User Innovators: When Patients Set Out to Help Themselves and End Up Helping Many

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In der vorliegenden Arbeit untersuchen wir die Motive und Aktivitäten einzelner Kunden-Innovatoren (Patienten mit verschiedenen Krankheiten) im Gesundheitswesen. Dabei interessieren uns insbesondere ihre persönlichen, durch das Gesundheitssystem hervorgerufenen Situationen sowie ihre Rollen bei der Entwicklung neuer Behandlungsmethoden, Therapien und medizinischer Geräte. Patienten sind eine mögliche Gruppe von Innovatoren im Gesundheitswesen. Im Gegensatz zu Produzenten-Innovatoren (z. B. Pharmafirmen und Medizingeräteherstellern), die typischerweise von der Kommerzialisierung ihrer Innovation profitieren, entwickeln Kunden-Innovatoren im Gesundheitswesen in erster Linie, um die Innovation direkt an sich anzuwenden. Die vorliegende Arbeit erweitert insbesondere die Arbeiten von *Oliveira et al.* (2011), *Oliveira* (2012) sowie *Shcherbatiuk/Oliveira* (2012), in denen Patienten und deren Familienangehörige als ernst zu nehmende Innovatoren im Gesundheitswesen identifiziert wurden. Danach gehen etwa 50% aller neuen Behandlungen, Therapien und medizinischer Geräte für Mukoviszidose auf Entwicklungen von Patienten zurück. Das Wissen dieser Betroffenen über ihre Krankheiten kann folglich ein wichtiges Innovationspotenzial für das Gesundheitswesen darstellen. Die etablierten Akteure stehen der Patientenintegration in ihre Innovationsprozesse – aus verschiedenen Gründen – bislang jedoch verhalten gegenüber. Vor diesem Hintergrund besitzen Patienten nicht selten einen starken Anreiz, selbst zu innovieren. Unter Bezug auf die Theorie der Pfadkreation („path creation theory", vgl. *Garud/Karnøe* 2001) wurden eine Reihe von Patienten-Innovationen – wie zum Beispiel elektronische Hosen, die Querschnittsgelähmten das Stehen und Laufen ermöglichen, ein Injektions-Port, das Diabetes-Patienten die tägliche Verabreichung von Insulin erleichtert und das Shower-Shirt, mit dem sich Brustkrebspatienten beim Duschen vor postoperativen Infektionen schützen können – analysiert. Auf Basis dieser Fälle wurden drei Mechanismen des Gesundheitswesens (seltene individuelle Umstände, starke Beeinträchtigung des täglichen Lebens und eine individuelle Sackgasse) identifiziert, die systematisch zu einer aus Patientensicht unangemessenen Leistungserbringung

führen. Weiterhin wurden vier wiederkehrende individuelle Innovationsstrategien identifiziert, die Patienten einsetzten, um ihre Bedürfnisse mit eigenen Innovationen zu befriedigen. Schliesslich zeigen die analysierten Fälle, dass Pfadkreation auf einem doppelten Rollenwandel des zentralen Akteurs Patient basiert. Indem (Gesundheitsleistungen empfangende) Patienten ihre Rollen zu aktiven Patienten-Innovatoren änderten, waren sie in der Lage, ihre individuellen Bedürfnisse zu befriedigen. Indem Patienten-Innovatoren schliesslich zu Produzenten medizinischer Geräte wurden, konnten sie einen ausichtsreichen Weg für die Verbesserung der Situation vieler Menschen mit ähnlichen Bedürfnissen sowie zur Bereicherung des Gesundheitssystems mit ihren wertvollen Beiträgen beschreiten.

We investigate the motives and activities of individual user innovators in healthcare, focusing on patients of various diseases. More specifically we investigate the role of patients in the development of new treatments, therapies or medical devices (TT&MD). Whereas producers typically benefit from commercializing innovations, user innovations are, by definition, developed by those who intend to use them. In health care, patients are one possible group of user innovators since they expect to benefit from using the solutions they self-develop. We draw upon and complement previous work of Oliveira et al. (2011), Oliveira (2012) and Shcherbatiuk/Oliveira (2012) that found that patients and family members display innovative capabilities and have developed a significant number of TT&MD for themselves (e.g., about 50% of TT&MD for Cystic Fibrosis were developed by the patients). The knowledge of affected people about the disease holds important potential for the health care sector, but the main players have – for several reasons – been hesitant to integrate them into their development processes. Given these circumstances, patients themselves have a strong incentive to innovate. We draw on path creation theory (Garud/Karnøe 2001) for analyzing a number of new therapies and medical devices developed by patients (i.e. user innovators), including the case of electronic trousers that help paraplegics to stand and walk; the injection port, a medical device for diabetes patients who need daily injections, and the shower shirt, to protect mastectomy patients from post-surgical infection, among other. We identify three particular mechanisms (i.e., rare conditions, strong constraints on daily life, and dead end situations) that systematically produce inappropriateness in health care provision as perceived by the patient. Furthermore, we identify four individual innovation strategies that patients used to transform their needs into innovations. Last, we show that by changing their role once – from patient to patient-innovator – individuals were able to help themselves, and by changing it again – from patient-innovators to producers of medical devices – they succeeded in helping many others and in finding a way to add their valuable contribution to the existing health care system.

1. Introduction

Health care is a sector of critical importance for the economy and the society at large. Health spending reached on average 9.5% of GDP of OECD[1] members in 2009. Total health care expenditures around the world are difficult to determine, but $5.7 trillion would be a fair estimate for 2011. That would place health care at about 8.7% of global

1 www.oecd.org/health/healthdata [Accessed 18.12.2011].

GDP, with expenditures per capita at about $800.[2] In the United States alone it provides 4.5% of jobs.[3] While health care attracts considerable resources and provides many jobs, its growing size raises severe concerns in developed countries. According to the Economist Report about the future of health care in Europe, its increasing cost cannot be covered by current levels of public funding, raised through taxation and insurance. The two main cost drivers are the increasing percentage of older people in western populations and the increasing financial requirements for research in and provision of health care. High regulation and bureaucracy add to the problem, as they make medical research even more difficult and costly (The Economist Intelligence Unit 2011).

Despite the growing efforts, current health care provision often fails to meet patient's needs. This failure is partly innate to the system, as we will briefly sketch using the prevalent example of rare diseases. In the European Union rare diseases are defined as diseases of which less than five in ten thousand people in the EU are affected (Commission of the European Communities 2008). Hence, even on an international level, they represent micro-markets and it seems costly and difficult for the health care industry to find solutions for so few patients. This is one of the reasons why rare diseases are also called orphan diseases. Nonetheless, there are between 5,000 and 8,000 known rare diseases and "an estimated 29 million people in the European Union" are affected (Commission of the European Communities 2008, 2). This situation is a typical long tail phenomenon (*Anderson* 2006), implying that there are no substantial economies of scale which typically drive the efficiency of health care provision. Hence, in order to meet resource constraints and goals of health care provision at the same time, national health care systems are forced to focus their efforts in innovation and provision in areas with economies of scale. As a consequence, resource devotion to rare diseases is limited. To make things worse, rare diseases often have a high impact on the quality of life of the affected people which often leaves them with considerable unsatisfied needs.

But some of the patients with a rare disease are very innovative. They are users who, when no appropriate solution is available, try to resolve their problem by themselves. This behavior can be easily applied to general health care services. If doctors cannot provide a patient (user of a service) with proper treatment (solution offered), a patient, who wants to be cured (has a strong need), starts to look for the solution by himself (innovates). *Von Hippel* was the first to show that users innovate, especially those who have very strong needs and who are ahead of the market (*von Hippel* 1976; 1986; 1988). According to this view, user innovators are individuals or firms which expect to benefit directly from using the product or service they create. Producer innovators, on the other hand, are firms or individuals who expect to benefit from selling a new or better product or service. In other words, a health-care innovation is user-developed if the developer expects to benefit from use and provider-developed if the developer expects to benefit from sales (adapted from *von Hippel* 1988; 2005).

Traditionally it was thought that users in the health care industry could only come up with incremental innovations. This was justified by their assumed incapacity for understanding complex technologies and simply the absence of desire from users to innovate. In

2 By Plunkett Research®, Ltd, http://www.plunkettresearch.com/health-care-medical-market-research/industry-overview [Accessed at 16.12.11].

3 By US department of labor data, http://www.bls.gov/oco/cg/cgs035.htm#nature, [Accessed at 16.12.11].

contrast to this view, recent studies show that users are able to develop their own solutions for radical innovations (e.g. *Røtnes/Staalesen* 2009). Still, user innovation in health care has not been sufficiently studied yet. In particular it remains unclear what really drives patients to innovate and how they actually go about. For this reason, we analyze cases of patient innovation in health care. We show how patients, by developing medical treatments and devices for themselves, were able to help many other patients with similar problems.

In order to study such individual endeavors within a heavily controlled system, we apply path creation theory. Path creation theory advances the well established path dependence theory by – in contrast to the latter – focusing on change from within a system. Specifically, path dependence explains an organization's reluctance to break with established ways of doing (*David* 1985; *Arthur* 1989; *Sydow et al.* 2009). It recognizes external shocks, coincidence and accidental events as triggers for change (*David* 1985). Path creation expands this understanding as it accepts internal sources for purposeful change (*Galunic/Rodan* 1998; *Garud/Karnøe* 2001). One prominent example of purposeful change from within is the Schumpeterian entrepreneur (*Schumpeter* 2008).

Path creation may, thus, help understanding and explaining how to successfully leave the defined user roles in the health care domain in order to create better ways of dealing with particular health care problems. For this purpose we describe and analyze the situations of individual actors, namely patients, who become user innovators as a consequence of leaving their foreseen roles. Beyond this, by successfully improving their own situation, they become motivated to change a part of the health care system in order to improve the situation of others like themselves. More precisely, they create a business based on their innovation which closes a previously unattended gap in health care provision. Ultimately, this process creates a new path, a new self-sustaining way of delivering better health care services or products for a particular problem by circumventing barriers of the established system with entrepreneurial efforts.

This path creation perspective will be employed to answer the research questions: (1) How do individual actors become user innovators in order to deal with a particular health care problem? (2) How do these user innovators succeed in helping others with their innovations?

2. Literature Section

2.1. User innovation

User innovations are innovations realized by those who intend to use it (*von Hippel* 1988). In order to become innovators, users first of all have to have a strong unfulfilled need (*Urban/von Hippel* 1988) and they need to possess "local" information that is valuable for the innovation (*Lüthje et al.* 2006). In addition, and due to various reasons, the chances of others to come up with a solution to their need must be low (*Morrison et al.* 2000). Naturally and for numerous reasons, not all users become innovators (*Franke et al.* 2006). But there are, however, users who will serve themselves by modifying existing products or even creating new products from scratch. And if they have adequate interest and resources to get exactly the product they need, they will be driven either to develop it for themselves or to pay a custom manufacturer to develop it for them (*von Hippel/*

Katz 2002; *Thomke/von Hippel* 2002; *Franke/von Hippel* 2003; *von Hippel* 2005; *Churchill/von Hippel* 2009).

Von Hippel called such users lead users and defined them as those who are ahead of a market trend and expect significant benefit from innovating. The uniqueness of users who innovate is that they expect to directly benefit from their innovation. An important part is also user's enjoyment or simply need for learning and challenging when innovate (*von Hippel* 1976; 1986; 2005). According to *von Hippel*, this phenomenon is relatively common and can be hugely important for particular industries.

For instance *von Hippel* (1976) found that approximately 80% of innovations of different scientific instruments were invented by users. Other facilitating factors are level and type of education, sex, type of product and country of origin. When a consumer has higher education (Bachelor's, master's or Ph.D. degrees), precisely in a technical area (in science or engineering or as a technical professional) and is male, the likelihood that he will innovate in consumer product is 260% higher than likelihood that the average citizen will do so in the UK, 210% higher in the US and 140% higher in Japan (*von Hippel et al.* 2011).

Most studies on the economic importance of innovation have ignored user innovation. Only recently empirical evidence on the incidence of user innovation at a macro/national-level started to be being collected. Studies showed that 6.1% of the UK's population over 18 have at least once created or modified a consumer product. In the US it is 5.2% and in Japan 3.7% (*von Hippel et al.* 2011). Different research in PC-CAD software, library information systems, sport products (canyoning, boardercross, handicapped cycling, and sailplaning), Apache web server software, surgery at university clinics, consumer outdoor products industry and kite surfing found that users are actively involved in 20% to 30% of the innovations. In rodeo kayaking, mountain bikes and banking services this percentage goes from 44 up to 100 (*Urban/von Hippel* 1988; *Morrison et al.* 2000; *Franke/Shah* 2003; *Franke/von Hippel* 2003; *Lüthje* 2003; 2004; *Franke et al.* 2006; *Baldwin et al.* 2006; *Lüthje et al.* 2006; *Oliveira/von Hippel* 2011a, b).

Moreover, users frequently become entrepreneurs of their own invention. User entrepreneurship is the commercialization of a new product/service by an individual or group who are also users of that product or service. *Shah/Tripsas* (2007) define two types of user entrepreneurs: professional users and end-users. In the first category are those who work in organizations and innovate in their professional life. When they have invented a product or service, they may leave their firm in order to start own business to commercialize the invention. The end-users are those who use the product in their everyday life. Examples of user entrepreneurs have been identified in numerous industries as different from each other as fun sports, e.g. rodeo kayaking (*Baldwin et al.* 2006) and mountain biking (*Lüthje et al.* 2006), juvenile products (*Shah/Tripsas* 2007) and health care (*Oliveira et al.* 2011).

2.2. Health care innovation

Innovation is an essential driver for health care. Genetics, nanotechnology, and increased general understanding of biological processes have facilitated radical changes in the innovation process of industry. Many products which are on the market today (e.g. human insulin, new vaccines, technologically advanced equipment) were unthinkable 50 years ago (Enterprise and Industry, European Commission, 2011).

The current health care system rewards innovation which prolongs life. This was appropriate when infections and short-lived decisions dominated the landscape. Because chronic diseases have taken a leading role now, the challenge is to develop treatments and technologies to improve the quality of patients' life (The Economist Intelligence Unit, 2011). As a result, technological advancement is a major driver of health care costs. These advances improve quality of health care but create major increases in expenditures. Improvements should be done carefully and technology can be overused if it is offered to patients for whom the innovations provide no benefit (*Bodenheimer* 2005).

Herzlinger (2006) provides a typology of innovations that can make health care better and cheaper. For one, consumer-focused innovation changes the way of buying and using health care by providing convenient, more effective, and less expensive treatment. Second, technological advancements lead to new products and treatments or otherwise improves care, making it less costly and painful (e.g. new drugs, diagnostic methods, drug delivery systems and medical devices). Third, new business models, particularly those that involve the horizontal or vertical integration of separate health care organizations or activities increasing efficiency, improve care, save consumers time and create economies of scale. Due to the specificity of the industry, innovation in the health sector faces several barriers, such as size and complexity, the dominant non-profit orientation of actors in this sector, specific demands, weak incentive alignment, as the buyer is mostly not the user, risk aversion, and the requirement of deep technological knowledge for innovation.

In a very simple model, health care systems comprise five central actors. The *consumers of health care* services and products are patients. The *providers of health care* services are health professionals (doctors, nurses, and other qualified personnel) who have accomplished a professional education which ensures the required knowledge standards. Their professional role also comprises the improvement of current as well as the development of new therapies. In their work, health professionals again rely on the producers of health care products, e.g., medical devices and pharmaceuticals. Those companies provide the necessary means for the rendering of therapies. This third group of actors can be seen as *enablers of health care provision*. With respect to innovation, the profit-oriented nature of their industries fosters the development of new products and services to be used by health care professionals. *Insurances* regulate most of the financial aspects of health care provision. Their role comprises the risk sharing among health care consumers but also the listing of health care services and products as eligible means for insurance-backed up health care provision. As a moderator among professionals, producers and insurances, *national health care agencies* ensure the quality standards for all health care products and services by means of market approval. Their role with respect to innovation is the design and control of standards for the development of medical devices, pharmaceuticals and treatments.

In the traditional view, the innovative forces of health care systems are primarily situated with the professional innovators of those actors who advance the field of health care provision. With respect to treatments and therapies this concerns health care professionals. With respect to the means for health care provision, this concerns the producers of medical devices, pharmaceuticals and other treatment-related means. In this traditional view, patients are not considered to contribute substantially to the advancement of the field. Their role is merely the one of a passive consumer. We will analyze under which conditions and in which ways patients leave their foreseen role as health care consumers and become innovators.

2.3. Path creation for innovation

Path creation theory is applied in this study to gain an in-depth understanding about the genesis and breakthrough of patient innovations in the context of the respective national health care system. Whereas protagonists of path dependence argue that new paths emerge only due to accidental events, contingency and exogenous shocks (*David* 1985; *Vergne/Durand* 2011), path creation theory takes a contrary stance, emphasizing that social systems can, thanks to human activity, consciously be changed (*Garud/Karnøe* 2001; *Schumpeter* 2008; *Garud et al.* 2010).

Researchers in various fields recognize the phenomenon of organizational path dependence as an explanation for organizational development over time (*David* 1985; *Arthur* 1988; *Noda/Collis* 2001; *Sydow et al.* 2009). According to path dependence, historical events shape possible futures of organizations (*David* 1985). In particular, it emphasizes that organizations follow specific paths they cannot easily break-away from, e.g. because of identities, strategies, structural and spatial arrangements. The reasons for such inertia are referred to as lock-ins. According to *Staw* (1976), lock-ins are defined as the escalating commitment of an actor to a chosen course of action. The main property of such processes is self-reinforcement, that is, increasing returns on activities (*Arthur* 1994). "When a process possesses the property of path dependence, then lock-in will occur on one of the possible outcomes if no exogenous shock disturbs the system. Lock-in characterizes a state of equilibrium with a very low potential for endogenous change – put simply, lock-in is a hard-to-escape situation" (*Vergne/Durand* 2010, 743). In particular routines, structures, locations, rules and identities can manifest over time and result in organizational inertia (*Gioia et al.* 2000; *Collinson/Wilson* 2006). For instance established professional rules and legal regulations in health care systems determine the allocation of resources in innovation activities, processes of service delivery and the assertion of patient's claims.

Interrelated with this perspective, path creation theory emphasizes that endogenous forces may trigger organizations to leave their path. Path creation theory suggests that human activities such as described in (1) entrepreneurship (*Garud/Karnøe* 2001; *Schumpeter* 2008) and (2) strategic leadership (*Noda/Collis* 2001) represent such endogenous triggers. Today, an increasing number of scholars focuses on endogenous forces to actively create organizational paths (*Garud/Karnøe* 2001; *Noda/Collis* 2001; *Sydow et al.* 2009; *Garud et al.* 2010). *Garud/Karnøe* (2001, 21) emphasize this understanding by stating: "[…] path creation as a process must be thought of as unfolding over time that is projected into the future and not just as a natural unfolding of historically conditioned events from the past." In our further analysis, we follow the argument of path creation. Our claim is that the setup of a national health care system with respect to dealing with particular problems of patients can be actively influenced. More precisely, we focus on patients who circumvent and ultimately change the system by becoming entrepreneurs.

3. Methods

For our exploratory empirical study on the sources of treatments, therapies or medical devices, we decided not to focus on specific diseases. We purposefully looked into different diseases in order to get a broader overview about the nature of barriers and of innovative user behavior. Our research approach follows a three steps approach, namely:

- *Step 1*. Sample of treatments, therapies or medical devices;
- *Step 2*. Identification and description of the market introduction (indicator for successful path creation) in order to examine real impact for a broader group of users. We browsed the internet, scanned trade journals and/or articles for dates of introduction;
- *Step 3*. Identification and coding of the sources of innovation and the particular behavior of the innovators, i.e. which barriers were faced and what needed to be done in order to overcome them. We identified user practices through literature searchers, internet browsing and episodic interviews (*Flick* 2000) via telephone with the innovators.

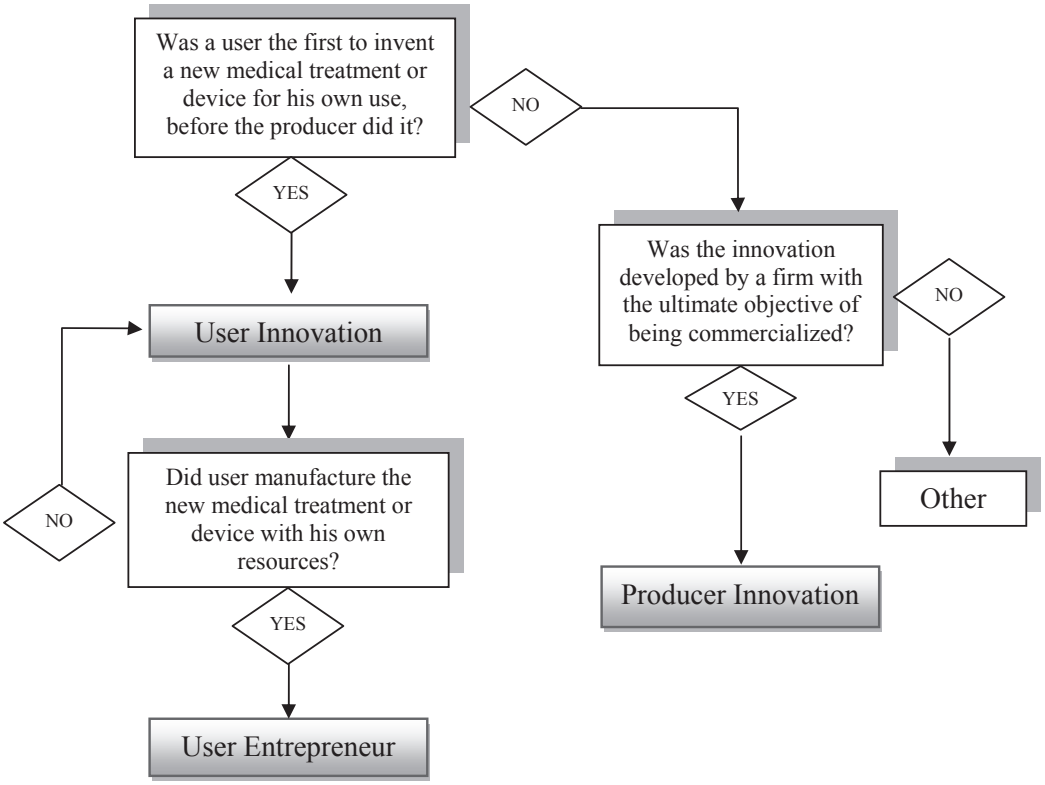

Figure 1: Coding of treatments/medical devices as user and producer innovations (Source: *Shcherbatiuk/Oliveira* 2012)

4. Results

In our empirical studies, we identified and analyzed a set of exceptional cases of patient innovation that we report in this section. More specifically, our analysis has revealed three particular contexts in which patient innovations occur, these are: (1) rare conditions, (2) strong constraints on daily life, and (3), dead end situations.

4.1. Rare conditions

In our research, we identified numerous cases where patients encountered a very particular situation. As one example, rare (or orphan) diseases were sketched in the introductory sec-

tion. The systematic problem with such individual states is threefold. For one, the number of people with the same problem is – by definition – so small that there are nearly no market incentives for profit oriented companies to develop health care products or services which are fine-tuned for precisely this respective situation. Hence, existing devices and pharmaceuticals do in most cases not quite fit the particular patient needs. Second, the primary goal of health care systems is to deliver as much health care to as many people as possible by employing a given amount of resources. This allocation constraint implies that there is a focus on conditions which are faced by many patients (common diseases), because by solving their problems, many patient's situation can be improved at the same time. Third, health professionals rarely come across a sufficient number of patients with the same rare disease throughout their working life that would allow them to systematically build up expertise for this particular rare patient condition. As a consequence, patients are left with health professionals who may – at best – acquire some first expertise in the course of their own treatment. We have chosen three examples of patients in rare conditions to illustrate this type of situation and to show how the patients coped with it.

Cystic fibrosis (CF) is a chronic rare disease that causes the body to produce abnormally thick and sticky fluid called mucus, resulting in life-threatening lung infections. It is one of the roughly 8,000 described rare diseases. So far, no cure exists and the patients constantly live with the threat that a high amount of mucus in their lungs will nurture potentially life-threatening infections. In traditional ways, this means that – whenever a severe infection is diagnosed, the patient has to undergo an aggressive antibiotic medication. A second side effect of CF is the latent tussive irritation which suddenly erupts in heavy coughing. In order to prevent this situation, CF patients regularly need to receive a manual therapy that brings up as much mucus as possible. We analyzed a sample of CF treatments and found that patients or members of their families have developed a number of significant treatments and medical devices to counter this problem. One example is the use of low frequency vibrations for bronchial drainage that was developed by a CF patient named *Louis Plante*. One day *Louis Plante* had to leave a concert because of excessive coughing while sitting in proximity to a large speaker. Using his skills as an electronics technician, *Louis* developed a device that could generate the low frequency vibrations (*Oliveira* 2012). His primary goal was to develop a treatment he would benefit from. Much later, he decided that his tinkerer efforts were actually so useful that he created a firm (Dymedso) to commercialize his solution. So in the end, he also became a user entrepreneur.

In line with this example, consider the personal story from *Hanna Boguslawska* who developed chest percussion with electrical percussion and founded a firm named eper ltd to commercialize it: "My daughter, 26 with CF, depended for most of her life on us, her parents to do her chest physiotherapy. So her independence was constantly compromised and she hated it. On the other hand, we not always delivered the best physiotherapy; simply because we were tired, or didn't have all this time required, or were sick. Sure, you know all of this. (...) Many times I was thinking about a simple solution, which would deliver a good physiotherapy and wouldn't require a caregiver. And I am very happy I could do it. My daughter uses my eper 100 (stands for electrical percussor, and 100 symbolizes all my percussion ideas which were never realized) all the time. According to her it is much better than the human hand and she can do it alone." (*Hanna Boguslawska*, mother of CF patient and founder of eper ltd.)

An allergy is a chronic condition that obliges patients to strictly adjust their lives. Whereas allergies as a whole are becoming more and more common, very severe forms such as the twins *Eric* and *Evan Edwards* have, are extremely rare. As young children, both *Edwards's* brothers were diagnosed with life-threatening allergies to a wide range of items. Life-threatening in their case means that the exposure to one or more of the allergy-causing substances may very rapidly lead to a physical shock which, when remained untreated for a certain amount of time, will result in death. In order to prevent them from an allergic shock, they had to carry with them a life-saving epinephrine dose all the time. Over time, however, the epinephrine delivery systems became more and more uncomfortable for them. In the twins' opinion, the devices were awkward to carry and difficult to use. In their late teens, *Eric* and *Evan* decided to develop a better solution for people just like themselves. They designed a new epinephrine delivery system that was really developed thinking about patients' needs. They took special education to develop their skills for designing, and together with their family and some initial financial supporters, they formed the company Intelliject. The E-cue solution, a novel epinephrine auto-injector, was approved by FDA in 2011 and currently the company has 33 patents issued and more than 60 others pending.

The common trigger for the described user innovations was the rareness of the patient's conditions. In all examples, the user innovators employed their personal expertise to invent a medical device that was beyond the market scope of existing medical equipment manufacturers. In the example of the *Edwards* twins, the patient innovators even purposefully build up engineering knowledge to solve their particular problem.

4.2. Strong constraints on daily life

Dealing with a disease day after day and hour after hour is the essence of a patient's situation described in this section. This is particularly true for chronic diseases, as the patients cannot escape their situation. But also other long-lasting situations such as a post surgery phase are characterized by strong constraints on the patient's daily life. By living through such inevitable processes, patients acquire astonishing in-depth knowledge about coping strategies and about which means really would help them keeping up. Despite that, knowledge generation in medical sciences treats patients often as mere consumers. In this view, to find out what a patient really needs is part of the professional diagnosis. This kind of research and development is reluctant to integrate the abundance of user expertise and by that imposes limits upon the ability to provide really useful tools to the patients or doesn't even discover their real needs. Hence, numerous examples of patients with rather common problems remain who perceive their situation as highly constrained – so much constrained that they decide to change it as the following examples show.

Amit Goffer was paralyzed in a car crash in 1997. He received the usual therapy starting with life-saving first aid and reconstructive surgery followed by physiotherapeutic treatments and a wheelchair that would allow him to somehow cope with his paralysis. But instead of accepting his disability, he used his skills as an engineer to invent a device which could help him get out of his wheelchair. He invented electronic trousers ReWalk that, with a computer and complex construction, help paraplegics to stand and walk, using crutches for stability, let them move their upper body in different ways. A harness around the patient's waist and shoulders keeps the suit in place, and a backpack holds the computer and rechargeable 3 1/2-hour battery. It is now available in rehabilitation hospi-

tals and centers in Europe and in the USA. *Amit* is also the founder of a company that produces the device (Argo Medical Technologies). In 2011 ReWalk got FDA approval. In January 2012 it was awarded the iF product design award 2012. In the beginning of May 2012, a paralyzed woman has become the first person to complete a London marathon wearing ReWalk.

Diabetes is one of the top 10 endocrine diseases in developed countries. In most cases it is chronic and it obliges the patient to completely adapt his/her day-to-day habits. The standard (and for most cases the only available) treatments are a healthy diet in combination with insulin injections. Understanding that neither health professionals nor producer innovators are able to find a cure, patients invent and modify existing treatments in order to better facilitate their individual lifes. Using injection therapy, *Catherine Patton*, type 1 diabetes patient since 2001, as time passed, quickly grew tired of having to give herself a shot each time she needed insulin. The multiple daily injections often left her skin bruised and she even preferred to skip meals in order to avoid taking injections. She also tried pump therapy (which had to be taken only once in 3 days), but to her it was rater uncomfortable. After getting completely tired, she started to research and experiment on a device that could meet her medical needs, yet have a minimal impact on her life. This led to her invention of i-port®, a medical device for diabetes patients who need daily injections. "I don't bruise; I don't have scar tissue", *Patton* said. "Even if you don't have a huge fear of needles... it's really a quality of life (improvement) and a convenience. It has changed the way I look at this disease." This injection port eliminates the need to puncture the skin for each dose. It might also be useful for parents of small children with diabetes. Lately, *Catherine* became a founder of Patton Medical Devices in 2004 to manufacture and distribute her invention.

Growing up deaf, the Australian *Alex Jones* always wished he could have better access to the classroom without having to rely on lip-reading or guess-making skills. In Australia, if there is a deaf student in the classroom, there are an Auslan interpreter, an Itinerant teacher and a note taker to help them during class. Jointly with his friend *Tony Abrahams*, *Alex* thought of creating something that could help deaf children to access the same information in the classroom as hearing ones. So they created Ai-Live. This software streams out the audio from the teacher to the captioners in other locations, those in turn re-speak that audio into the streaming text software, which appears on the laptop of the students in class in less than 7 seconds. To use the system, a regular teacher uses a radio microphone when addressing the classroom. This system overcomes many of the problems that are holding deaf children back from reaching their full potential. In 2003, *Alex* and *Tony* created the social enterprise Ai-Media to distribute Ai-live. It is continually under development and currently being used in schools, TAFEs, universities, events, workplaces, courts; with personalised captioning delivered to client's iPads, tablets or laptops.

Lisa Crites had breast cancer. After her mastectomy operation, the doctor said that she should not shower for 2 to 3 weeks, because exposure to water would increase the risk of infection. "After being told that I could not shower, I immediately began looking for a water-resistant garment to protect myself", *Lisa* says. To her surprise, no garment existed for such purpose. Some people used trash bags, but still this was not a good option. She created the ShowerShirt, which enabled her to shower while protecting herself from post-surgical infections. This convenient item meanwhile is also used by patients with other dis-

eases (e.g dialysis). *Lisa* became the founder of a company that produces the garment. It is still in approval FDA stage, but it can already be bought in the USA.

The examples above give evidence about the fact that inappropriate health care services and products are not restricted to peripheral phenomena, but are also faced by many patients with widespread diseases. The activities of the user innovators display the properties described for lead users by *von Hippel* (1986). In every example, the user innovator expressed a strong individual need (e.g. want to walk, to have really convenient insulin treatment, to receive comprehensive class room information, etc.) to overcome a status quo. From their in-depth user experience they got an understanding of how it should be and employed their personal skills (e.g. engineering, software programming, sewing and shirtmaking) to invent a device that would deliver the aspired improvement of life. Last, with their strong personal needs they anticipated a sufficient market for their invention as the founding of a company in every case indicates.

4.3. Dead end situations

Besides facing an everyday dilemma, e.g. with a chronic disease, a radical and negative change in the situation of a patient can trigger patient innovations. We have collected two examples of patients, who – facing a personal dead end situation – showed considerable innovative behavior.

John Kanzius did not live long enough to see his invention. He was diagnosed with leukemia and underwent chemotherapy, the standard therapy for reducing the size of cancer tissue and number of cancer cells in the human body. While he went through this physically and mentally challenging process, *John* was shocked by the number of young people who still were dying. Reviewing the negative side effects of the chemical substances and the strength it took to recover after every treatment, he came up with a radically new idea: "I wondered if I could make the cancer cells act like little radio receivers … and when they picked up the signal, they would get hot, they would create a fever, and the cancer cell would die". He introduced his idea to oncologists and to cancer surgeons. He convinced them to start developing the prototype of such a medical device and after long and difficult modifications and approvals, the clinical trials of *Kanzius'* Machine started in 2012. Currently, the group of researchers in MD Anderson cancer care, Houston, Texas (USA), tries to bring to life *Kanzius's* dream. The therapy is now viewed as a real alternative for chemo and radiotherapy in cancer cure. There are no known side effects, and the patient would feel nothing.

Tal Golesworthy is a process engineer who was diagnosed with the Marfan syndrome in 1992, an inherited disorder of aorta. It is a rare disease and labels the phenotype of several fibrillopathies (disorders of connective tissues). The disorder results in a decreasing functionality and resilience of the aorta. *Tal Golesworthy* came to the point when a surgery was unavoidable. And even worse, after the surgery he was obliged to a lifetime anticoagulation therapy. He considered both options – surgery or leaving it as it is – as being very unattractive. Being an engineer, he decided to create a more suitable solution for himself: "So I said to myself, I'm an engineer, I'm in R&D. This is just a plumbing problem. I can do this. I can change this". He invented External Aortic Root Support (ExoVasc), that exactly matches the patient's aorta and eliminates the need for anticoagulant drugs. In 2004 *Tal* became the first patient to have ExoVasc implanted. In 2009 there were already 19 patients wearing this implant. In 2011 External Aortic Root Support Project was the

winner of the Medical & Healthcare category of The Engineer's Technology and Innovation Awards 2011. To date, operations with ExoVasc implants are available in the U.K. and Belgium.

In the first described case the patient innovator was confronted with a fatal diagnosis which motivated him to resort to a completely new therapy approach. Lacking the technological expertise as well as the required resources, he succeeded to motivate health professionals to take his amateur idea serious enough to engage in substantial research and development activities. This will ultimately lead to a completely new and hopefully more patient-friendly cancer therapy. In the second case, the patient innovator was confronted with a substantial worsening of his condition which lead him to invent a completely new alternative medical device and to volunteer for being the first tester. He used his personal expertise as engineer and had so much trust in his invention, that he put his health on the line and became the first person to test his invention. What both cases have in common is that a personal dead end situation triggers extraordinary risk taking behavior in the process of innovation. It opens up new therapeutic ways so radical that they were not considered by health professionals before.

5. Discussion and Conclusion

In this chapter we will analyze the results in the light of path creation theory. For this purpose, we will first describe self-reinforcing mechanisms in current health care systems which result in a perceived inappropriateness that is described by patient innovators as the strong need to change their situation. Such reinforcing mechanisms are seen as the core mechanism for the establishment of organizational inertia and resistance to change (*Arthur* 1994; *Sydow et al.* 2009). We will then analyze patterns of innovative patient behavior, who – by trying to improve their situation – become patient innovators. In their micro analysis of the post-it innovation, *Garud/Karnøe* (2001) provide a detailed account of deviation steps which need to be undertaken in order to push a new idea forward. We will not take on this micro perspective, but focus on identifying patterns by looking at broader innovation strategies. Such change behavior can ultimately lead to a change in the system. In our study, this is the situation where patient innovators end up helping many others who face the same situation. In sum, this chain of mindfully conducted activities to change a system is described as path creation (*Garud/Karnøe* 2001; *Noda/Collis* 2001; *Sydow et al.* 2009).

5.1. Mechanisms of organizational inertia in the provision of health care

In chapter four we have given evidence of three different mechanisms of organizational inertia which ultimately drove the introduced patients to leave their traditional consuming role and to become innovators.

The first identified mechanism of organizational inertia gravitates around the rareness of a patient condition. Naturally, rare diseases such as CF are one reason for patients to be in a rare condition. But as the case of the *Edwards* twins shows, also fairly common diseases such as allergies can occur in very rare and sometimes extreme forms. Rare conditions provoke a number of side effects that impose severe limits to the provision of appropriate health care. Rareness implies very limited market attractiveness on the side of the producers of medical devices, pharmaceuticals and other means for health care provision.

At the same time, it also limits the attention and resource provision dedicated to this particular phenomenon on the side of national health care associations and health insurances, because their primary goal is to help as many as possible as much as possible. The same innovation effort dedicated to improving a very common (in contrast to a rare) patient condition will serve many more people. As all three cases of chapter 4.1 show, this can lead to a lack of well fitted therapies and therapeutic devices. Furthermore, rareness limits the establishment of sound expertise and systematic experimentation with the disease on the side of health professionals. This leaves many patients with professionals who have difficulties in diagnosing, deciding about the best therapy and suggesting the best supportive devices – if they exist at all. When only few health professionals get the chance of actually treating one or more patients with a particular rare disease, the advancement of knowledge is naturally limited and a substantial part of all desirable innovations is left to patient innovators.

The second mechanism of organizational inertia is rooted in the limited integration of perspectives – and in particular the patient's perspectives – into the innovation processes. Taking into account multiple perspectives is a facilitator of change per se, because it requires the involved actors to reconsider their approach in the light of the other's experiences. Despite that fact, the tradition of knowledge generation in the medical field is deeply rooted in natural sciences which follow a positivist stance and argue strongly for a distance between quasi objective knowledge producers (researchers, health professionals, etc.) and their objects of inquiry (diseases, patients, etc.). This causes a gap between science-driven health care innovation and actual patient needs. Even relatively common patient conditions such as diabetes in which the objective medical need to improve existing treatments seems to be low and the required technological functionality of the existing devices seems to be ensured, usability aspects remain of minor concern. The collected cases draw a striking picture where patient needs as basic as the wish to walk (no matter how), really comfortable insulin injectors, and individual hygiene after a surgery remained to be tackled by patient innovators.

The third identified mechanism of organizational inertia has actually to do with the core processes of minimizing the patient's risks and ensuring highest possible quality for every health care service and product. Innovation processes in the health care sector are strictly regulated and take a lot of time – for good reason. In two of the presented cases, however, time was the one thing the patient innovators didn't have. In this particular situation, rules that are of highest value to the system as a whole may become obstacles to personal well being. Both, *John Kanzius* and *Tal Golesworthy* showed considerable motivation to take additional risks and to stretch the borders of the system in order to solve their personal situations. As a positive side-effect for others, they initiated radically new ways of dealing with their personal diseases.

5.2. Patterns of innovative patient behavior

The patient innovators in the analyzed cases have displayed a number of innovative strategies in order to realize an improvement of their personal situations. One innovation strategy was the exploitation of personal professional expertise that was re-used to solve the patient's health care problem. For instance *Amit Goffer* the innovator of ReWalk used his profound engineering knowledge to design and build his walking pants. Similar strategies were used by *Tal Golesworthy* to design the external aorta, by *Louis Plante* and *Hanna*

Boguslawska to better deal with CF as well as by *Lisa Crites* for prototyping her Shower-Shirt. Going one step beyond, *Eric* and *Evan Edwards* even went through personal education in order to acquire the necessary designing skills for improving their epinephrine auto-injector. Following a completely different strategy, *John Kanzius* provided just the basic idea of how to kill cancer cells with the microwave effect. His main activity was the motivation of numerous experts in the medical field to carry on with his idea. *Catherine Patton* and *Alex Jones/Tony Abrahams* used the same strategy, as they lacked the professional expertise in the design of medical devices and software programming respectively required to prototype their idea themselves. As a third strategy, most of the patient innovators, namely *Plante, Boguslawska,* the *Edwards, Patton, Jones/Abrahams,* and *Crites* heavily drew on their own in-depth user experience in order to bring about substantial improvements of the patient's situation by better usability. As a fourth strategy we identified the exceptional individual risk taking of patient innovators in order to quickly promote radically new therapeutic approaches. This was in particular the case with *John Kanzius* and *Tal Golesworthy*, who resorted to radically different approaches when no other or no individually acceptable option was available.

5.3. Path creation in health care – ending up helping many

In general, successful patient innovators are hard to identify. This is particularly the case for those whose inventions never make it to the market. Our research interest was precisely in the identification of patient innovators who not only helped themselves, but who strived for, and succeeded in helping many others. For this purpose, we limited our search to patient innovators who were involved in the founding of a company that now provides their innovation to others in similar situations.

What's interesting about the presented cases from a path creation perspective is that by changing their role from patients (primarily consumers of health care) to producers of medical devices (enablers of health care provision), those patient innovators change the health care system from within. They found a way to add their valuable contribution to an existing system. Eventually, some of their new approaches may capture market shares from established companies. But as all of them took on a – for different reasons – unattended problem, their innovations are more likely to become enhancing complements to existing therapies. Hence, we are explicit not to have presented cases of replacing anachronistic, obsolete or even counter-productive parts of an organization by something new. Neither did we give evidence of external forces which triggered organizational change, as path dependency theory would suggest (e.g. *David* 1985; *Vergne/Durand* 2011). We have collected cases of path creation in the sense of *Garud/Karnøe* (2001) in which patients mindfully change their role in the health care system because they had something of value that could not be brought about if they had chosen to simply remain patients.

5.4. Concluding remarks

In our research, we observed vivid evidence of patient innovation in health care. The introduced patients are motivated to innovate for multiple reasons which reflect several shortcomings of the existing health care system with regard to their particular needs. These inadequacies result from self-reinforcing mechanisms which on the one hand ensure

the quality of health care on the level of the population but on the other hand, impose barriers to proper health care provision for particular problems.

Although we do not claim to have discovered even a substantial part of potentially existing mechanisms and resulting health care constraints, we claim to have given evidence that they indeed exist in many areas. Moreover, we have shown that they ensure the overall function of the system and at the same time they impose (sometimes severe) limits to the provision of appropriate, patient-friendly health care.

In the face of such situations, some individuals grow to challenge the unsatisfying status quo. Although every actor in the health care system may eventually become an innovator, we have focused on patients, precisely because they are believed to be a passive receiver, a consumer of health care services and products. Innovating new devices and treatments in this highly technology – and expert knowledge-driven field is beyond their foreseen role. Taking this situation as a context for user innovation, we described and analyzed the behavior of patients who not only figured out ways to help themselves, but who proceeded to providing their innovation for many others.

Our results also show that patients have mainly created complementary treatments. Their work does not generally find a cure, since that would require profound research on the respective diseases which was beyond the innovator's knowledge and resources in the described cases. In many cases, patients simply want to improve their quality of life during their illness or recovery period. This confirms the *von Hippel* (1986; 2005) hypothesis that "one size fits all" theory used by producer innovators is creating a place for users/patients/innovators who are ahead of the market. Treatments and medical devices are created by scientists and doctors to reach the root of the disease and so to sustain patients' lives. Such therapies may create uncomfortable feelings or situations, even as they help and cure. They could be difficult to use, or simply of an inconvenient size. In such cases, patients have considerable opportunities to take the initiative to improve these treatments or medical devices.

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