most influential international levels of these many critical activities.

Pre-founding phase in the academic environment

The fact that INVs and BGs engage in cross-border activities from their establishment has pushed several researchers to focus on the pre-organization phase as a part of the internationalization process (Hewerdine and Welch 2013). However, not many scholars have emphasized the role of academic entrepreneurship in the process of internationalization. By incorporating the process from an idea's inception and following the process from there, we try to capture the origin of the internationalization process.

We found many similarities with processual studies of spin-off formation (Ndonzuau et al. 2002; Vohora et al. 2004), in which the spin-off process is described as a sequence of distinct phases of activities (Djokovic and Souitaris 2008). In both cases, academic entrepreneurship is a pre-founding phase of start-up development. In our study, we extend the process up to international commercialization; nevertheless, our findings are compatible with Vohora et al. (2004), who asserted that each phase is an iterative and non-linear process, and that the technology has to pass through the previous phase in order to progress to the next one.

Analyzing the pre-founding phase in the context of a higher education institution, we found that the relation to international networks of researchers stimulates connections to the international society that may support global development. The transformation of the actors in academic networks into sources of knowledge and expertise is another advantage of connecting to existing networks of researchers for the development of business opportunities. It is much harder for domestic firms with no international relationships and extensive domestic experience to change their mental models and processes than it is for networked BGs (Sharma and Blomstermo

2003). The fact that the connection to an international network of experts is a critical aspect of early internationalization is consistent with the findings of Hewerdine and Welch (2013), who claimed that internationalization emerges during the idea gestation phase, rather than upon startup launch.

It took more than 10 years from the conceptual idea until the PVT company had established a working business for TAVI development. This observation of a rather long pre-organization process is clearly in line with Laurell et al. (2013). Focusing on the establishment of the legal entity of an entrepreneurial company might create a false idea of the speed of internationalization and relate the ability to internationalize early to the internal capabilities of the firm (Autio et al. 2000). Internationalization during the pre-founding phase as a defining feature of BG contradicts the conventional understanding that age is the basic advantage associated with internationalization (Zahra 2005).

Multiple inception processes

In each situation in which new entrepreneurs further down the value chain moved in to take control, there was also a new inception process of variable length. In the three incidents in this case (SST/Heartport, PVT and Edwards), the inception period lasted 2-4 years before they eventually moved in to acquire control and re-combine the acquired assets with complementary resources and competencies. While they were doing whatever they could to move the venture forward, somebody also worked on bringing in actors further down the development path and up the value chain that could take the venture through the next phase - some time ahead.

With the loss of control by those who have pulled the project through some stage of the process, the exit options become critical, and Andersen, Heartport and PVT investors and entrepreneurs managed to harvest substantial economic benefits from their efforts, even though somebody else took control of the firm. In fact, this ability to exit from the process when somebody else should be driving it is a key mechanism for aligning the different actors and negotiating stakeholder roles during the entire process. Without it, the early stage entrepreneurs would have had limited options to harvest from their efforts in such a rapid growth born global venture as TAVI.

Understanding internationalization processes

The study confirms that internationalization of medical technology does not necessarily expand according to the early Uppsala model where internationalization depends on the learning capabilities of the company itself (Johanson and Vahlne 1977). Nor can it convincingly be seen as a process in which entrepreneurs expand and internationalize by building on their own networks in line with arguments in the entrepreneurial network literature (Coviello and Cox 2006; Sharma and Blomstermo 2003). The case rather confirms that in highly internationalized industries the rapid expansion process may be described as a successive handover of the project from business network to business network, including the transfer of legal ownership and control and the physical moving of the core of the activity to different locations. It is not a long run competition, but rather a relay run across very different landscapes.

The case illuminates three successive handovers to different development processes organized by different entrepreneurial actors. First, there is the opportunity framing and early attempts of the start-up founding phase driven by the academic entrepreneur. Then, there is the handover from the early search to the potential building of an operational business that might execute a plan and enroll the resources, driven by entrepreneurial business

developers. In this case, the first start-up never really moved forward, which led to a second try by a different entrepreneur and business network who managed to move rapidly forward. Finally, there is the accelerating and ramp-up stage, performed by a large incumbent firm. These observations confirm that a more open approach to studying the roles of different entrepreneurs that see different opportunities for themselves in such processes, may lead us to a different integrative model with a different and more dynamic view of the process (Peiris et al 2012).

In line with Andersson et al. (2013), this study confirms that actors with solid bases and networks in large incumbent firms become important entrepreneurial drivers at a certain critical stage, essentially transforming the venture from a research and development modus to a marketing modus. Their experience in regulatory procedures, sophisticated product development, broad mobilizations of resources, activities, actors and competencies, and on raising the necessary financial resources significantly accelerates the process.

The transfer of ownership and control through the process

The moving of the property rights through license agreements, investments and acquisitions moved the technology development from context to context with different resources, competencies and strategies. It illustrates the fact that the process of internationalization involves having adequate knowledge of external resources and capabilities (Sharma and Blomstermo 2003). However, to understand the process of global opportunity development, it is not sufficient to follow a particular entrepreneurial firm, but rather to follow the path of the evolving entrepreneurial opportunities (Chandra et al. 2012; Styles and Seymour 2006).

The case illustrates that the venture's internationalization process should not primarily be seen as a process in which entrepreneurs create a new technology and push it towards the market by building their network (Coviello and Munro 1997; Pettersen and Tobiassen 2012). It is rather a process in which successive entrepreneurs and actors further down the value chain, are the dominant drivers of the process. They find opportunities relevant to them at different stages of the innovation process and act by moving into the venture to take control by means of financial investments. From there, they move the venture into their business networks and start pulling it from the less developed stages through the next level of development. The reason why these actors obtain such dominant entrepreneurial roles and completely alter the process is that they control the resources and competencies required to carry out the next phase. It is accordingly, 'the needs' of the new venture that implicitly drive the moving of the innovation and global business development process, and it is those who can supply what is really needed that are the critical entrepreneurs in the various stages of the process. In our case, this moving in of next phase entrepreneurs always occurred through the acquisition of real control over the venture and the exclusive licenses through venture capital or industrial investments.

The reduced need for learning that speeds up the internationalization processes

Pettersen and Tobiassen (2012) suggested that entrepreneurs build networks with actors that can develop into more multiplex networks. We agree that networks provide a key mechanism for INVs and BGs to gain access to resources that they are unable to develop themselves (Oviatt and McDougall 1994), but networking is very expensive, and small firms possess fewer resources (Perez and Sánchez 2003). Since BGs internationalize quite rapidly, one may assume that only entrepreneurs with extensive networks can internationalize rapidly. We have demonstrated another mechanism that radically reduces the need for learning. A multi-actor perspective reveals

that by handing over the project from one network to the next, the need for learning is radically reduced – because the new actor-network can much more easily develop what the previous one could not. Because they have been going through similar processes several times before.

This study also observes that the business model of typical venture capital firms often practices the staging and handing over of innovation projects. To understand INVs and BGs, we obviously have to understand the critical role of the international venture capital industry as a professional industry in the very business of moving new technology ventures from local start-ups to global firms as rapidly and effectively as possible. BGs may be seen as the offspring of such highly structured industries that clustered around the most concentrated academic-business environments around the globe. From the perspective of academic entrepreneurship, it is accordingly critical to understand that building BGs locally around a university also requires the strong presence of the venture capital industry – or something similar – to take on this functional role as the "orchestrators" of the BG business venturing processes.

Conclusions

This study of the emergence of the TAVI confirms that the internationalization of a new technology venture may not be consistent with the early Uppsala model. Its ability to move from a position as "born global" results from its actual roots in international academic networks, and from its connectedness to some of the core nodes in these networks to business networks – included in particular Venture Capital firms – that are in the business of developing and scaling such technology ventures. While the early experimenting and patenting associated with the particular invention may occur anywhere in the academic network, the new venture may have to circulate towards the most concentrated academic-business networks around the world in order to move from invention to successful innovation. The crucial explanations of the INV and BG phenomena is not solely related to the network building capabilities of the founders; it is rather the existence of these very capable and interactive innovation eco-systems that matters. Accordingly, the study supports an integrative model of entrepreneurship (Peiris et al. 2012).

Secondly, the case illuminates that the reason why technology-based INVs and BGs are able to move so rapidly, may be because the need for learning that requires a lot of time, is radically reduced by the staged, handover of ownership and control business development model applied. People, companies and networks who have done similar things before, move in, take control and bring the new venture through the next phase. Later, the venture may be handed over to somebody else and eventually some incumbent player may acquire it and scale it through its already established international apparatus. The study indicates that the ability to expand and scale a new international venture like TAVI, is closely associated with what can be referred to as "the global scaling industry", which in particular contains the Venture Capital industry. The role of the global Venture Capital industry as core drivers of INV and BG processes should be more thoroughly studied and theorized by IE, INV and BG researchers.

Furthermore, this study confirms that the inception period may be very long, also when the new venture depends on patents that will expire some time ahead. However, we also argue that in order to understand the innovation

process as a successive handover of entrepreneurial control process, we also need to understand the inception process of each of the major actors that eventually take control at later stages of the process. In this study, we found that all of them had inception periods of between 2 and 4 years before they moved in to acquire control of the IPR or the company.

These conclusions add elements to the integrative model (Peiris et al. 2012) to provide a more adequate view of in particular technology-based INV and BG innovation processes. Entrepreneurship is a networked and staged process where different nexuses of actors, activities and resources address the opportunities in the different stages of the process, and act to take advantage of them. As also indicated by Peiris et al. (2012), the integrative model can be modified by including a timeline, and we suggest that this should be represented by different stages of the innovation process.

Limitations

As is the case of most empirical investigations, this study faces some limitations as well. First, the study is restricted to technology firms within highly knowledge intensive sectors. Although it seems that proactive international venturing is significantly typical for these firms, it may also be interesting to investigate the research question in other industries such as various consumer product sectors. This may increase the variance of explanation and may further differentiate the knowledge reducing mechanisms utilized to increase the speed of internationalization and scaling. As noted in the methodology chapter, a single case study is subject to obvious limitations with respect to generalizability and such biases as misjudging the representativeness of single events.

Implications for practitioners and policy makers

To academic entrepreneurs, this case suggests that it is necessary to acknowledge that the venturing process critically depends on others, and that usually, the critically important "others" will prefer to take control over the venture if they are to engage. Any strategy will then have to consider how far into the internationalization and scaling process one should aim at controlling it, and how one should work to mobilize those who control the resources required to bring the project through the next phase. Beyond this, the engagement with global knowledge networks that are particularly relevant to the invention is a core activity that could be of critical importance to the success of the venture. The venture capital model clearly reflects the characteristics of this kind of ambitious global growth innovation project based on scalable technologies.

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