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The roles of deals and business networks in innovation processes

Abstract

This paper analyzes the roles of deals in innovation processes based on our definition of a deal as the interaction of social-material value creating processes with money-handing processes. The paper is based on a study of Transaortic Valve Implantation (TAVI) as an innovative new technology in the area of thoracic surgery in a global setting.

We found that deals play important roles in innovation processes as critical junctions marking entries to different phases and generate major shifts in location as well as the combination of resources, activities and actors. These shifts include radical changes in control, where actors in possession of resources necessary to bring the project through the next phase, move in to take control, thereby expanding their businesses into new growth niches. Based on the analysis of seven deals, we argue that the innovation process is a process pulled by later stage entrepreneurial interests, rather than pushed by early stage entrepreneurs. This poses a critical argument against the entrepreneur-oriented explanations in the international new venturing literature, and points to the international venture industry and incumbent companies as the primary drivers of new international ventures.

This work also highlights why and how an innovation that may initiate anywhere in the periphery, will tend to move to the most competent and capable networks around the globe, that are most relevant to the needs of the innovation project. Hence, the more powerful business networks and eco-systems will tend to pull interesting inventions in from their periphery, and effectively grow them.

Introduction

This article reports on a study of the innovation processes that created a radically new technology and medical procedure called TAVI in the domain of minimal invasive thoracic surgery. This study is part of a broader study that primarily researched how practitioners at various Scandinavian hospitals adopted, organized and used this new technology. In these studies, it became very clear that two major global companies, Edwards Lifesciences and Medtronic CoreValve, played particularly important roles in these adoption processes. Both have their headquarters in Irvine, California, and until recently were the completely dominant producers in this rapidly growing medical technology niche market. To understand how these two companies emerged in their particular roles, and the background for the formats they apply in their interactions with the hospitals, we started investigating the innovation history of TAVI and following the two firms' pathways back to the early invention by a Danish interventional cardiologist in 1988/89.

At the same time, we were working on an analytical project to expand industrial purchasing and marketing theory (IMP) from its present focus on what we called 'social-material interaction processes' based on Håkansson et al., 2009, to include the role of money and financing in networked business activities in a new and different way (Håkansson and Olsen, 2015). This introduced a particular definition of 'deals' to IMP theorizing, as a first step in systematically exploring this dimension of business networks, to expand our understanding of the roles and functioning of such deals in general.

In the following, we present one of the two paths of development that eventually brought TAVI from early invention to actual use in medical practice, by presenting the Edwards Lifescience case. In this paper, we will not address any of the issues related to the challenges of adoption of new technologies at hospitals. We will concentrate solely on analyzing the innovation process that moved the Danish invention to the US west coast and into a rapidly growing new market niche controlled by one of the major incumbents in the global medical technology industry. We also included a piece about how Edwards engaged with one of the Scandinavian hospitals, Århus University Hospital in Denmark, to illustrate this latter part of the innovation process through a single example.

We conducted the analysis by identifying and discussing deals made during the process. As such, we believe this method is also a new approach to the analysis of innovation processes in relation to the broader literature on this topic. While recognizing that complex phenomena like global innovation projects, and processes in general, need to be investigated and explained in multiple ways to establish robust, complex and realistic theories about them, our study aims to add to this broad literature by maintaining a disciplined focus on investigating and analyzing the particular roles of deals in these processes. This will be done at the expense of leaving out other events, causal effects and mechanisms that may also be at work in the very same process we are studying (Chandra et al., 2012).

What fundamentally triggered our interest is partly the empirical observations of how these companies acquired the technologies and established such powerful market roles; that is, what characterizes these innovation processes at the overall level. Partly, it is triggered by the apparent paradox in our understanding of innovation processes. This paradox derives from the basic understanding in IMP theory that business networks, due to very substantial dependencies on 'investments in place', tend to be highly stable and robust against major changes in resource, activity and actor bonds (Håkansson, ed. 1982; Håkansson and Snehota 1995; Håkansson and Waluszewski 2002). This is apparently opposed to the more popular, broad and general argument that radical innovations emerging out of local entrepreneurship in garages as well as university research labs around the globe, may rapidly grow their start-up businesses to become the new dominant companies of the world, as exemplified by such companies as Google, Microsoft, Uber, etc. So, what is the relationship between radical

entrepreneurial innovation processes and stable business networks? Can we productively explore this issue by starting with an interesting innovation process study focusing on deals?

The research questions we addressed were:

- How did TAVI move from a Danish inventor back in 1988/89 to Edwards Lifesciences and become a successful innovation?
- Which deals can we identify in the case of Edwards Lifescience's TAVI innovation process?
- What were the particular roles of these deals in the innovation process?
- What can we learn about the general characteristics of innovation processes from our understanding of the roles of deals?
- What can we then propose to say about the roles of relatively stable business networks in light of the perceived dynamics of innovations and new business developments?

From other IMP studies, we know that innovation processes are highly complex and more or less impossible to forecast or predict (Håkansson ed., 1987; Håkansson, 1989; Lundgren, 1994; Laage-Hellman, 1997; Håkansson and Waluszewski, 2002; Wilkinson, 2008; Ingemansson and Waluszewski, 2009; Ingemansson, 2010; Hoholm, 2011). This includes both dramatic changes and adaptations to standardized routines. We also know from these studies that any innovation will have to find its place in a world already full of business activities, objects and processes (Håkansson et al., 2009). There will always be confrontations and restrictions when a new solution requires a 'place' or 'position' in a given business landscape. Thus, an innovation will always require that there are some key adaptations of other resources and related processes – human, organizational and technical ones. This will always also take time as it usually requires lengthy trial and error processes (Håkansson and Waluszewski, 2007; Hoholm and Olsen, 2012). It will thus never be clear from the beginning how a new solution may fit in. The outcome of the innovation process in this way will tend to be highly dependent on what other resources it is being combined with and adapted to, and with which processes it involves as it emerges (Lundgren, 1994; Laage-Hellman, 1997; Jahre et al., 2006; Gadde and Håkansson, 2008; Ingemansson, 2010).

The innovation process literature

The apparent controversy between the IMP literature's emphasis on the dependency of new innovative ventures on established business networks and investments in place, and the view of the entrepreneurship literature that entrepreneurs actually grow their new companies very fast from small local size to large global enterprises that capture substantial space and roles in global markets, is intriguing. In order to dig deeper into these matters, we recognize the need to bring the financial aspects of innovation processes more into the core of the analysis in more decisive ways than what is represented in the literature in both IMP and international entrepreneurship research. In Håkansson and Olsen (2015), it is suggested that studies of innovation processes should focus on deals, and it presented a definition of deals that builds on and expands from the network and process understanding of value creation and real world business activities in IMP theory. This study will apply and further explore this research strategy in a study of an international innovation process in a complex empirical setting.

The discussion in the international entrepreneurship and new business venturing literature particularly relevant to our focus is the debate over the Uppsala model of staged expansion from local to national, to export oriented, to international stages of operation (Johanson and Vahlne, 1977). The International New Venture (INV) literature (Oviatt and McDougall, 1994; Knight and Cavusgil, 1996; Madsen and Servais, 1997) challenged these earlier theories and models pointing to different ways new firms

became international in much more direct and immediate ways. The new models and the discussions about them brought attention to the growing role of young firms in the global business landscape and the role of early, pre-internationalization networking in facilitating their later growth. New global firms came out of small start-ups and apparently grew in qualitatively different and more effective ways. Oviatt and McDougall's article attracted substantial attention and the research that followed emerged under umbrella names such as "Born Globals", "International New Ventures", "International Entrepreneurship" and "New Business Venturing", combining theories from business network studies, entrepreneurship, strategy, psychology, etc.

Despite the diversity of these new research traditions, reviews of the literature also illuminate interesting, almost paradigmatic similarities and striking shortcomings (Coviello, 2006; Zhara, 2005; Gassman and Keupp, 2007; Jones et al., 2011; Chandra et al., 2012; Laurell, Andersson and Achtenhagen, 2013). In particular, they seek to understand the dramatic growth and expansion of these new firms primarily through lenses that see them as entrepreneurial enterprises emerging out of their own internal competencies and capabilities, including a capacity to grow and expand without owning the resources they need and use. Even though they are seen as extremely dynamic, they are also systematically seen as continuous processes controlled and driven by the entrepreneurs in charge and in control of their company. We assert that this view may be rather problematic.

These theoretical challenges point directly to the apparent conflicting views between the IMP theory about the dominant roles of existing business networks and investments in place, and the entrepreneurial school's view of the new business venturing processes. We will not review the literature more broadly, but concentrate our analysis on this particular matter.

In order to do so, we propose to focus on identifying and analyzing deals that represent particular interactions between social material value-creating processes and financial and monetary processes. By identifying and analyzing the deals that occur through the entrepreneurial process, we hope to be able to better understand how these innovation processes actually evolve, to identify their driving forces at different stages and to delve deeper into the relationship between entrepreneurs and existing business networks.

What is a deal?

One important result from studies of inter-organizational business interactions is that they often tend to be thick as they include a variety of development, improvement and problem-solving processes that necessitate a variety of such interactions. It is also a general observation that informal networks of engaged actors across company borders tend to govern and execute these interactions in multiple ways. (Håkansson ed., 1982; Håkansson and Snehota, 1995; Håkansson et al., 2009) However, within the total interaction there are also specific formal agreements as soon as monetary means exchange. Håkansson and Olsen (2015) identified these formal agreements involving money as 'deals'. Deals is an analytical construct at the intersection between social-material activities on the one hand, and monetary transfers on the other. It formalizes when the social-material interactions between two business units need to be delimited and specified in relation to a necessary monetary component.

These deals are analytically interesting to our analysis and somewhat problematic as well, as they can never fully cover or represent the total interaction. The total interaction is usually based on informal agreements (Turnbull and Valla, 1986). Instead, the formalized deals are based on simplified conceptual constructions that the two parties establish to address some share of their overall interactions. However, they are usually important elements in the overall interactions, and they will

typically affect how interactions will continue and develop after the deal-making event. The parties typically specify and formalize them in some contractual, institutionalized form as they involve money flow between them, thereby establishing the connecting and translating relationship between social-material value-creating activities and the financial and money-handling activities.

Figure 1 here

These deals regulate parts of the exchange situation, and define and shape parts of the relationships among the involved actors, resources and activities. Thus, we have on the one hand a complex and, to a large degree, informal value-creating interaction process about actual work, services, products and technologies. On the other hand, we have financial resources and monetary cash flows. In between, we have constraining formal deals that are based on these activities that define the exchange conditions between them. Thereby the deals can be seen as more or less connected and constructed 'islands' or an 'oil platform' in a larger sea of interaction. It has specific boundaries that can even be tried out in legal disputes.

We will start the analysis in the model presented by Håkansson and Olsen (2015). As Figure 1 indicates, we suggest that to understand and analyze a single deal in a dyadic relationship, we have to identify the different components affecting the deal. This means that we have to specify and characterize the two actors, the content of the social-material interactions and the characteristics of the monetary process. We must understand a deal in the context of the activities to which it actually relates.

We have to advance such an analysis in two different analytical perspectives. Firstly, we may investigate the emergence of such a deal through its history of becoming, and then follow its paths as it interacts and develops in relation to other influencing forces and events over time. This is the process perspective. Then, we may investigate how the deal relates to other deals on both sides of the dyadic relationship and study how the dynamics of deal structures and additional deals both shape the conditions for, and influence the further development of, a given deal. This is the structural perspective. In this way, we suggest looking at such a deal as something that co-evolves with related deals in contexts that include laws and regulations and other broader governance systems.

Given these two perspective we can identify in principle two very different types of deals that we will investigate in this study. One is the routinized daily deals that every company must do to handle sales and procurement. These deals are made regularly, mainly with known partners and usually also connected to other counterparts. The second type are ad hoc deals that can both happen by chance or after a long and planned process and with a completely new counterpart. In these cases the deal can be complementary or contradictory in relation to the routinized deals.

For both regular and ad hoc deals it is an agreement at the intersection of social-material and monetary interactions. Each deal is a specific configuration of relationships between networked social-material resources, actors and activities, and financial, monetary and control resources, activities and actors. Because deals must be based on a conceptual freezing and judicial codification of identified and named elements, deals always include some elements and exclude others at this level of business development configuration.

Methods

Our study regards the development and the adoption of a new medical technology in the domain of minimally invasive heart surgery. The study departs from and builds on a structured investigation into the history of such adoption processes at eight different Scandinavian heart clinics, seven of which are at university hospitals and one is a self-governed foundation. We also inquired into the trajectories of the new technology internationally from its invention in the late 1980s until its first introduction at Scandinavian heart clinics around 2006-2009.

The initial study conducted by the research project, is a detailed anthropological study of practices, projects and processes associated with TAVI at the Intervention Centre at Oslo University Hospital (Masovic, Mørk and Nicolini, 2013). Based on that study, the research project has done less detailed, structured studies at other hospitals in Norway, Sweden and Denmark. Through these investigations, we came to recognize the very important roles in these adoption processes played by the technology suppliers, and decided to further explore the entrepreneurial history of the technology from inception to use at these hospitals. The research project then emerged to include investigations into the historical emergence of the technology and the history of how it ended up in the two dominant international TAVI technology suppliers, Edwards Lifesciences Inc. and Medtronic CoreValve LLD, both located in Irvine, CA, USA. Medtronic CoreValve is a subsidiary of Medtronic Inc. which has its HQ in Minneapolis, MI, USA.

This article presents selected results from one of these two studies – the one about Edwards Lifesciences and how it became a dominant actor in this new area of medical technology. It focuses on the particular roles of deals, where as other interesting aspects of the story will be published separately. This article primarily builds on data from interviews during 2014 with hospital administrators, medical doctors and others involved with TAVI activities in Scandinavia, but will only present a few illustrative results from one of these hospitals where we did five interviews in May 2014. One of these was with the inventor of the first TAVI valve, Dr. Med. Henning Rud Andersen. This article also pulls from two interviews with representatives of the two technology suppliers in Scandinavia, from participation at several medical conferences and seminars on the topic of TAVI. Finally, it also used a number of secondary data sources to further explore and verify the entrepreneurial history of TAVI.

From these sources we extracted and constructed a historical narrative about how TAVI evolved internationally, and we also included a piece about how it moved to become an integrated medical procedure at one of the Scandinavian hospitals, Århus University Hospital at Skejby, Denmark. On the basis of this narrative, we analyzed and discussed our observations and findings by focusing on and analyzing the various deals between core actors that appear throughout the story.

What is TAVI?

The TAVI procedure offers 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 of concern to the elderly. TAVI is a minimally invasive procedure where an artificial valve can be implanted using a wire passing, for instance, through the femoral artery instead of having open-heart surgery.

TAVI, as a technology and medical procedure, has evolved since its early invention in Denmark in 1988, receiving a first CE approval of the technology in Europe in 2007 and a first FDA approval in the US in

2011 for the first generation of TAVI valves (Dvir et al., 2012). In 2007, the aggregated number of procedures conducted worldwide was approximately 1,000. Two years later the number had grown to 10,000, and by early 2014 the total number of TAVI procedures had risen to 100,000, particularly due to rapid growth in Germany since 2007 and in the US since 2011.

The procedure is still at a relatively early stage in terms of challenging the open-heart surgery procedure in relation to the major share of the patient population. Around two thirds of the severe aortic stenosis patients are still not being offered TAVI as an alternative. The traditional open surgery procedure is generally appreciated as a thoroughly established procedure that is proven very safe through long-term studies of treatment results. For TAVI to compete directly with the open surgery procedure for operable patients requires documentation of medical results over time, at least at the same level of quality, including results for younger patients who will have to live more years with the heart implant. A first study indicating that TAVI performs even better than the traditional open heart 'gold-standard' procedure, was presented at The American College of Cardiology in Washington D.C. in March 2014. (http://www.startribune.com/business/253029961.html). Accordingly, we are studying a new, non-invasive procedure that may, some years ahead, become the new gold standard for heart valve implantation also for operable patients.

The innovation journey of Edwards' TAVI valve

The story of TAVI starts with the Danish cardiologist Henning Rud Andersen at Århus University Hospital. At an interventional cardiology conference in Phoenix, Arizona, in 1988 he was inspired by presentations of coronary artery stents to start thinking about how to enlarge such a stent to place an artificial heart valve within it. Back in Denmark, he went on to build a prototype by constructing a larger metal stent, sewing it together and placing within it a valve made from pig hearts obtained from the local butcher shop. He then used a transcatheter delivery device that had been developed by Dr. Alain Cribier in France in the 1980s that at the time was being used for the balloon aortic valvuloplastry procedure (BAV) (European-Hospital, 11.02.2012).

Andersen managed to proof his concept through implanting the homemade prototypes in pigs over a three month period. Then he filed several patents, after which he aimed at presenting his ideas at international conferences. He did not receive much attention, though, and the rejection was devastating when leading cardiac medical journals also rejected his paper presenting the results of his early research and development study. However, eventually, in 1992, his article was accepted for publication, at the time, in the newly started European Heart Journal (Andersen, Knudsen and Hasenkam, 1992).

Andersen then began searching for companies that would like to licence and further develop his technology, and approached major international companies in the heart valve industry to offer them a licence. All of them rejected the offer, including a company in Minneapolis called Medtronic and another in California called Baxter International, the two major players in the heart valve industry at the time.

In 1992 a representative of a small company called Stanford Surgical Technologies (SST) also approached him at a conference. This company was established to commercialize other minimal invasive heart surgery technologies out of Stanford University School of Medicine. With the help of patent experts at The Danish Technology Institute, Andersen eventually managed to establish a licence agreement in 1993 that gave the company exclusive rights to exploit his patents worldwide, for a modest yearly up-front payment and a licence fee per item sold (Interview, Andersen, April 2014).

Stanford Surgical Technologies later changed its name to Heartport Inc. and was backed by two major Silicon Valley venture capital firms, Sierra Ventures and Kleiner, Perkins, Caufield and Byers (New York Times, August 25, 1995).

However, SST never really engaged in developing Andersen's idea. On April 1st 1995, the company's two founders, Wesley Sterman and John Stevens, performed the first minimal invasive single-coronary artery bypass operation, which caught considerable attention at the time, and ultimately the company decided to concentrate on this line of development rather than on Andersen's TAVI approach, and hence did nothing to develop Andersen's technology. The invention was apparently stuck with a company holding a worldwide exclusive licence that was not going to exercise it. Minimally invasive bypass procedures, however, became a hot new area in the mid 1990s when large medical technology companies like Baxter, Medtronic, Johnson & Johnson and Boston Scientific all entered the field (Klaidman, 1998).

Of course Andersen was frustrated by this, but nothing happened before he came across a man named Stanton Rowe, a veteran in the industry who worked for Johnson & Johnson (J & J) marketing medical products such as coronary stents. He had also worked for Datascope Corp marketing intra-aortic balloon pumps and vascular closure devices (Levin, 2010). They met at a thoracic centre in Rotterdam in the mid 1990s. Andersen introduced Rowe to his invention and the situation, and tried to persuade Rowe to engage J & J to acquire Heartport. Back in the US, Rowe presented the case to J & J , but Andersen did not receive any positive responses at the time (Andersen interview, 2014).

Several years later, in January 2001, J & J actually acquired Heartport for USD 81 million in J & J common stock. However, one week before this, another company called Percutaneous Valve Technologies (PVT) acquired the worldwide exclusive licence to exploit Andersen's patents, so that the licence was actually not part of what J & J got when they acquired Heartport the following week.

PVT had been established in 1999 as a heart disease interventional cardiology technology start-up company (Cribier, 2012). It was established by Stanton Rowe who, together with his colleague in that company, Stan Rabinowitz, left J & J. However, J & J also took an ownership share in PVT, indicating that these initiatives and deals were negotiated openly. The two men joined with Professor Martin Leon, MD, a world famous professor in interventional cardiology at Columbia University. The three of them invited Alain Cribier, MD, the inventor of balloon technology for the BAV procedure, to also become an owner of PVT and part of the team. Now, the four of them started building balloon-expandable valves and testing them on animal models.

Based on these results, PVT went on to acquire the Andersen patents from Heartport in an agreement dated December 2000. Then J & J acquired the other parts of Heartport one week later. The two combined agreements provided a complete exit for Heartport's founders and executives. PVT thereby controlled both the balloon expandable delivery technology invented by Cribier and the exclusive Andersen licence. So, the time from when Andersen and Rowe met in Rotterdam had in fact been used by Rowe to work out a plan, put his team together, raise initial money and prepare for a structured agreement between J & J 's top managers, Heartport founders and executives and his new start-up PVT company. As a result, all the eggs available to develop TAVI were put in the PVT basket, with a highly competent team and with J & J as a heavy load participating industrial owner at the company board. Even though Andersen was not part of the PVT company, as the owner of the patents he has been working closely with the four others since PVT acquired the licence (Andersen interview, April 2014).

Professor Martin Leon is an interventional cardiologist at Columbia University Medical Center. He is originally from Israel, and through his network in Israel, PVT managed to bring in a medical technology

R&D partner (Aran R&D) to assist with technology development work, and two Israeli venture capital firms to the New Jersey based US company, to fund further development of the TAVI technology. The company raised USD 19.5 million in two successive funding rounds (2001 and 2003) that first brought in two venture capital firms, Medical Venture Partners and Oxford Bioscience Partners, and in the second round the two medical technology companies, Boston Scientific Corporation and Medtronic, as investor owners with representation at the board (Levin, 2010). In the first round in 2001, the company was evaluated at USD 15 million, whereas the perceived value had increased to USD 54 million in the second round in January 2003 (http://www.haaretz.com/print-edition/business/pvt-medical-technology-firm-sold-to-edwards-lifesciences-1.108902)

The accelerated work on the TAVI technology resulted in the first successful in-man implantation in April 2002 conducted by Alan Cribier in Rouen, France. This first in-man transaortic valve replacement operation was performed as a live case at the EuroPCR conference using the first generation PVT valve and delivery equipment. The successful event caught substantial interest in the industry, and came to represent a first significant breakthrough for PVT and its new technology (Cribier, 2012).

In 2000, Edwards Lifesciences was spun out of Baxter International Inc., a major US medical technology company. Edwards became a highly specialized company focusing mainly on selling products in the area of structural heart disease and critical care, within which human heart valves were a dominant product area. At the time, the company was looking for new product markets outside this traditional core business area, in search for new products to speed up growth. These efforts went into different areas, leading to a number of agreements to acquire technologies in new areas. The search also included the new percutaneous transaortic valve opportunities in the interventional cardiology market. But, it was not until Cribier's first-in-man procedure in May 2002, that this area got particular attention from Edwards' top management. Already in 2000 the company had started its own internal program, called 'Patriot', focusing on transcatheter valves, where they started developing prototypes based on the use of self-expandable materials rather than the balloon expanding technology done by PVT (Levin, 2010).

Following Cribier's 2002 operation, Edwards discovered that this new technology could in fact work. At the time Edwards's customer base was completely dominated by surgeons, and to maintain a close and trusted partnership with this profession, the company had stayed away from the many new and rapidly expanding markets for interventional cardiology that gradually challenged the surgeons by taking over their patients and their jobs. But until now, this had not included the really seriously ill heart disease patients such as those suffering from severe stenosis. On the other hand, only between 30% and 60% of those suffering from this disease were in a condition where they could go through an open surgery procedure. This meant that to Edwards, if the new approach could address the most critically ill patients, TAVI potentially represented a substantial expansion of its customer base. It would not compete directly with the surgeons, but address patients presently not regarded as treatable (Levin, 2010).

Edwards eventually decided to engage and to take a lead position. The strategic question then was whether to acquire PVT and build this effort on their technology, or to expand on the basis of Edwards' own internal development of a slightly different technology using the self-expandable material (which was similar to the technology developed by CoreValve, its later main competitor). However, the fact that PVT had already done a successful first in-man procedure meant that it was at least one year ahead of any competitor. Besides, PVT also held the licence to exploit Andersen's early patents, which was potentially an important advantage. Furthermore, Edwards had no internal knowledge of cardiology as this had not been part of their business until now, whereas PVT had a world leading team reaching out to the entire world of interventional cardiologists, which could be acquired as well. So,

the company decided on a strategy to exit from several of its other new non-core activities by selling them off to competitors, and to try to acquire PVT in a daring attempt to establish leadership in a new potentially fast growth product area firmly within its traditional main business focus on structural heart disease and critical care (Levin, 2010).

The negotiations were quite challenging to Edwards, because it was far from being the only company interested in PVT. Johnson & Johnson, Boston Scientific and Medtronic were all investors in PVT and were all represented at the company's board. Edwards was the last one to enter the game. It was the only one without established significant roles in the cardiology markets, and the others had various kinds of preferential rights as owners of PVT. In this situation, Edwards apparently had to strike a quick and complete deal based on a hard to reject offer. To the PVT company the general business situation still faced substantial risks on all fronts: technology risks, regulatory trials, commercial uncertainty, financial risks, etc., causing the other industrial companies to wait for risks to decrease as additional targets were met. Risks were also considerable to the team of four, as waiting it out would require additional funding and hence less control over the company and its negotiating position. But, first and foremost, the Venture Capital owners were – as always – working hard to establish exit options within the tight time constraints of their investment funds.

In early 2004 Edwards acquired PVT with the exclusive Andersen licence for USD 125 million in cash up front and USD 30 million in three stages upon successfully reaching stated benchmarks such as CE approval of a first valve device in Europe and FDA approval in the US. It was clearly a strategic acquisition with high risks and at a high price. However, Edwards managed to come up with a sufficiently convincing offer to be decided within a short time, and got the deal, thereby acquiring the technology and the IPR as well as the professional team. Both Rowe and Rabinowitz moved on to Edwards and became the leaders of the new business area, and Leon and Cribier moved on to work with Edwards.

PVT was not the only acquisition in this area done by Edwards at the time. A few months earlier the company also bought a bankrupt start-up company called Jomed for USD 20 million. Jomed was working with percutaneous aortic and mitral valves, in order to build up competence and gather a broader intellectual property right basis in the domain (Levin, 2010).

Edwards went on to further develop the technology and to organize the processes to obtain CE approval in the EU and FDA approval in the US for its first balloon expandable Edwards Sapien Valve. It focused on getting approval only for the non-operable high-risk patients consistent with its strategy to expand the user market and not compete directly with the thoracic surgeons. The Sapien Valve received CE mark approval in 2007 and a first approval from the FDA in 2011 (Edward's homepage).

Edward's European headquarters is in Nyon close to Geneva in Switzerland, and as it received the CE mark, from there the company initiated a broad marketing campaign to try to get ahead of its rival CoreValve. Thus, commercial marketing and sales to European hospitals started in the late autumn of 2007. In the following, we present in brief how this process evolved at one of these hospitals, Århus University Hospital in Denmark.

TAVI at Århus University Hospital, Skejby

The inventor of TAVI and owner of the early TAVI patents, Henning Rud Andersen, is still an interventional cardiologist at Århus University Hospital in Denmark. As we already learned, he was involved from time to time in the efforts to commercialize his invention, which finally ended up as a new technology at Edwards Lifesciences, Irvine, California. Because the commercialization was based on an exclusive licence agreement on Andersen's patents, he never obtained a formal role in the

companies that sought to exploit the licence. However, he has been a close partner with PVT and, in collaboration with Edwards, has been deeply involved in several battles over patent infringements with Medtronic CoreValve over the years (interview Andersen, 2014; Milford and Cortez, 2014)

An immediate consequence of this origin of TAVI was, of course, that Århus University Hospital indirectly also had a stake in the collaboration with Edwards Lifesciences, as a major global innovation had emerged out of their hospital in an area of medicine that is generally seen as extremely prestigious – structural heart diseases. Contrary to this strong affiliation of Århus to Edwards, the major university hospital in Denmark, Copenhagen University Hospital Rigshospitalet, ended up as a close partner with the other supplier, CoreValve, which in 2009 was acquired by Medtronic.

This was part of the background of why Århus got involved in the TAVI procedures to obtain the European CE approval. In early 2006 Andersen and his team at the cardiology department began doing their first TAVI procedures. There were no cardio-thoracic surgeons to support the cardiology team; they had stated their opposition to the experimental treatment. However, a vascular surgeon got involved with the team. For the first procedure, they selected a relatively low-risk patient. Unfortunately, this first patient died on the operating table because of an inability to control and stabilize the blood pressure of the sedated and sleeping patient. This was, of course, a very serious incident that was even conducted by the inventor of TAVI himself. Given the complex and potentially damaging situation, the cardiology department did a thorough medical analysis of what went wrong and decided to try once again, also on a perceived low-risk patient. Once again, however, the patient died on the table.

These events, of course, resulted in a full stop and severe crisis to the TAVI project at Århus University Hospital. The embarrassed Anderson had to commit the failure both internally and externally towards the international TAVI community, who, however, had already experienced a number of such incidents. The case became another incident for substantial discussions within the Edwards associated networks that contributed to shaping an enhanced strategy for patient safety through a number of measures. The core strategy that emerged from this, with Andersen as a contributor at a number of conferences and presentations around the world, was that TAVI was said to require a team-based approach with close collaboration among cardio-thoracic surgeons and interventional cardiologists, anesthesiologists and radiologists. To safeguard the procedure, Edwards moved its argument further to insist on a strong role for the thoracic surgeons.

As a result of these events, Anderson and his team at the cardiology department invited thoracic surgeons to collaborate on TAVI procedures. They suggested moving the procedure from the cardiology to the heart surgery department, and jointly the two professions asked the hospital and received funding to establish an advanced hybrid operational room in the heart clinic of the new hospital. To assist in the re-start of the TAVI project in February 2008, with the active support of Edwards they invited John Web from Vancouver to serve as a proctor during the first procedures in Århus, and also got solid support from Edwards and their 'TAVI start-up support package' (Anderson interview, April 2014). Based on this, the hospital engaged in a collaborative agreement with Edwards to buy valves and services needed to build the teams and start doing the procedures in accordance with Edwards' policies.

The new collaborative team decided to concentrate on the transapical and transaortic access point procedures in which a thoracic surgeon will have to provide access to the heart. These new procedures had been developed by John Webb in close collaboration with Edwards. Århus thereby became an early specialist in conducting these procedures in Scandinavia, a place where teams from other hospitals were sent by Edwards to observe and learn (Lars Evald interview, 2014).

When doing these kinds of challenging medical procedures with high risks to the patients, sufficient practice in doing a particular procedure is a critical factor to ensure good medical results. These are kept track of and evaluated through the various national TAVI registers. Given Edwards' highly structured team approach, a 50/50 split gradually emerged between procedures where surgeons had to take the lead role (transaprical and transaortic primarily) and transfemoral and subclavial procedures where cardiologist had to take the lead.

By April 2014, Århus University Hospital had conducted around 400 TAVI procedures using the Edwards valves, with Edwards as the sole supplier. The hospital administration had been arguing that this practice was not in accordance with the procurement regulations and policies. At the time of our visit to the hospital in May 2014, the hospital had just recently started inviting an open tendering competitive bidding procedure for the first time on TAVI valves. In April 2014 six different suppliers, including Edwards and Medtronic, presented their products before a board of medical experts and purchasers representing the hospital.

> *..but it was really a good meeting, and in media we see all these companies, the same thing. I think I could use all these products, it was fine equipment, fine organization and how…eh, will not be afraid to use them in patients, but I think we have to have one, two, maybe three different companies. That is the maximum for this centre. (*Head of department Lars Ejby)

In Denmark the hospital and the regions responsible for financing the hospitals push for open tender processes, and in discussions over budgets and demands for more funding to do more TAVI procedures, the introduction of tender processes had been forced. However, at Århus the tender process was introduced after more than five years where purchasing from one selected supplier has been going on below the radar, or with no one seriously interfering with the practice. Given the established collaborative team structures in Århus, for a competitor to outcompete Edwards and win an open competitive tender appeared difficult, as the team-oriented practices are rooted in broad political consensus and established routines at the hospital that are closely tied to the collaboration with Edwards. The affiliation between Andersen, the hospital and Edwards is also such that to reject Edwards would seem unlikely.

Deals as critical turning points in a staged and geographically re-locating innovation process

From this case description, we identified seven specific deals where 'money-handling processes' and 'social-material value-creating processes' combine and interact.

We first analyze each of these seven deals, before bringing the analysis to the more general discussion about the roles of deals in demanding innovation processes and about how we may think of this entire process of deal-making activities along the developmental paths of a new medical technology and procedure.

When analyzing the deals we cover the following six points:

1. Who is involved in the deal?
2. Who is taking the initiative?
3. What is the deal about? What are the specific challenges faced by the project?
4. What characterizes the money-handling process?
5. Are there clear relationships to other deals?
6. Are there particular consequences for the involved actors with respect to future participation in the project?

Deal 1: *Andersen files and obtains patents on his invention, 1989-1991*

The two parts in this deal are the inventor Andersen and the patent legal system in specified countries. The inventor initiates the process and has to cover the costs of obtaining patent protection. To establish a clearly defined and defendable ownership to his 'idea' or 'invention', he has to comply with the requirements of the international legal system. This includes demonstrating that the idea is sufficiently new, unique and proprietary to deserve legal protection as a patented property filed in his name.

To get the protection he has to pay for the international investigation processes, and if found worthy of protection, a fee for each of the countries where he wants his property to be protected over a defined period of time. To extend it into successive periods, he has to pay additional fees as well. Thus, the deal established a defined property right to the invention in time and space that can now be traded to others, who will then obtain the same legal patent protection to the property in given countries.

The deal defines a payment flow to be paid by Andersen as the patent owner to the legal patent system, which requires access to financial resources somewhat larger than what can be paid for through a normal salary. Hence, to own and protect several patents requires sufficient financial funding or revenues. The patent protection only lasts for 20 years, which means that the clock starts ticking towards the expiration date, leaving a gradually shorter period to build a business that may gain from it. Hence, the economic value of a patent in principle declines over time due to this time limit. Both the payment requirements and the time effect represent strong pressure on the inventor to act rapidly to create revenues from his newly created property. The alternative is to stop paying, in which case the property falls into the public domain and becomes exploitable by anyone.

The most significant result of the deal is that Andersen obtains the property rights to the new TAVI technology as described in the patents filed. The property rights and the associated rights to exploit the patents commercially can now be traded to others in a legally safe way. This deal is a necessary passage point as it makes it possible to trade the created property with others with a strong legal protection of the property.

There are typically two ways that Andersen may now proceed. One would be to establish a company based on an initial valuation of the patents and then raise money from others in exchange for direct ownership in the company, which indirectly also includes ownership of the patents. The other approach would be to maintain ownership of the patents, and then sell the rights of commercial exploitation to others, typically through a licence agreement. Recognizing the developmental challenges and lack of appropriate partners in Denmark, Andersen went for the licence approach directly towards the international medical technology market.

Deal 2: *Andersen sells exclusive commercial rights to Stanford Surgical Technologies, 1993*

The second deal that marks an important crossroad is the result of Andersen's search for a company in the industry that would pay him for the opportunity to develop his idea. After a couple of years of active search, he ended up engaging in an exclusive licence agreement with the California based start-up company Stanford Surgical Technologies (SST), when all the major heart surgery equipment companies turned him down. While initially addressing companies with vast resources, established market shares and adequate development, manufacturing and marketing capabilities, their rejection left him with less desirable alternatives.

The alternative that emerged was initiated by SST than rather by Andersen. SST was on the outlook to acquire early stage technologies and patents with close proximity to the non-invasive heart disease technologies it had developed itself, and aimed at developing into a fast growth business in the emerging dynamic market for minimally invasive medical technologies. As a Silicon Valley based technology start-up backed by major venture capital firms, it also aimed at becoming an attractive acquisition object based on proven technologies and a portfolio of potentially interesting technologies and patents. Hence, the two parties negotiated a deal through which SST acquired the worldwide exclusive rights of commercial exploitation of Andersen's TAVI patents. In exchange for this, Andersen would receive a yearly fee to maintain the legal patent protection, and a licence fee for every TAVI product sold as defined in the contract.

Apart from being able to fund his patent obligations, Andersen's revenues from the deal completely depended on SST's success in actually building a new business venture to exploit the patent. If not, SST would still have to pay the relatively small upfront fee, but nothing else. Hence, apart from inducing the pain on SST of having to pay the upfront fee every year, there is not much Andersen could do to move SST forward from here. The ability to initiate progress thereby moved to the other part. To SST, developing Andersen's invention into an actual business effort would clearly depend on its own internal assessment of the alternative paths of development available and the access to funding from others.

To Andersen, this meant that he could no longer sell any part of his property to any other customer. He had sold everything in a one shot deal, and consequently, he would have to just wait it out and see.

For SST, it meant that for a modest yearly fee it had obtained the option to either develop Andersen's technology into a new business activity, or simply add it to its portfolio of technologies and patents. Such a portfolio might increase its attractiveness to large incumbent companies on the outlook to acquire companies that control technologies in attractive growth niches. Either way might work as the company, even though being relatively small, had obtained funding from major California venture capital companies, and enjoyed substantial attention from the industry due to its own inventions, which also needed resources to become sustainable businesses.

Deal 3: ***PVT acquires the exclusive licence to exploit Andersen's patents from SST***

The third deal represents a dramatic shift, and was only one part of a whole set of related deals. These deals involved Stanton Rowe and his close partner Stan Rabinowitz, two world famous interventional cardiologists, the huge medical technology company Johnson & Johnson and the company called Heartport – the new name of Stanford Surgical Technologies. The initial initiative came from Andersen who was frustrated to find someone to help him move his invention out of SST. However, from there the initiative is clearly driven by Stanton Rowe, who appears as the most important entrepreneur in this entire story.

In 1999 he established the new company, PVT, jointly with his close business partner from his time at J & J. He also got a world leading representative of interventional cardiology as well as another world famous cardiologist and inventor of the balloon technology patents on board. Jointly these four worked out a basis and a strategy for acquiring the Andersen licence. By demonstrating both the competence base and the actual capabilities of the new company, Rowe worked out a deal with his former employer J & J, to have J & J acquire Heartport and to restructure Heartport's assets. A part of this was to transfer the Andersen licence from J & J to PVT in exchange for J & J taking an ownership share in PVT.

This operation was carried out through a set of related deals, where the Andersen exclusive licence was first formally purchased by PVT from Heartport. Then J & J acquired Heartport and moved its different assets to some of its own businesses. Then, J & J took an ownership share in PVT to also obtain an interest in Andersen's licence and the new TAVI business.

Heartport was acquired for USD 81 million in common J & J stocks, plus the price PVT paid for the licence (which we do not know). The owners of Heartport could then sell their J & J shares at the stock exchange.

The PVT company stands out as the agglomeration of critical nodes in networks of different origins that were deliberately collected and orchestrated to exploit the perceived opportunities associated with Andersen's invention 10 years earlier.

This third deal is a typical multi-actor deal structure consisting of a whole set of closely related two-party deals. It was a complicated operation that moved the property to a new home and new business networks. The complexity is a reflection of the complexities associated with finding suitable compromises among all involved actors in a situation where the entrepreneur controls limited resources and thereby has to offer ownership shares to J & J in order to engage sufficient resources to move the property out of SST. We also note that the owners and founders of Heartport were able to sell their company at a reasonable profit. Heartport is then out of this game and Andersen's licence transferred to a company ready and eager to exploit it.

To Andersen, this meant that he was back in the game and had a clear role as the owner and defender of the core intellectual property rights. PVT had acquired the same rights as those obtained by SST, however, already some nine out of the 20 years of patent protection had already passed. Hence, to PVT, speed of progress was obviously a critical issue. Apart from this, the third deal set the stage for an innovation journey with critical networks and resources on board. This also included J & J, who obtained both a share of ownership and a board of director position in PVT with a preferential position to take control of PVT at a later stage. Hence, all parties appeared to have gotten substantial benefits or attractive opportunities out of these deals.

So far, three different deals had moved the property from Denmark to California and now to New Jersey, Israel and France but nothing had happened in terms of developing the medical solution.

Deal 4: *PVT obtains financial funding, 1999 - 2002*

A fourth set of deals concerned the financing of the PVT company. After having established the company with the critical competences on board and acquired the Andersen licence by the help of J & J, the company managed to raise the first financing from two Israeli venture capital firms through the networks of Martin Leon. This implies that these investors were familiar with this domain of medicine in both the US and Israel. These connections also provided opportunities for PVT to engage with Israeli engineering companies who also specialized in the dynamic interventional cardiology technology domain. The company raised USD 5.5 million in the first round in early 2001 that funded the early efforts leading to the first in-man TAVI procedure in April 2002. By bringing in venture capital, PVT also moved strategically to position itself as an object for acquisition.

Following the first in-man procedure, the company once again raised more money. This time it raised USD 14.5 million in early 2003, which included investments from two other major med tech companies, Boston Scientific and Medtronics. As a result, three major players in the global medical technology industry gathered at the board of directors in PVT.

To the two venture capital investor companies, this meant that the stage was set for negotiations with all of them about who would be willing to pay the highest price to acquire the company. This would obviously depend on whether the company would be able to reach certain targets, in particular those that would reduce the technology and regulatory risks. However, it would also depend on the emergence of other companies working on similar approaches, which might turn out to be more promising. Anyway, this seemed to have been a great position to both the four founders and to the VC investors.

The position of the three medical technology companies was that as the latest investors in PVT, they obtained preferential shares in terms of safeguarding financial returns and options to acquire PVT. Hence, in their perspective, the most relevant rivals in the game were the three of them. Alternatively, a fourth bidder would have to pay a high price to get its hands on the company. To all of them, this meant that they could wait it out while watching one another and closely observing the emergence of the TAVI start-up market around the world.

This, however, also implied that both the founders and the VC investors would actually prefer a fourth actor to come up with a bid, to trigger action and increase the price of the company.

Deal 5: *Edwards acquires PVT, 2004*

This turning point deal was the final result of a fairly long process within Edwards since its spin-out from Baxter in 2000. Even though Edwards started working with TAVI solutions right away, it was Cribier's first in-man procedure in 2002 that triggered the strategic focusing. The PVT deal was clearly initiated by Edwards who, as a major incumbent in the market for heart surgery technologies and equipment, found itself facing a difficult strategic decision. Given the ownership structure of PVT, it would have to gamble with a high price offer with tight time constraints to be able to fend off the three rivals holding preferential positions.

The choice was between such a high price at high risk strategy to acquire PVT, or to expand its own internal technological 'Patriot' project. There were two major concerns to the latter alternative. Firstly, there was the potential patent infringement problem in relation to the Andersen patents, and secondly, there was the time to market advantage/lower technology risks that PVT had obtained as demonstrated by Cribier's successful procedure. If one of the major rivals acquired those advantages, it would gain substantial advantages over Edwards. Hence, the company decided to go for the bigger opportunity by placing an attractive bid of USD 155 million on the table with short time constraints for the owners of PVT to decide. The price gave the investors who invested in the first round of financing in 2001 a 10-fold return, whereas those who invested only one year before, in early 2003, received a return three times that of their investment. This was, by any standard, a great financial success.

The deal moved Edwards to the potentially leading role in the new TAVI niche industry. As noted above, both the founders and the VC investors would welcome such a bid and would accept it. This forced the three industrial owners to make their decision in response. To each of them, the situation required both sufficient internal strategic consensus to be able to decide on placing a bid at the same high price, and a capacity to evaluate both risks and alternative strategies within a very short time frame. Apparently, neither of them was in a position to either do this or to agree on a competitive bid. So, they all decided to take the financial gains and let Edwards acquire the option to develop a lead position in the TAVI industry.

As Edwards completely lacked competence and capacity within interventional cardiology, it was critical to also acquire the team and the entire PVT operation. Accordingly, the deal included an upfront element of USD 125 mill and an additional part worth USD 30 million, which was to be paid if and when certain future targets were met, such as CE and FDA approval of the first TAVI valves. Hence, the deal had two major components that needed to get everything moved to Edwards.

To Edwards, this deal meant that the company essentially acquired a real option to take the lead in the new domain, as well as the core of international medical researchers and practitioner networks needed to expand into the domains of interventional cardiology. As such, the deal had a substantial strategic impact on the entire structure of Edwards. To advance the new activity, PVT became a separate division with the same top management as before. From there, Edwards moved very strategically to include a substantial role for surgeons who represented their entire established market.

To the PVT founders, the deal meant both a substantial financial return and a possibility to advance TAVI though access to substantially larger and more extended networks of resources, activities and actors. To the investors in PVT, the deal was highly profitable even though some of them had to let PVT go to a competitor with substantial developmental, manufacturing and marketing capacities.

Through this deal, Andersen's licence finally ended up in the hands of a company with the capacity to rapidly bring it to users at a global scale. At this point in time only seven years of the patents' protection time were left. Now the licence was also in the hands of a company with the resources to defend its property rights. This initiated a succession of patent infringement cases in relation to its main competitor Medtronics CoreValve. This brought Andersen into close collaboration with Edwards as he still was the owner of the patents and had to play a major role in these court cases.

Whereas the monetary flows in deal four went into the activities of building the TAVI venture, the monetary flows in deal five did not go to any such activity, only to the owners. It is not an investment in the company, but a transaction to transfer ownership control rights from some owners to others including licences, technologies, employment contracts etc., and to move the property from New Jersey, Israel and France to an operation headed from Irvine, California. To develop TAVI, Edwards had to invest in all these other efforts as well.

Deal 6: *The Århus – Edwards deal (2008).*

This sixth kind of deal is what brought TAVI to practitioners at heart clinics. It marked the crossroad from early development and initial regulatory approval, to commercial marketing, sales and scaling of the industrial and logistical operations. For the first time there was a small revenue stream from the actual use of the new technology. Up to this point, all the financial gains were the results of calculated expected future net positive cash flows, while there were still no actual revenues from sales.

The deal is between Edwards as represented by its marketing and sales organization, and the thoracic surgery clinic at Århus University Hospital. As this is the hospital where Andersen is still working, there are strong relational elements represented in the context of this particular deal. There is a substantial and rather dramatic pre-history about early TAVI experimental procedures at Århus, which substantially influenced the local configuration of the internal resources and competencies, and moved Århus, as a partner with Edwards in Scandinavia, to strongly support the team approach.

Essentially, the deal is a collaboration agreement connected to purchasing a number of Edwards valves. However, what is striking with this deal is its complexity, its dependency on a particular form of collaboration and guidance orchestrated by the supplier, and its connectedness to Edwards' entire

international networks. It is a node in something very extended and specifically formatted on the side of Edwards. Hence, this required a particular kind of match with the internal strategic context at the hospital, which would have to adopt to the complete package offered, including a particular emphasis on the need for cardiologists and surgeons to collaborate, something they usually do not, or even would not like to do.

While the core of the deal is the purchasing of a number of valves, it also includes a number of other elements. These are essentially different services that are there to educate and train practitioners, to help them organize the new procedures, to ensure quality of patient evaluations, support activities, access to partners at other hospitals, etc. It is a whole package to ensure the transition from initial non-experienced novices on doing TAVI procedures, to stable, experienced professional practice at a high patient safety level and with a comprehensive routine based organization. Through this process, Edwards had the opportunity to influence the internal formatting of procedures, organizing and skilled routine practices and thereby establish substantial specific investments in the relationship. An interesting observation is the core role of the 'team' approach advocated by Edwards, and the development and adaptation of procedures that required surgeons to take important roles in TAVI procedures.

By offering similar deals to a large number of hospitals, Edwards was able to develop a network of customers that were both relatively similar in their internal organizing, making it easier to exchange learning and experience, but also left some room for local differences that generated experimental learning across the network.

Here we also have a multi-actor type of deal, even if it is only signed by two counterparts. Instead of having to go through a complicated process in each case, the 'package', including the team approach, is a summary of all earlier experiences. It includes the complex learning process that is required for making these operations safe. The deal is promoted by the sellers and is an attempt to both handle the complexity in the process and at the same time create a positive monetary return.

Deal 7: *The tender procedure introduced (2014)*.

This last deal is the outcome of the initiative in 2014 by the centralized purchasing department at the hospital to introduce a public tender purchasing procedure. Following five years of purchasing based on the deal presented above, a public tender process as prescribed by public sector regulations, is finally introduced. At this point, the hospital had established the internal organizing of TAVI with trained expertise in all relevant professional areas, with laboratories, a hybrid operating room, etc. Over these years, the hospital invested into this area of practice and thereby gradually reduced the need for various kinds of support from the supplier. It has thereby become less dependent on the supplier, and may proceed to introduce other suppliers of valves as well without having to substantially invest in new procedures, laboratories, training, etc. The higher level of experience and expertise at the hospital represented a much more solid basis for evaluating the alternatives offered by different suppliers, including the ability to productively use the tender process to advance the practice of TAVI incrementally and thereby continue harvesting from the established organizing.

The introduction of a public tender procedure was also a move by the hospital to negotiate prices from suppliers who now for the most part only delivered the valves without a whole set of support services. At this point in the process, the suppliers had also increased their scale of manufacturing and business operations to a level where substantial cost reductions would normally be feasible.

By now the 20 year patent protection period for the Andersen patents expired, and several new competitors entered the market with new valves with slightly different features. Hence, the actual ability to engage with other suppliers had substantially changed since 2008.

The resulting expected deal would keep the incumbent supplier, Edwards, as the completely dominant supplier to Århus University Hospital. But two other suppliers were also being considered. One of these had a valve quite similar to those offered by Edwards, hence it was a competitive valve introduced for the purpose of forcing down the prices on Edwards' valves. The other newcomer had a different valve that was useful in cases where the Edwards' valves had certain disadvantages. Hence, this second supplier was there to complement the capacity of the hospital to offer TAVI to more patients.

With the introduction of standardized public tender procedures, a cumbersome process of 'below the radar' public purchasing of an innovation ended. It represented the crossroad where TAVI entered the phase of becoming a mature and routinized medical technology and procedure, still in development, but now more or less to be treated as other well-established medical activities. The interface between the suppliers and the hospital became standardized and focused on economizing rather than development. It thereby closed the circuit of the innovation process, from where there will most likely only be incremental improvements that may bring the new technology to more patients in need of a new aortic heart valve.

Roles of deals in the innovation process

Let us now first have a look at each of the seven deals before identifying more general findings.

The first deal we identified and discussed was about the creation of defendable property rights and ownership to the invention. Through the granting of patent rights, ownership became defined in an international judicial system that enhanced the ability of the invention to be traded as some value. The first deal is thereby a necessary step towards doing the second deal.

What the second deal does is move the commercial rights to exploit the property to someone on the other side of the globe who would be able to exercise it, in exchange for sufficient money to maintain patent protection and keep the inventor in the game. It thereby connected the invention to resources, actors and activities that would potentially be able to move it forward, after the inventor found no opportunities to organize it himself. Thus the deal shifted all the critical control rights from the inventor to the SST.

The monetary flow defined in the second deal is only about the control rights, not about financing any part of the development activities needed to develop the technology and the business. At the time, SST appeared as a reasonably good opportunity to Andersen, with its location in Silicon Valley, association with Stanford University and expected ability to raise financing from the venture capital community, which SST in fact did. However, Andersen's idea was not the only option to SST, and clearly not the lowest hanging fruit to SST's founders and investors at the time.

When it became clear that Stanford Surgical Technologies did not move to develop Andersen's invention, this gave others the opportunity to take the initiative. The third deal is based on the initiatives by Rove to gather the critical resources and networks to establish a technology start-up able to acquire the technology from SST and build a business through equity financing.

The establishing of PVT and the two rounds of equity financing identified as the fourth deal, as well as the mobilization of Rowe's relationship to J & J, made it possible to move the technology from SST to

PVT and start building a new entrepreneurial venture. The objective was the same as in the second deal, however this time the rights of commercial exploitation moved to a company with networked actors dedicated to moving the technology forward, and with access to the means to bring it some way down that road.

The fourth deal is about financing development activities, linking up actors and buying resources. This deal is actually a staged process in several steps where new actors are engaged in each step. Also in these deals, the object of the transaction is ownership of the invention. In exchange for ownership shares, money is supplied to pay for development activities. Because the first round of investors were venture capital firms, not industrial investors, the new venture established an ownership strategy to either sell the company to a larger company or to organize an initial public offering (IPO).

In the second round of this equity financing, two additional industrial investors invested in the company, indicating a clear strategy by the Venture Capital investors to go for an industrial sale of PVT. This second round of financing brought the company into a set of potential industrial relationships with different incumbents in the industry, where the destiny of the company would depend on an expected acquisition by anyone of them some time ahead. Because of the preferential shares given to the last to enter investors, this also set the conditions for external companies with an interest in acquiring PVT.

The fifth deal once again concerned a transfer of ownership that moved the innovation to a completely different network of resources, actors and activities within or associated with Edwards Lifesciences. This time there was a lot more money involved in a highly strategic takeover by Edwards to take control of PVT out of the hands of its industrial rivals. None of the money involved in the deal went to developing activities. Everything went to the various owners of PVT. The innovation thereby moved from a relatively constrained technology start-up firm to become a division within a large incumbent company with a developed network including substantial resources, competencies and activities in nearly all areas of activity relevant to the further development and marketing of TAVI. In the perspective of Edwards, it is very clear that the acquisition of PVT not only brought a new promising technology, it also radically expanded its knowledge networks and customer base to include the dynamic new area of interventional cardiology.

In all of these deals, the initiative had a distinct entrepreneurial flavour. That is to say that it is the buying side who engaged to mobilize efforts, resources and other actors to pursue perceived opportunities who are the drivers of the deal initiatives and the overall process. At the same time, it is clear that it is those actors who have control over more extended resources and networks, who are the ones able to take the relevant initiatives and gain the necessary control of ownership and strategy as the project moves from early to later stages of the innovation process.

The two last deals (sixth and seventh) were related to sales of products and services, not ownership of the firm or of the invention. The monetary flows concerned the exchange of valves and support services, and these were essentially structured to orchestrate fast growth of sales on relatively standardized but content complex terms to many heart clinics across the world.

The sixth deal was about mutual investments into the supplier to professional users' relationships as well as into the learning processes through which the hospital gradually built up the capabilities to perform most of the procedures without direct support from the supplier. Through this process, the hospital gradually expanded its leverage to move more independently and engage with rival suppliers as well. Through the development and regulatory approval processes, each supplier developed different and very specific conceptual and practical approaches that required a number of specific arrangements and investments on the side of the hospitals. Because the adaptation and learning

processes were highly demanding, there were substantial first mover advantages to the suppliers in building and maintaining a dominant supplier position over time.

The initiative to establish a competitive bidding procedure did not come from the practitioners but rather from the institutionalized purchasing system that is there to force down the costs of providing public health care. This shift in the deal format marks a transformation from user driven and supplier supported innovation and adoption of a new innovative technology based procedure within the hospital, to an established routinized procedure subjected to standardized governance systems. At this stage of the process the critical innovation activities occurred in the user setting in the hospitals, in close interaction with the global supplier networks that enforced and aggregated these learning processes. Gradually, these innovation processes converged, stabilized and became routinized medical procedures subjected to production and economizing-oriented governance.

When focusing on these deals in the innovation journey of the Edwards TAVI case, it is clear that all the identified deals play significant roles in the process. In three of the deals, the role of money is to move the innovation from its existing context and networks into another where additional resources, actors and activities may be mobilized (Hoholm and Olsen 2012). At the same time, there is a complete moving of proprietary control rights over the innovation to those controlling the new context/network. Hence, we may conclude that whereas these deals themselves did not move resources to the invention in the direct sense, the moving of the social-material activity and the shifts in control definitely led to a new position within much more extended social-material as well as a monetary resources rich network. In this way deals can have a significant role in moving a development process to new segments within the total business network (Ingemansson and Waluszewski 2009; Hoholm and Håkansson 2012).

Other deals were much more about increasing the strength of the existing position by getting funding for the existing development process, or for establishing customers or suppliers to the developed product/service (Håkansson, 1989; Lundgren, 1994; Laage-Hellman, 1997; Harrison and Waluszewski, 2008; Olsen, 2012). One important lesson from these deals is that they, at least partly, influence the broader network. One example was that by suggesting a deal including a whole set of operations with both products and specialists, the producer is trying to develop competent users who, in the next round, can be active cooperative partners in relation to new users. If the first type of deal was to move the innovation, the second type is more to develop the existing position and to make it more central for a number of related actors.

During the innovation process, the project moved through the deals from one actor-network to another and between different geographical locations. It is a striking observation that those who engaged in acquiring control, at some point were actors who controlled a network of resources, activities and competencies required to move the project through the next phase. Overall, it looks as much a pulled process as a pushed one. It is the perceived business opportunities and strategies of those yet to engage that drives the overall process, not so much the entrepreneurial push of those who are presently in control. The basis for this moving of the project is the needs of the project to become interacted with adequate, already established resources, activities and business actors (existing company networks) that are actually able to move the project towards commercial realization with sufficient speed and force. Thus the deals are used to both strengthen existing networks (through regular and routinized deals) and to change the composition of the activated network through ad hoc deals. Thus, the deals both develop the existing network around an innovation and force it into quite another position.

It becomes clear from this study that the overall process does not depend on the ability of the entrepreneurs to learn whatever is needed to rapidly move their companies from small start-up technology ventures to mature international operational firms. We suggest that nobody would have the capability to learn, acquire resources and carry out the complex tasks as well as the rapid international scaling process at a sufficient speed and with sufficient authority to succeed. The learning process is much slower than the speed of new complex emerging challenges. This is resolved by a business system in a networked industry already in place that is designed and operated to bring the innovation through different development stages by successively handing the innovation over to those who already can.

Not surprisingly, very challenging global innovation projects in this way move from the periphery where someone may have gotten a great idea, to the complex global centres of expertise where the most relevant and competent networks of actors are located. The story illustrates why the elite networks in science, medical practice, venture capital and medical technology are those who stepwise move in to take control and to move the innovation from idea to operational practice around the globe, from where to command the industrial scaling and the global marketing and distribution network. It is similarly clear that without these concentrated capabilities, the innovation is hardly going to break into and re-shape complex local practices and networks at local hospitals around the world. These actor networks move in to exploit the opportunities because they already control an existing network including resources, activities, authorities and competencies required to succeed, in already interacted business and academic networks. How could such an innovation develop elsewhere?

Finally, another type of deal is exemplified by the first described deal where the idea becomes established in a legal environment (Johanson and Waluszewski, 2007). Deals have an important legal dimension that is not just important in an early innovation phase, but also later exemplified by the last described deal. There are legal rules influencing the hospitals on how they should behave in relation to business partners. These rules, furthermore, are designed based on a certain ideal type of ‘deals’ that are problematic to use for more extensive interaction situations.

Conclusions

The deals presented and discussed in this article play particular roles in a rocky, emergent innovation process. A first observation is that they don’t all describe or explain the whole process. Instead, each deal is part of a larger process and is only building on some specific dimensions of it. However, each deal is in some critical way a precondition for the next, as the object acted upon by the actors in the following process is the outcome of the processes initiated by the previous deal. This regards both the regular daily deals as well as the more isolated ad hoc ones. Together they create a pattern. But again this pattern only gives a partial and very specific picture of the total process. One important reason is that every deal has to cut out, in a very distinct way, what is included in the deal. In the first three deals it is rather simple because in principle it is a document giving some rights that are exchanged. The same with the fourth one, but here the rights are in terms of ownership. The fifth and the sixth are much more complicated and include a set of resources and activities that must be separated out through a much more complicated process. In the seventh it is moving back to a rather well-defined product. Consequently, deals are based on a clear specification of what is included, and this is only possible to do in certain situations. Complex interacted business structures are difficult to slice up in suitable pieces for making deals.

Overall, we may see these deals as important but partial parts in this staged, conditional and emergent process that gradually moved the innovation from invention to actual use in hospitals around the world. But it was no simple and straightforward process and the deals created both problems and new opportunities. It was a deal creating a dead end (the second one) as well as quite large jumps in terms of location. Over the course of this process, many small day-to-day deals mobilized more and more extended business networks in order to bring the process to the next level in new contexts of development, production and use where it eventually was able to conquer some space for itself in medical practice.

To conclude this analysis of the roles of deals in innovation processes, we would like to suggest a few general propositions regarding what we may perceive of as advanced globally oriented technological innovation processes aimed at demanding user applications such as in medical procedures.

Firstly, the process including deals is a combined pulled and pushed process. The driving force comes from both sellers and buyers who see their business opportunities in light of the resources they control directly or indirectly. These can be more or less relevant to different stages in the innovation process. Different actors with different combinations of activities and resources accordingly engage in the different stages in between small start up and mature global operations. It can be an actor pushing the innovation through a stage using and combining the existing resources. Or it can be a buyer that pulls it to the next stage in order to use new combinations of resources controlled by this buying actor. To return a profit from their investments, actors move down the development path to enter a new venture at a less developed stage, acquire control in one way or another, and move the invention through the next stage. At some point they may leave the control position because they do not control the resources needed for the next phase, preferably through a direct sale if the innovation and its network can be specified precisely enough to make a deal possible. If nobody with sufficient capacities sees the opportunity to move in, the earlier stage actors will soon run out of needed resources and face severe competence constraints.

Secondly, some of the ad hoc deals are turning points that represent new points of departure through the innovation process. They generate important shifts and radical movements of the project from one actor network and its resources and activities to another with other resources and activities, and from location to location. This movement is especially possible as long as the innovation has not been firmly embedded into a network and it is thereby recombining the innovation project with particular other existing social, material and financial resources and activities.

Some deals create new fixed points or ‘foundations of order’ from where to engage in next step innovation journeys (as the fifth deal above). They are the outcomes of strict conceptualizations of monetary flows and control rights that exclude alternative options. As such, we may perceive of them as created institutional ‘islands’ in a larger sea of interaction and interdependencies from where particular routes are pointed out as new directions for the innovation journey to proceed, and for particular resources, actors and activities to be connected and brought on board the following voyage.

Purchasing/marketing and partly financing are continuous activities that are highly dependent on a set of often very regular deals with existing counterparts. Individually these deals are not so important, but instead they provide a basic platform that is absolutely necessary for the continuation of the process.

Thirdly, deals and development requirements will tend to move the innovation activity from some periphery where the idea may emerge, towards the globally most competent interacted business networks capable of bringing the innovation through a staged process of becoming successful in wide spread use.

Even though a radical invention may emerge, for instance from a regional hospital somewhere, to become a successful global product or practice it must engage with and become part of advanced, competent and resource abundant networks typically associated with the most prestigious universities, their surrounding innovation eco-systems and some of the incumbent firms in the given network.

Fourthly, the analysis of the deals indicate that innovation is not primarily about creating new resources, activities and businesses. Instead the deals focus on using and recombining existing resources to expand business opportunities and user benefits from new creations and combinations of knowledge that are typically being baked into some new technology and some new organizing network to be scaled and distributed with high speed and in large volumes.

To succeed, a business must have a network controlling necessary resources for some part of the process. The business must have a network that is able to acquire control at a level of business development below the level that corresponds to the capacities it's network controls, and it must be able to orchestrate a controlled exit if these collective resources are not sufficient to bring the innovation all the way to the relevant use. The clue is to be able to place the new project firmly within the business network, and then to adapt the resources, activities and actors to move it forward.

Along this journey, it is never a given that there will be a next deal, as this in particular depends on (1) whether someone with a network in control of the necessary resources, actors and activities evaluates the new innovative object to be sufficiently interesting in relation to its own requirements and (2) that the innovation can be separated out in such a way that a deal can be made.

Finally, we observe that the suppliers' global networks play critically important roles in the moving of new technologies from the technology development phase to wide spread use in public hospitals. Without this driving role and without the substantial business networks of these international companies, the new technologies appear unlikely to be adopted into practice simply because of the very high performance standards, regulatory requirements and quality of support to the users that are required.

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