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Application of User Innovation – How Doctors Affect the Development of Modern Medical Equipment

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ABSTRACT

User innovation, as its definition, refers to innovation by intermediate or consumer users rather than by suppliers, has an extremely wide range of applications in many fields. From the automobile industry to food processing, where there is innovation, we can almost find the existence of user innovation, it has become an indispensable step in the innovation phase of products and services.

In this thesis, I will focus on the application of user innovation in the medical field. More precisely, I will discuss how doctors, the users of modern medical equipment, participate in the innovation phase of those various kinds of equipment and affect their development.

In the first two chapters, starting from the definition of user innovation and lead users, I will also discuss some classic and practical examples and scenarios where user innovation is applied in different fields deeply.

Then, in the third chapter of the thesis, I will study the application of user innovation in the modern medical equipment innovation phase in detail, as well as the innovations in surgical techniques developed by surgeons. Also, the positive and negative effects on account of the involvement of doctors in innovative and developing activities will be discussed.

Moreover, in the following chapter, I will make a comparison of the extent of participation of innovation and influences between doctors and patients because both of them can be considered as users of that medical equipment.

At the end of the thesis, we will respectively talk about the latest cutting-edge application of user innovation in the medical field and my point of view about this topic.

CONTENTS

Chapter 1 The Definition of User Innovation

1.1 User Innovation

What is user innovation? According to the explanation of Wikipedia, user innovation refers to innovation by intermediate or consumer users rather than by suppliers. While Eric von Hippel, who developed the concept of user innovation, defines it as the "one that a firm or individual makes to use themselves."

In the 1970s, Eric von Hippel firstly noticed the role of users as innovators. He perceived that many products and services are developed or at least refined by users instead of by producers, which means that users are no longer simply consumers of products created and supplied by producers. But they participate in designing and manufacture products for themselves. That because products are usually developed to satisfy the widest possible demands, so, if an individual user meets a problem that most consumers do not, he has no choice but to modify the existing product or develop a new one to solve his problem.

This leads to an important difference between the innovation by users and by producers – products developed by producers are typically intended to serve the average needs of a wide range of people, therefore, may only approximately meet the requirements of specific consumers, in contrast, products that users modify or develop to satisfy their own needs are more precise.

With the continuing technological advances in Internet and communications, the phenomenon of user innovation has been reinforced by easier information access and heterogeneity of user demand. It can be observed particularly within the new generation of customers, who was born and grew up in the digital era, since they are partial to individuation and more willing to get the customized products and services or at least the freedom to modify the products according to their own needs.

An example of the effects the internet brings to user innovation is the rise of the virtual customer environment (VCE), a web-based forum that facilitates user innovation or customer co-innovation. Since customers can partner with companies in different phases of product or service innovation, from product ideation to product design and development, and from product testing to product diffusion, VCEs can be designed to help companies corporate with their customers in these various phases of product development as well as value creation activities. For instance, the T-shirt manufacturing company Threadless establishes an online community that includes a group of volunteer designers. In the design process of its products, the company relies on the contribution of these designers. They submit their designs and vote on the designs of others. In return, the winners will get a basic monetary award and a percentage of the T-shirt sales designed by themselves. These incentives ensure Threadless obtain continual contribution from its volunteer community.

Based on recent empirical studies, 10 to 40 percent of users engage in developing or modifying products. The roles of consumers gradually transform into prosumers, who both consume and produce. The products or solutions provided by them are usually the outcome of cooperation within globally dispersed communities and certainly have competitive advantages with fully commercial products.

What's more, after developing the products on their own, user innovators are often willing to share their ideas with manufacturers and hoping they can consider producing the products, the so-called process free revealing.

There are many different degrees of user innovation: 1) innovation of use 2) innovation in services 3) innovation in the configuration of technologies and 4) the innovation of novel technologies. Most user innovation is concentrated in the use and configuration of existing products and technologies, and it is already a normal part of long-term innovation. However, new technologies which are easier for end-users to change and innovate and the development of new channels of communication are making it much easier for user innovation to occur and exert an impact.

In 2014, Piller and West summarized the three key premises of user innovation in their article as follows: 1) users have unique information about their needs 2) when enabled they will create solutions to those needs by themselves 3) they usually freely reveal those solutions to others.

Since the concept of user innovation came up, it has been an important proof of the argument against the Linear Model of Innovation, which is an early model designed to understand the relationship of science and technology that starts from basic research that flows into application, development, and diffusion. In other words, this model posits scientific research as the basis of innovation, and innovation comes from research and development is then marketed and diffused to end-users, which eventually leads to economic growth. But obviously, this linear model is limited and hard to believe in practice. In fact, it has been criticized by many scholars over decades, and one of the major criticisms pointed out that this linear model has evident crudeness and limitations in capturing the sources, process, and effects of innovation.

Therefore, the existence of user innovation demonstrates further that innovation is a non-linear process involving innovations at all stages.

According to Ilkka Tuomi's research on Open Innovation based on analysis of Internet-related innovations and open-source software, users are fundamentally social. Therefore, user innovation is also socially and socio-technically distributed innovation. Also, Tuomi pointed out that key uses are usually unintended uses invented by user communities in a user innovation process, and it reinterprets and redefines the meaning of emerging technological opportunities.

1.2 Lead Users

After the growth of the concept "user innovation", Eric von Hippel introduced the term "lead users" in 1986 to describe innovating users with needs ahead of the general market.

He defined the lead users as users whose present intense demands will be general in a marketplace, but they will become normal months or years in the future. And the solution to the immediate needs of lead users should bring significant benefits to them, so they have the motivation to innovate.

Lead users usually act as pioneers. They often develop new types of products and applications earlier than producers. More precisely, according to the study of Urban and von Hippel, 82% of a given cluster of lead users had developed a new version or had modified a specific type of the industrial products under study. By comparison, only 1% of the non-lead users had done this before. That's also why lead users are a very valuable source of innovative progress. Besides, being pioneers of innovation benefits lead users themselves because their innovation is innovated to serve their own needs.

For this reason, lead users don't need to consider whether others will also want the products when they are developing them. They are only concerned about their demands. On the contrary, producers or suppliers must wait until there are some pieces of evidence that a general and profitable market will raise for such innovation, then they can invest in it. An example is mountain bikes which were developed by individuals who enjoyed biking down mountains at the beginning, and bike producers simply watched and waited for years until the rise of the sport of mountain biking. With thousands of enthusiasts participating in this new sport and starting to build their mountain bikes by themselves, the extent of the market became clear and bike producers entered the new market with the first commercial mountain bike products.

Because lead users also modify the existing products or services except developing the new ones, they are relevant to the terminology “creative consumer”, which describes any “individual or group who adapt, modify, or transform a proprietary offering”. Different from mass consumers who simply use and consume the products, creative consumers also change them in some way.

As some companies rely on taking advantage of the creativity of their consumers, many companies may hold the opposite attitude and feel threatened by the actions of creative consumers. For example, the hacker who unlocked the iPhone and hacked other electronic devices, or the Disney fan who designed and delivered the tourist guide of Disneyland without authorization. Although both the hacker and the big fan of Disney received negative or even threatening reactions from the companies whose products and services they had repurposed, they also meet the definition of creative consumers.

It leads to the classification of the company’s standpoint towards creative consumers. According to the company’s attitude towards these creative consumers are positive or negative, and whether the company’s actions toward creative consumers is either active or passive, the company’s standpoint can be divided into:

- Resist standpoint (negative attitude / active actions) – restrain consumers’ creativity.
- Discourage standpoint (negative attitude / passive actions) – tolerate or ignore consumers’ creativity.
- Encourage standpoint (positive attitude / passive actions) – don’t actively promote consumers’ creativity.
- Enable standpoint (positive attitude / active actions) – actively facilitate consumers’ creativity.

Back to innovation by lead users, according to the research of Philip et al., on average 54.4% of the major innovations have the first functioning prototype created by users in the following nine innovation sets: 1) disruptive innovations 2) corporate banking services 3) mobile banking services 4) retail banking services 5) medical apps 6) off-label drug therapies 7) scientific instruments 8) kayaking equipment 9) windsurfing equipment. Actually, user innovation activity appears in all fields in which users have an interest and it’s easy to find that innovation development by users covers services as well as products. For instance, in the research of Philip et al., based on the empirical study of Oliveira and von Hippel, the share of user innovations in innovation sets corporate banking services and retail banking services are 67.5% and 44.0%

respectively.

Lead users are an important information source for innovating companies in the development process of new products concerning the following three aspects:

- Firstly, lead users can provide insights for future market needs, especially in a rapidly changing market. At the front of the trend of the technological development, lead users are more able to provide accurate information to help companies understand the user needs which massive users will face in the future. In a word, lead users serve as “a need-forecasting laboratory for marketing research”.
- Secondly, lead users usually have developed their own innovative solutions to satisfy these new market needs which could be an important source of innovative ideas for companies.
- Thirdly, lead users are expected to obtain significant benefits from the solutions for needs, therefore, they have strong motivations to provide the most valuable information to marketing researchers. The greater the benefit that lead users may obtain from a new product, the higher will be their input in the marketing researches.

Empirical experience has proven that cooperating with lead users in the new product development process enhances companies’ market success and leads to a reduction of both development times and development costs. Therefore, it is important for companies to identify the right lead users and to manage the cooperation with the lead users over the entire innovation process.

1.3 Lead User Method

The lead user method is a market research tool that has been developed to help producer firms that have an interest in their customers to identify the newest user-developed innovations and analyze their commercial potential. Since lead users are often the originators of novel product and service innovations, the lead user method is used by companies or individuals seeking to develop breakthrough products. Developed by Eric von Hippel firstly, the lead user method is different from traditional market research skills that collect information from the users at the center of the target market. The lead user method collects information about both needs and solutions from the leading edges of the target market and from analogical markets which face similar problems but in a more extreme form.

The methodology includes four main steps: 1) start of the lead user process 2) identification of needs and trends 3) identification of lead users and interviews 4) concept design.

Since lead users are defined as pioneers in the associated marketplaces and breakthrough products may be developed by identifying leading trends, marketing researchers of innovating companies must first specify the underlying technological and market trends on which lead users have a leading position. In addition to having interviews with industry experts about the market trends, other means like technological forecasting and environmental analysis are also widely used by researchers to explore and assess the most important market trends in a competitive environment at this stage.

Except identifying lead users through identifying the market trends, another possible way is to take advantage of the second characteristic of lead users, which is the high expected benefits they want to obtain from the new product. The extent of benefits that lead users expected to acquire can be measured by:

- Product development or product modification that has already been undertaken by users in order to improve the corresponding product or technology. The higher users' investments in these innovations, the higher their expectations of related benefits.
- Extent of user dissatisfaction with existing products. The degree of user dissatisfaction is positively correlated with the expected benefits that users hope to obtain from improvements.
- Users' speed of adoption of new products or their innovativeness. Highly innovative users at the leading edge of technology expect higher benefits from new products and usually show faster acceptance of new products and higher innovativeness. To select more appropriate lead users, researchers always consider a user's technology strategy carefully.

Once the market trends and indicators of the extent of expected benefits have been identified, the marketing researchers of innovating companies seek out "lead users". Based on data from interviews and questionnaires with potential users, researchers group them employing cluster analysis and finally find a subgroup of people or organizations that are at the cutting edge of the focused market and show high expected benefits from solutions to their respective needs.

An example can be a company that wants to create a breakthrough flashlight design. The marketing researchers of the company may find out policemen, home inspectors, or others who require brighter and more concentrated lights in their daily work as lead users. Once they have been identified, researchers will interview them to obtain their insights about how they solve the problem for themselves. In addition, the lead users are also asked that if they know about individuals or organizations who are considered to be outside the market and face even more extreme lighting needs than the policemen or home inspectors, for instance, photographers, divers, or movie lighting designers in our case. By learning from both the lead users and the users outside the market, innovating companies may find new methods or approaches to create innovative products that are truly breakthrough and may not realize by simply investigating existing users with traditional market research techniques.

The most important task of the application of the lead user method is searching for lead users with valuable innovation to share. There are two basic types of lead user search methods that exist. The first one is more appropriate for searching product innovations developed by consumer lead users, while the second one is much suitable for identifying innovations developed by professional lead users like medical personnel or developers within firms like banks who may have developed process improvements for their use. The two methods are:

- AI search of user-generated content posted on the web

  Lead user consumers always post descriptions of their developments openly on the web to share their innovative results to others with the same interests. For example, sporting enthusiasts may post improvements they have made on sporting equipment or techniques for use. Another example is parents who may post their parenting innovations on a specialized web platform to help other parents, and to gain experience from improvements shared by others.
  Since these innovations are openly posted on the websites, their content is searchable by AI methods. More specifically, the method scans thousands of websites which is openly available to all, searching posted textual content that both describe an improvement in a field that the searcher is interested in and contain phrases that indicate the presence of innovations such as “I invented” or “I solved”.
  To separate these innovations that users are generally interested in and have potential commercial value for producers, the corresponding innovation descriptions must be evaluated carefully to determine the frequency of being the subject of web searches. The higher the frequency, the higher the possible commercial potential.

- “Pyramiding” search process for identifying lead user innovations not publicly posted

  This method involves a sequence of telephonic or email interviews with experts in a professional or industrial circumstance. Each interviewee is initially selected based on his writings or reputation in the interested field and is contacted and asked whether they know about someone who faces extreme problems on the topic of interest and whether he or she has innovated any solutions by their knowledge.

For example, in the medical field, when a general surgeon is asked such questions, he might point out surgeons who deal with immune-compromised patients who are more probably get infections than average patients. The individuals who are confronted with extreme situations and identified by this way are generally further up the "pyramid of expertise" than the initial interviewees, and then, are contacted and interviewed in turn. In general, about 5 to 20 of these pyramiding interviews are sufficient for marketing researchers to seek out the lead user innovators of their interested field.

The above two types of lead user search methods have wide usage in many industries and for different complexity levels of products. There are some examples where the lead user method was utilized to innovate a new product that satisfied the specific needs of lead users:

- 3M's Medical-Surgical Division utilized the lead user method to develop a breakthrough surgical drape product by establishing a team of lead users which included a veterinarian surgeon, a makeup artist, doctors from developing countries, and military medics.
- Hilti AG, the famous mechanical manufacturer, utilized the lead user method to develop a simplified pipe hanger with a lead user group consisting of layout engineers, researchers from construction departments of institutes, an engineer from a professional organization, and two engineers from municipal building departments.
- Local Motors, the first car company to utilize the lead user method to co-create vehicles, utilized vehicle designs provided by its online virtual community of designers, fabricators, engineers, and enthusiasts to develop its first co-creative vehicle – the Rally Fighter.

After the most necessary step, which is the identification of lead users, of the lead user method application in the new product development process, there are two more main steps following. They are the generation of new products with lead users and testing of lead user products.

The generation of new products with lead users is important because the innovating company can draw on the experiences of the lead users and consider their novel ideas in modifications of existing products or the creation of new products which will meet the lead users' specific needs. The new product development process with lead users should be coordinated. Therefore, a joint development team can be established to combine the lead users' solutions with the know-how of the innovating company to enhance innovation success.

Besides, the needs of today's lead users may not consist with the needs of future users, which will make up a major share of the predicted market. Hence, the product concepts developed with lead users need to test for general users in the target market before being commercialized.

The three main steps of the lead user method application in the new product development process have been elaborated in detail in the previous paragraphs: 1) identification of lead users 2) generation of new products with lead users 3) testing of lead user products. In the next chapter, I will discuss some of the most representative applications of user innovation in different fields.

Chapter 2 Some Examples of Application of User Innovation

Over the past decades, empirical research has shown that, in many fields, users can often contribute insights regarding solutions responsive to their needs. In some fields, users have been found to be the actual developers of most of the successful new products eventually commercialized by manufacturers. As the importance of users participating in various phases of product development is highlighted, the applications of user innovation exist almost in any development phase of any product of any field. In this chapter, we will elaborate on some of the most representative cases.

2.1 PC-CAD System

It is a classic example of user innovation to test the first empirical application of the lead user methodology and studied by Urban and von Hippel. In their article about lead user analyses for new product development, first of all, they put forward to integrate market research techniques with the lead user hypothesis and came up with a four steps methodology for new product concept development and testing. These steps are:

- Specify lead user indicators – including “finding market or technological trend and related measures” and “defining measures of potential benefits” based on the two characteristics of lead users. Before one can identify lead users in a given product category of interest, one must specify the underlying trend and its reliable measures and define measurable indicators of potential benefit.
- Identify lead user group – once trend and benefits indicators are specified, one may screen the potential market and identify a lead user group. With a series of analyses of lead user indicators collected from surveys, one can find a subgroup that is at the leading edge of the trend being studied and shows relatively high expected benefits from solutions to related needs.
- Generate product with lead users – after identifying the lead user group, one can derive novel attributes and/or product concepts of commercial interest from lead users related to their real-life experience. These may include modifications to existing products or new products created to meet lead users’ specific needs. Then,

a creative group can pool user solution contents and develop a new product concept.

- Test the lead-user product – the needs of today's lead users are may not precisely the same as the needs of the users who will make up a major share of tomorrow's predicted market. Therefore, it's necessary to access carefully how lead-user data are evaluated by the more typical users in the target market before the concept comes true.

To test the lead user methodology in an industrial setting and make clear the detailed procedures involved in the implementation of the method, Urban and von Hippel picked computer-aided design (CAD) system products for their in-depth case study. More specifically, they examined the CAD systems used to design the printed circuit boards which hold integrated circuit chips and other electronic components and interconnect these into functioning circuits. The PC-CAD systems take engineering designs and convert them into detailed manufacturing specifications for such printed circuit boards.

Urban and von Hippel sought out many engineers who were expert users of PC-CAD systems by telephoning managers of the PC-CAD groups of several firms. After deep discussions with these expert users, they found out that an increase in the "density" with which chips and circuits are placed on a board was and would continue to be a very significant trend in the PC-CAD field. An increase in density means that it is possible to mount more electronic components on a given size printed circuit board. In turn, the costs will be lower because of less material used, and the speed of the circuit operation will be faster due to signals between components traveling shorter distances.

This technological trend is valuable in the PC-CAD field, and there are several ways to increase the board density, including increasing the number of layers in a printed circuit board, decreasing the size of electronic components, and narrowing and packing more closely the printed wires which interconnect the electronic components. Each of these density-related attributes offered an objective measure of determining a respondent's position on the trend towards higher density, therefore, were included in the formal screening questionnaire which was sent to respondents by Urban and von Hippel. Also, in the questionnaire, for assessing the level of benefit which a respondent might expect to gain through improvements in PC-CAD system and identifying the early adopters of the technology, questions like whether respondents had developed and built their PC-CAD systems rather than bought the commercial ones; the satisfaction level with existing PC-CAD equipment; when the firm first started to use PC-CAD; rate of innovativeness of respondents' own firm in the field of PC-CAD were asked as well.

To identify the subset of lead users who were designing very high-density circuit boards and were able to gain especially high benefit from increasing board density, this questionnaire was sent to 178 respondents who qualified as PC-CAD users, supervisors, or technical support personnel by Urban and von Hippel, then, they received 136 answers (76.4%) by phone or mail. After a simple inspection of the questionnaire responses, Urban and von Hippel surprisedly found that fully 23 percent of all responding user firms had developed their in-house PC-CAD hardware and software systems. Firms allocated substantial resources to build systems that satisfied their needs and seek to achieve better performance than commercially available products could provide in several areas: high routing density, the faster turnaround time to meet market demands, better compatibility to manufacturing, interfaces to other graphics and mechanical CAD systems, and improved ease of use for less experienced users.

In the following phase of identifying the lead user group of PC-CAD systems who could design high density printed circuit boards, Urban and von Hippel conducted a cluster analysis of the screening questionnaire data and chose the two-cluster solution as the more simplified one for further analysis. According to the analysis result, the lead user cluster (28% of answered respondents) is distinct from the nonlead user cluster on all attributes measured. The lead user cluster members report more use of surface-mounted components, narrower lines, and more layers. Many more respondents in the lead user cluster report building their own PC-CAD system (87% versus 1%), judge themselves to be more innovative (3.3 versus 2.4, 4-point scale, high value more innovativeness), are earlier adopters (seven years earlier than nonlead user cluster on average), and are more dissatisfied with commercially available systems (4.1 versus 5.3, 7-point scale, high value more satisfied with commercial products).

After identifying the lead user group by cluster analysis, Urban and von Hippel selected a small sample of the lead users to participate in a creative group exercise to develop one or more concepts for improved PC-CAD systems. Experts from five lead user firms were recruited for this creative group. Four of the five firms had built their own PC-CAD systems, all of them were working in high-density applications (many layers and narrow lines) and had adopted the CAD technology early.

The task of this creative group was to specify the best PC-CAD system for laying out high-density printed circuit boards that could be built with current technology. Therefore, the PC-CAD system concept developed was specified could only include features that one or more of them had already implemented in their own organizations. The new concept which was developed by the creative group integrated the output of

PC-CAD with numerical control machines, had easy input interfaces, and stored data centrally with access by all systems. It also provided the capability of fully functional and environmental simulation (electrical, mechanical, and thermal), designing boards of up to 20 layers, routing thin lines, and locating surface-mounted devices on the board.

Since the new PC-CAD system had been generated with the lead-user creative group, the next step was to test whether other lead users and more ordinary users preferred this new concept. Hence, Urban and von Hippel designed a new questionnaire which contained measures of both user perception and preference regarding the following four systems being compared: each user's currently used PC-CAD system; the best commercial PC-CAD system available at the time; the system concept developed by the lead user group; and a system for laying out curved printed circuit boards (to detect whether there is a response bias). One-page descriptions of these systems except the user's current one were prepared and sent to respondents at the same time with the questionnaire.

The questionnaire asked respondents to rate the four systems mentioned above on 17 attribute scales after reading the one-page descriptions and comparing them with their current system. Each scale was scored by respondents based on a five-point agree-disagree judgment. 173 users (the 178 respondents who qualified in the screening survey minus the five firms in the creative group) received the questionnaire, and 71 (41%) were entirely or substantially complete to respond to it.

Through the analysis of the questionnaire data, Urban and von Hippel found that respondents strongly preferred the lead user group PC-CAD system concept, 78.6% of the respondents selected the lead user creative group concept as their first choice. The questionnaire also measured the probability that respondents were willing to pay for the different systems at different prices. The result showed that the lead user group concept had an average possibility of purchase of 51.7 percent and was significantly higher than the other concepts, and the preference for the lead user group concept was at all different price levels.

In order to better understand the reasons for respondents' preference for the PC-CAD system developed by the lead user group, Urban and von Hippel factor analyzed the attribute ratings and selected the following five dimensions: 1) "power/value" – placement/routing power, value for the dollar, powerful, and high density 2) "ease of use" – easy to learn and easy to use 3) "manufacturable" – manufacturable and enough layers for needs 4) "integrability" – easy to customize, integrate with manufacturing and other CAD systems 5) "maintenance/upgrade" – easy to maintain, upgrade, and reliable. The importance of the five dimensions to users was estimated, and the most important were found to be "power/value" and "integrability". While "manufacturable", "ease of use", and "maintenance/upgrade" were found to be less significant.

The result of the factor analysis of the rating data showed the lead-user-developed concept to be higher than other concepts on a power/value and integration dimension, but lower on manufacturable and maintenance/upgrade dimension and the same on an ease-of-use dimension. Based on this analysis, it appears that more ordinary users might prefer to choose the lead user concept if they were convinced that the system would be easy to maintain and upgrade, and the printed circuit boards designed by the system would be simple enough to be produced.

In their study, Urban and von Hippel also indicated that the product preferences of typical nonlead users were similar to the preferences of lead users. Back to the questionnaire data of choice of preferred PC-CAD system, when Urban and von Hippel looked at the lead and nonlead user clusters separately, the overall similarity of preferences in these groups was apparent. While both groups preferred the system concept developed by the lead user creative group, a slightly higher proportion of lead users selected this concept as their first choice (92.3% of lead user groups versus 80.5% of nonlead user groups). Besides, lead users were found somewhat less likely than nonlead user respondents to switch from their existing system to one of the three alternative concepts, however, if they did switch, they were more likely to switch to the lead user group concept.

To understand the finding of similar preferences of lead and nonlead user clusters at a deeper level, Urban and von Hippel examined the attribute ratings and developed factor analyses of the rating data for each group separately. The examination showed that the lead and nonlead users appeared to be using a similar set of dimensions to evaluate PC-CAD concepts. So, Urban and von Hippel assumed the same underlying structure of dimensions for both groups and tested if there was any difference in the importance of each dimension for lead and nonlead users. The result showed there were some differences between the coefficients across the two groups, but these differences had been proven to be not statistically significant. This result further verified the viewpoint that the lead and nonlead user groups similarly evaluated PC-CAD systems and their preferences for the product concept were also similar – the concept developed by the lead user creative group.

At the end of their article, Urban and von Hippel summarized that the lead user methodology is a logically straightforward combination of the following three empirically tested components:

- First, the lead user method assumes that users who have experience with solving a practical need are better able to give accurate information regarding it than those without such experience.

- Second, the method requires that, in fields where need-related trends exist, some people will experience a need before others, which means, they will “lead” concerning the trends.
- Third, the method assumes that users differ on the amount of benefit which they can expect from a solution to a need and that the amount of effort which they will exert to understand and resolve the need will vary with the expected benefit.

In their case study of the PC-CAD system, the evidence supporting the above three underlying assumptions of the lead user methodology was sufficient. The results of this first empirical application were also encouraging. Lead users with the hypothesized characteristics were clearly identified; a novel product concept was created based on lead user insights and their existing solutions for problems; the lead user concept was voted to be superior to currently available alternatives by a separate sample of lead and nonlead users.

Both the supporting evidence of assumptions and the case study results represented that the lead user analysis can improve the productivity of new product development in industrial markets. However, at the same time, Urban and von Hippel pointed out that there were certainly problematic issues that must be explored before the hypothesis became confident.

Although, this case study completed by Urban and von Hippel is established on some hypotheses and has not been carried to the point of testing actual products in an actual marketplace. It is a successful exploration of the application of lead user methods to industrial products. It not only verified the feasibility of the lead user methodology but also gave an example to manufacturers to demonstrate the importance of user innovation in a rapidly moving field.

2.2 Sporting Equipment

The second example of the application of user innovation focuses on sports equipment. Other than the previous example studied by Urban and von Hippel, which focused on industrial products, in this section, we will concentrate on user innovation in a consumer goods category.

Starting with Sonali Shah’s study. She investigated the innovation and commercialization histories of 57 important equipment innovations developed for three relatively new sports: skateboarding, snowboarding, and windsurfing. Contrary to conventional wisdom, she found that the equipment for these new sports was not developed by existing sports equipment manufacturing companies. Instead, innovations were developed by a few early and active participants in the new sports who built innovative equipment for themselves, their friends, and often established businesses focused on producing such equipment in order to appropriate benefit from their innovations and found a lifecycle around the sport. This phenomenon existed even in a closely allied field, for example, the snowboarding equipment was not developed by makers of other winter sports equipment such as skis or sleds.

At the beginning of Sonali's study, she selected these three sports to investigate based on the following two criteria:

- The sport was developed relatively recently. So, it could be possible to collect accurate and detailed data regarding the key innovations. Information about the histories of the innovations could typically be obtained by interviewing the innovators and others who were also present when the innovation was being developed or commercialized.
- The sport has grown to a significant market size, having at least a million participants, and having equipment sales in the range of $100 million. So, both users and manufacturers should have an interest in participating in the development of innovations in this sport. Users because of the attractiveness of the activity, and manufacturers because of the commercial attractiveness of the market.

The selected sports – skateboarding, snowboarding, and windsurfing all met the two criteria noted, and each of them had a group of great enthusiasts and a contingent of professional racers, as well as mass-market sportful participants.

After selecting the sports to be studied, Sonali identified a sample of crucial equipment innovations for each of the three sports. At first, she applied the pyramiding search process to identify a 3 to 5 experts' group for each sport. Every identified expert had comprehensive information on the histories of crucial equipment innovations in each sport, and a few of them were innovators themselves. Then, these individuals were asked to list "the important equipment innovations in the history of the sport". By comparing the lists of innovations, Sonali elected all innovations nominated by two or more experts, except the innovator if he was also a nominator. Finally, a sample of 7 important equipment innovations for skateboarding, 10 for snowboarding, and 40 for windsurfing was identified.

Next, Sonali collected the data of development and commercialization histories for each identified innovation through one-on-one telephone interviews with industry experts. They are the founders of the sports, those responsible for key innovations, designers, early manufacturers, current manufacturers, and so on. Interviews were designed carefully by Sonali to collect as much detailed information as possible. The interviewees were interviewed to get a better understanding of the local information employed and the specific circumstances, needs, and problem-solving methods surrounding the innovative activity.

Through analyzing the collected data, Sonali summarized the following three findings concerning the innovations developed for the selected novel sports:

- Patterns in the sources of innovation

  The initial first-of-type innovations of the three studied sports were 100% developed by sports equipment users.

  As for the major improvement innovations, innovating users (innovators who developed innovations and benefited only from using them) and user-manufacturers (innovators who developed innovations and benefited both from use and from participation in a small lifestyle firm that produced and sold innovative equipment for their sports, 10 full-time employees or less), together, developed 58% of them in the sample. Since the firms in the user-manufacturer category were lifestyle firms with small scale, Sonali put them together with the user category to conclude.

  Manufacturers (any type of manufacturing firm, including user-founded lifestyle firms that grew to exceed 10 employees in size) developed 27% of the major improvement innovations in the sample. Most of these innovations were developed by existing sports equipment component suppliers, and the innovations involved transferring specific technology and know-how from an existing sport to the novel one. The remaining 15% of the major improvement innovations were developed by other functional sources of innovation.

  According to this result, Sonali strongly rejected the hypothesis that existing sporting equipment manufacturers would be the dominant developers (responsible for greater than or equal to 90% of innovations) of innovations in novel sports.

- Users and user-manufacturers as lead users

  The users and user-manufacturers who developed improvement innovations were mainly lead users, defined as users who have a high need for innovation and experience that need ahead of the bulk of the target market. Most of the user innovators and user-manufacturer innovators in Sonali’s study were early participants of the corresponding sport, and their innovations often led to the emergence of the mass market by many years.

According to the interview data, Sonali also pointed out that the user innovators and user-manufacturer innovators were passionate users of the sporting equipment and were eagerly seeking and developing new techniques related to innovations in equipment. They always tried to test and push the limits of their sports via innovations in techniques and equipment. Meanwhile, they engaged in a learning-by-using process involving repeated trial-and-error in general.

- Patterns in the appropriation of innovation-related benefits

  There were several ways that innovators may capture benefit from their innovations. In her study, Sonali summarized that if innovators are also users, they may benefit directly from the personal use of their innovation in the practice of their sport. Also, anyone or any firm may benefit from the reputation increase associated with having developed an important innovation. But if innovators wish to capture monetary profits from their innovation, they must somehow first protect it via intellectual property law and license that protection to others. Alternatively, they must produce the innovative equipment for sale to others and obtain rents during the period when they still have an advantage over would-be imitators.

  In the sports fields Sonali studied, she found that manufacturers who patented innovations did not license others in general. They benefited from their patented innovations by producing and selling them. Meanwhile, individuals and lifestyle firms sometimes patented their innovations. But innovators did not find a very successful route to capture innovation-related benefits by patents and licenses.

  According to Sonali's study, there were several possible reasons for the low level of patenting. Firstly, the technical novelty of the innovation did not rise to the level of being recognized as a patentable innovation. Secondly, sometimes innovators were merely not interested in patents and licenses, because they were unwilling to pay the costs of obtaining a patent, or their immediate public use of their innovations made patenting legally impossible.

  As a result, 71% of all the expert practitioners whose innovations were classified into the users, user-manufacturers, and other categories in Sonali's study sought to profit from their innovations by founding small and lifestyle firms that would produce their innovations for sale to others. It was the most frequent mode of obtaining financial benefit used by the innovators in the studied sample.

At the end of her article, Sonali argued that the pattern of innovation by expert practitioners makes sense in observed sports fields. It could be explained in terms of both the relative expectations of innovation-related benefits held by users and manufacturers and the allocation of sticky information between lead users and manufacturers.

With respect to expectations of innovation-related benefits, although each of the sports studied had grown to have millions of practitioners who purchase equipment, in the early days of these sports, the market was small, and the ultimate size of the sport's market was very much in doubt. It meant that manufacturers might decide there was insufficient incentive to innovate when considering the eventual potential of a small and uncertain marketplace. In contrast, lead users gained significant and certain personal satisfaction from innovating in and playing their chosen new sport. At the same time, the costs of developing prototypes were low, easily available kits and simple techniques were sufficient to prototype almost all the equipment innovations studied.

On the other hand, with respect to sticky information between lead users and manufacturers, Sonali pointed out that the rich and complicated information regarding the enjoyment of the novel sports was generated by corresponding lead users and was not easily transferable to manufacturers. Lead users had invested plenty of time in the technique of the sport. These investments enhanced lead users' skills and made it possible for them to engage in innovative learning-by-doing activities. Besides, lead users had the chance to test their innovative solutions under field conditions in ways that could not be done by less experienced users or manufacturer personnel.

Sonali also argued that the pattern of the choice of most of the innovating expert practitioners to form small firms to exploit their innovations makes sense. In the studied sporting field, innovating users had only a very limited ability to get benefit from their innovations by patenting and licensing effectively and at low cost. Besides, manufacturing innovative equipment offered an opportunity for innovating users to get monetary gain, not just simple personal use. Taking these two conditions together, it suggested that innovating users would have an incentive to adopt the role of manufacturer. Not only because the role promised greater innovation-related benefit after considering switching costs, but also innovating users did not lose the opportunity to benefit from the use by adding on the role of manufacturer.

The cost for a lead user to add the role of a small-scale producer was often very low. Innovating users were already built the equipment prototype that incorporated their innovations for their own use. So, adding on the role of the manufacturer only required making additional copies of the equipment for sale by using the same methods used in prototyping. These used methods of production were observed to be relatively low-tech, low-cost, and easily accessible. Moreover, advertising was costless for the innovative equipment. Since it was done via word-of-mouth, and it was easier for the innovating user to be known among peers as an expert in such novel sports fields. The low cost associated with manufacturing on a small scale was also a reason for innovating users to adopt the role of manufacturer.

Finally, Sonali summarized that the patterns of innovation by lead users in a category of consumer goods were likely to be repeated in product categories where appropriability and sticky information considerations similarly favor user innovation. Meanwhile, the formation of firms by users was an independent phenomenon. It happened whenever patenting and licensing of intellectual property was costly and/or ineffective and where barriers to entry were low enough to make the transition feasible for individual users. Like in the studied novel sporting fields, founding a small and lifestyle firm was indeed attractive and taken by many innovating users. But in other innovation categories, innovators who wished to add on or switch to a different role with respect to innovation generally incurred more significant costs to do so and often had more attractive alternative investment opportunities rather than founded a firm.

2.3 LEGO Ideas Platform

In our last discussion example of the application of user innovation, we put attention on the most famous plastic bricks toys manufacturer in the world – the LEGO Group. Different from the previous two examples for the PC-CAD system and the sporting equipment of the three relatively new sports, in this LEGO case, we will have an insight into user innovation that happened on the open collaborative platform built by the company. At the same time, we will discuss the benefits and challenges of collaborating with user communities that LEGO meet.

Since 2014, the LEGO Group has been running LEGO Ideas as a crowdsourcing platform for proposals of new LEGO sets. In the collaborative platform built by LEGO, members of the LEGO fan community can upload their creative ideas and designs about the new LEGO sets and suggestions for others' proposals. Once a submitted idea goes into production, the creators are rewarded with 1% royalty on global sales and credited inside the build instruction booklet as the designer of the set. This openness has created a better innovation process, which starts from user needs and involves users in solving these needs. As a result, the products are more relevant and more attractive to users all over.

However, not all creative ideas have the chance to go into mass production. There is a very strict process for community members to achieve production of their creative proposals, which can be divided into the following three phases:

- User submission phase

  Where users express their idea by combining a written description of the idea and a sample of LEGO model that demonstrates the concept into a project page. Once the page is published, it is viewable to other users.

  According to the updated regulation, the condition for every submitted project that qualifies for entering the review phase is to get 10,000 votes of support from different users in two years. Precisely, a minimum number of 100 votes must be got in the first 60 days after submission of the project, or the project would expire, followed by a year to reach 1,000 votes, another six months to get 5,000 votes, and finally six months to get the 10,000 supporting votes.

  Once a project crosses the 10,000th support mark, it will be collected in the order of its time to reach the goal and submitted for review sessions that are held three times per year in January, May, and September.

- Review phase

  In this phase, the LEGO Review Board reviews the eligible projects according to a series of rules. There are various reasons for sets that have reached the 10,000 votes threshold to be rejected during the review session.

  Some projects were rejected due to the content matter presented. Any theme related to alcohol, sex, drugs, religious preferences, post-World War II warfare, or weapons is considered inappropriate for younger LEGO fans and is rejected absolutely. Other projects which have been rejected include ones based on banning intellectual properties owned by rival toy companies, needs of too many original molds, or third-party licenses already being produced by LEGO, such as Star Wars and Harry Potter.

- Production phase

  If the product is approved by the LEGO Review Board and is cleared for production, it is further developed by LEGO set designers and the final model gets released as an official set under the “LEGO Ideas” brand.

  It is worth noting that the LEGO Group retains not only the right to modify the original design of the accepting proposal but also the right to produce subsequent sets following the same theme.

Although it is apparent that the company retains tight control over the entire process, since 2011, LEGO Ideas has launched 39 sets successfully from the LEGO Ideas platform, and 44 sets in total have been announced the access to mass production.

Open innovation platform like LEGO Ideas serves as a tool for identifying valuable innovation from external sources, conducting market research, and engaging end-users. Submissions from creative users have yielded unconventional sets like "Birds" or "Ship in a Bottle" that would otherwise never make it into the company's internal product line and have achieved great successes. Also, comments from other community members for uploaded projects offer advice on how to improve the design and where to find inspiration for additional models. Such input is very valuable in the product development stage. In addition, the online voting mechanism serves as a tool for LEGO's core fan community to engage with the brand and allow the company to test for the financial viability of these ideas. Asking users who vote for a given project to list the price they are willing to pay for it allows the firm to better assess the idea's commercial potential.

As the platform attracts more and more members, LEGO needs to go beyond the purely transactional model and maintain the high quality of submitted projects by its community members. Since designing completely new sets is a complex task that requires significant technical skills and prior design experience, LEGO needs to encourage community members to share their tacit knowledge with others. One way is to encourage the formation of collaborative teams online and leverage the teams' diverse skills and tacit knowledge.

LEGO's online platform offers a way through which users can bring their innovations to LEGO. But there is another way the LEGO Group gets access to user innovations – users come to the LEGO Group with their innovations. The LEGO jewelry, the robotics sensors for the LEGO Mindstorms, and the LEGO Architecture sets were all initially proposed by adult LEGO users and co-developed with the LEGO Group.

For instance, the LEGO jewelry product line was developed by Lisa Taylor, a LEGO user who loved wearing LEGO bricks in a sophisticated way and was allergic to the metal used in lower-priced jewelry. In collaboration with the LEGO New Business Group, Taylor developed a series of jewelry with interchangeable LEGO bricks and sold them on her website.

While John Barnes, one of the users involved in the development process of LEGO Mindstorms, was also the co-owner of HiTechnic, a manufacturer of high-tech sensors. He developed and proposed a series of sensors, such as infrared receiver sensors, barometric sensors, and touch sensors, which helped expand the possibilities of the LEGO Mindstorms system. These sensors were the first components manufactured by an independent external developer to be included in a LEGO set.

The same situation happened on the LEGO Architecture product line proposed by Adam Reed Tucker. In this case of collaboration with an external user, the LEGO group was exposed again to ideas less likely to have been executed by the firm itself, with its focus on toys. As a result of this exposure, the LEGO Group expanded its distribution into new categories, like museums, souvenir shops, and bookstores. It helped to open up markets not usually associated with LEGO products.

In other examples, the LEGO Group has initiated the innovation process, such as the LEGO Modular Building series. It was derived from the result of a process in which the firm asked adult users to propose ideas for LEGO sets specifically targeted to adults. Since many users' ideas related to houses and buildings, the firm considered launching a set of buildings that could be connected to create a village or cityscape. Worked closely with adult fans of LEGO who had great knowledge and experience on building houses in the style adult fans liked by using LEGO bricks and collected feedback and ideas from these adult fans to further improve the building sets, the LEGO group has successfully launched seventeen LEGO Modular Building sets in the past 15 years, including the Café Corner, the Palace Cinema, the Brick Bank, and the newest released one – the Boutique Hotel, etc.

Sometimes, the LEGO Group has also handed over the entire development process to fans. The development of the LEGO Hobby Train represents such an example. Having noticed that some LEGO fans used the LEGO Digital Designer toolkit to design their own trains and accessories, the LEGO Group decided to gather a team of the best user train designers to create a physical train set that could encourage more adult train enthusiasts to make use of the toolkit. The team was composed of 10 fans from different countries and was involved in all parts of the development process, from idea conception and element selection to logistics and marketing. Finally, 76 different train models were proposed by the team, and the LEGO Group and the team members decided together to develop building instructions for 30 models. Compared to a typical LEGO product, which usually has fewer building instructions, the LEGO Hobby Train gave users many more opportunities to try out a variety of designs.

As we know, there are many benefits of user innovation, and most user innovations are designed to give the user any improvement in any dimension such as cost reduction, increased speed, quality, consistency, and so on. Also, user innovations provide great value to other consumers. The add-ons and improvements made by users serve needs that companies do not satisfy for some reason. Moreover, the innovations allow users to experience the products in a different and more relevant way.

On the other hand, for firms, user innovations identify previously unknown needs and offer some assurance that a market may exist for products. In this context, it is no surprise that accessing user innovation has emerged as a strategic approach to innovation. Using user communities as test labs, companies can get an early indication of the potential market value of a new product. By adopting users' innovations, companies often pick up years of accumulated product knowledge and experience about the precise needs and problems that consumers experience.

User communities are potentially rich sources of new product ideas and innovations. However, accessing these communities brings significant challenges. Between 2003 and 2013, Yun Mi Antorini and Albert M. Muñiz Jr. engaged in a multisite research program to examine community development and user innovation among adult fans of LEGO and to learn about LEGO's experiences and practices in working with external communities of these users. Their analysis identified the following four main challenges that are likely to arise in collaborating with independent user communities. These challenges are formidable, but they can be overcome by using a methodical examination of user and usage contexts (see TABLE 1).

Challenge	Explanation	Solution
Moderating effect of users' deep knowledge and specialization	Users' improvements and innovations may be too specialized or advanced for the mass market, or they may not fit with the firm's product strategy.	*Develop and share clear criteria for screening user innovations.* Companies need to develop methods for screening to distinguish those innovations that fit the company's needs and strategy.
Finding the best user innovators	Firms may find it convenient to establish close relationships with cooperative, firm-friendly innovators, but these may not be the most creative or useful innovators.	*Develop criteria for screening lead users.* Companies should systematically monitor communities for lead users and develop criteria to identify lead users and other desirable collaborators.
Integrating user innovations with firm systems	As user innovators may not conform to firm standards, there may be frictional costs involved in integrating user innovations into the firm's value-creating processes.	*Develop platforms for user innovators.* Companies should share goals and develop platforms and standards that innovators can use to present their ideas in a way that meshes with company needs and standards.
Untangling intellectual property issues	The process of adopting user innovations may be complicated or even stymied by questions around whether and how user innovators will be recognized or compensated for their ideas.	*Ensure both sides are adequately rewarded.* Seek IP solutions that are realistic and attractive for both parties.

TABLE 1. Challenges in collaborating with user communities

- Moderating the effects of users' deep knowledge and specialization

  LEGO fans' deep domain-specific knowledge and interests in many other things often facilitated them to develop very specialized, highly detailed LEGO models. For example, models of steampunk genre and the space theme. These models are typically quite complex. Also, for user innovators, specialization itself is a natural part of their engagement with the LEGO bricks.

  In this circumstance, companies may find that users' innovations are too complex or advanced for less-experienced consumers with less-specialized needs, or they may not fit with the firm's own product strategy. One example is the project Shaun of the Dead developed by a LEGO fan based on the 2004 British horror-comedy movie with the same name on the LEGO Ideas platform. Although it had won more than 10,000 votes on the platform but was not adopted for official mass production. The reason given by the LEGO official is that the set contained content that is not appropriate for the company's core target audience of children ages 6

– 11. This case exemplifies how the sometimes advanced and specialized likes that may be approved in user communities do not always fit with the aesthetics or strategic interests of the firm.

It is clear that not every user innovation will be relevant or beneficial to the firm. So, companies need to develop effective methods and criteria for screening user innovations and identifying those that fit the firm's needs and vision. One criterion may be the firm's strategic vision, like the LEGO Group's decision regarding the Shaun of the Dead project was driven by the firm's vision as a producer of toys for children. Clear criteria should be set and shared with external innovators to indicate the type of innovations that the firm is searching for. Also, these criteria are the foundation of the screening process of user innovations.

- Finding the best user innovators

Defining the word "best" for the firm is a task fraught with complexity. Does best mean the most prolific innovator or an innovator whose innovations are favored by more users? Or does it refer to user innovators who are more friendly or more cooperative with the firm, whatever the quantity and quality of their innovations? These are fundamental factors when defining the best user innovators, and their relative importance will depend on the firm's goals in engaging with user innovators.

Besides, external user innovators vary wildly in their attitude and stance towards engaging in firms' innovations. Some of them are quite direct and positive in collaborating with the firm, while others may have a less positive attitude or only seek indirect interaction. Companies may choose to interact primarily with users who are most open to the idea of collaborating with the firms and thus ignore those who are less direct or less open. The risk of doing so is that the company may mainly focus on users who are well innovators but who are not necessarily lead users or the best innovators for the firm to collaborate with. Focusing only on the visible innovators may also pose a risk to overlook lurkers for the company, whose ideas also deserve consideration, despite they always remaining below the surface.

Finding the best user innovators can be a challenge by considering mentioned problems. To avoid them, firstly, companies need to define what they mean by "best" and codify the definition across the departments that will interact with users or their innovations. Secondly, companies need to systematically screen user communities for lead users and ensure that users who want to share their innovations are encouraged to do so. Firms are suggested to arrange competitions or relevant events that motivate innovators to come forward with their innovations or develop platforms and sites that allow users to contribute their ideas whenever they want, such as the LEGO Ideas crowdsourcing platform.

- Integrating user innovations with firm systems

  User innovators typically do not develop their innovations for commercialized purposes. Instead, they innovate for fun or because of the use-related benefits they can get from improving existing products or inventing new solutions. Generally, they do not or little concern about the firm's technical standard, packaging practices, or marketing approaches, let alone profitability. As a result, there may be considerable frictional costs involved in transferring and integrating users' innovations to create a marketable product.

  To reduce these frictional costs, the firm should engage with users to clearly specify the range of solutions they are searching for user innovation contributions. A clear statement of the firm's goals will help users be more effective in suggesting appropriate solutions. However, due to the fundamental differences in why firms and user innovators innovate, and how they engage in innovation, some frictional costs are unavoidable. For example, communications with innovating users will involve some effort and give rise to some frictions because of the variety of approaches and media that users favor. But complete engagement with the user community can help minimize these frictions. Like the use of social media in its crowdsourcing platform in our LEGO case, it enables the firm to engage in an ongoing dialogue with users and address potential issues rapidly and directly. Moreover, such an approach can help to engage users in reducing these frictional costs, to the mutual benefit of the firm and user innovators. So that to locate and address frictional costs before they become too large.

  Collaboration platforms should include communication channels between the firm and its user collaborators. In the meantime, the creation and management of such channels require careful consideration. For example, users might not prefer the same modes of communication as employees of the firm. Most of them will respond after hours because their collaboration usually will occur outside of their work hours. Also, the firms should be careful about maintaining community vitality. They should consider how to balance their needs with the most innovative and contributing members of communities, for example, to be completely transparent in community engagement and collaboration efforts. Similarly, to recognize and respect users' independence.

- Untangling intellectual property issues

  Intellectual property represents perhaps the most critical challenge in accessing user innovations. Since the proportion of intangible assets of firms' value has risen significantly in the past decades, more than 70 percent according to Gapper's report on Financial Times. And intellectual property accounts for a large proportion of intangible assets. As a result, firms have a strong interest in protecting the innovations they bring to the market. It's a quite serious challenge for firms to fail to provide a satisfactory answer to the question of who owns the right to benefit from a certain innovation.

Meanwhile, user innovators have an interest in protecting their rights. In most cases, user innovators except to sell their innovations. But questions around intellectual property ownership always emerge in cases where the innovation is sold or handed over to a party other than the innovator. For instance, on some open LEGO user websites, members who sell their innovations as custom sets, so-called MOC (My Own Creation) sets, state explicitly that they are the innovators and have all rights to the model being sold. It means that the buyers cannot replicate or sell the innovations. However, these statements are more likely to be encouragements to respect the user innovators, not legal protections to user innovations.

In order to build strong relationships with user innovators, companies must find intellectual property solutions that are realistic and attractive for both parties. Firms should look to user communities as well as to their own legal departments when defining how to deal with intellectual property issues about user innovations. Solutions must be found at the intersection of the firm's interests and those of its user innovators. The most productive intersections between firms and user communities are characterized by transparency.

Looking back to the LEGO case, it's obvious that accessing user innovation brings several benefits to the LEGO Group. The company can utilize the deep knowledge that users have accumulated and embedded in their innovations to create better-looking, better-functioning, and more relevant products. Knowledge of what makes a product work well is often tacit and generally makes it difficult for firms to transfer user innovations to commercialized products without losing any vital information. Nevertheless, by co-creating knowledge-intensive innovations with user innovators, the LEGO Group avoids losing crucial skills and knowledge.

By collaborating with users, the LEGO Group also gains access to skills and competencies that may not be represented within the firm. For example, by collaborating with Tucker, the company was able to take advantage of his architectural expertise to develop a product line based on practical architectural principles. Besides, collaboration with users allows the LEGO Group to gain exposure of the usual range of interests associated with LEGO toys to external innovators who want to participate in the LEGO Ideas project.

However, there are some issues for firms to collaborate with user communities, such as how to find the best user innovators and how to integrate user innovations with firm systems. Due to the natural differences of motivations of innovation between user innovators and firms, potential frictional costs associated with the integration of user innovations are unavoidable. First, integration requires company employees to evaluate the right time to pick up user innovations and the right person who can provide feedback and help to coordinate with community members in the different phases of the integration process. Second, it requires the company to develop methods to distinguish the different types of innovations and their potential concerning the firm’s needs and strategy. Third, adopting user innovations requires the firm to have the ability to handle and further refine the innovations.

To overcome these frictional costs, firms need to consider on the side of user innovators, how they are compensated, and how their rights are recognized. Also, the most important thing is to be transparent through the whole interaction process with the user community.

Chapter 3 Application of User Innovation in Modern Medical Equipment

In the previous chapter, we have discussed three representative examples of the application of user innovation in different fields. We have known the working mechanism of the lead user methodology in detail and the truth that user innovation has become a crucial source of the company's innovative progress. Collaborating with user innovators brings significant benefits to companies as well as challenges. However, engaging with lead users is still strongly attractive for companies.

From this chapter, we will go in depth into the application of user innovation in the medical field. Precisely, the way doctors or clinicians who act as user innovators engage in the innovation of modern medical equipment and how they affect its development direction and process.

3.1 Modern Medical Equipment

Starting from the definition of modern medical equipment, also called medical devices, is any device intended to be used for medical purposes. Since using a device for medical purposes has inherently potential hazards for patients, the medical equipment must be proven safe and effective before regulating governments allow marketing of it in their country. As a general rule, with the associated risk of the device increases, the amount of testing required to verify safety and efficacy also increases. Moreover, the potential benefits for the patients must also increase with increasing risk.

Medical devices vary in both their intended use and indications for use. Examples range from simple, low-risk devices such as medical thermometers, tongue depressors, disposable gloves to complex, high-risk devices that are implanted and used for life-sustaining. For example, the artificial cardiac pacemaker is a medical device that generates electrical impulses to cause the heart muscle chambers to contract and therefore pump blood. This device is clinically applied to replace or regulate the function of the electrical conduction system of the heart.

The global medical device market size reached $484 billion in 2020 and was estimated to be more than $630 billion in 2025. However, it must note that there is not a global definition for the medical device. It is difficult to introduce because there are numerous regulatory bodies worldwide overseeing the market of medical devices. Even if these bodies often collaborate and discuss the definition in general, there are subtle differences in wording that prevent a global harmonization of the definition of medical devices. Therefore, the definition of a medical device depends on the different countries or regions.

For instance, the Food and Drug Administration (FDA) of United States defines a medical device per Section 201(h) of the Food, Drug, and Cosmetic Act as "an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is:

1. recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them,
2. intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or
3. intended to affect the structure or any function of the body of man or other animals, and

which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes. The term 'device' does not include software functions excluded pursuant to section 520(o)."

While the European Union defines 'medical device' in Article 1 of Council Directive 93/42/EEC means any "instrument, apparatus, appliance, material or other article, whether used alone or in combination, including the software necessary for its proper application intended by the manufacturer to be used for human beings for the purpose of:

- diagnosis, prevention, monitoring, treatment or alleviation of disease,
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap,
- investigation, replacement or modification of the anatomy or of a physiological process,
- control of conception,

and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means."

It's obvious that there are some subtle wording differences about the definition of medical devices between the United States and the European Union. The U.S. defines medical devices intend to use or affect man or other animals, while the EU defines medical devices are only used for human beings. Moreover, in the FDA's definition, the software is excluded from medical devices, but the European Union includes the necessary software for its proper application in the category of medical devices. These divergences in wording increase the difficulties to establish a global definition for the medical device.

Except for the definition of medical devices, each country or region defines the risk classification of medical devices in different ways based on their potential for harm if misused, design complexity, and their use characteristics. Comparing the classification between America and European Union, the U.S. Food and Drug Administration recognizes the following three classes of medical devices based on the level of control necessary to assure safety and effectiveness:

- Class I – devices are subject to the least regulatory control and are not intended to help support or sustain life or be substantially important in preventing impairment to human health and may not present an unreasonable risk of illness or injury. Examples of Class I devices include elastic bandages, examination gloves, and hand-held surgical instruments.
- Class II – devices are subject to special labeling requirements, mandatory performance standards, and post-market surveillance. Examples of Class II devices include acupuncture needles, powered wheelchairs, infusion pumps, air purifiers, surgical drapes, stereotaxic navigation systems, and surgical robots.
- Class III – devices that usually support or sustain human life are of substantial importance in preventing impairment of human health or present potential and unreasonable risk of illness or injury and require premarket approval. Examples of Class III devices include implantable pacemakers, pulse generators, HIV diagnostic tests, automated external defibrillators, and endosseous implants.

While the European Union classifies the risk of medical devices into four classes, ranging from low risk to high risk: Class I (including I sterile – Class Is, I with measurement function – Class Im, and class I reusable surgical instruments – Class Ir); Class IIa; Class IIb and Class III. This classification excludes in vitro diagnostics including software, the classification of in vitro diagnostics is established in another system which also includes four classes, from A (lowest risk) to D (highest risk). The European Union classification depends on rules that involve the medical device's duration of body contact, invasive character, use of an energy source, effect on the central circulation or nervous system, diagnostic impact, or incorporation of a medicinal product. A medical device that gets certified in the EU should have the CE mark on its packaging or insert leaflets.

Classifying medical devices based on their risk is essential for maintaining patient and medical staff safety as well as facilitating the marketing of medical products. By establishing different risk classifications, low-risk devices such as stethoscopes or tongue depressors are not required to undergo the same level of testing that high-risk devices like artificial cardiac pacemakers undergo. In addition, establishing a hierarchy of risk classification allows regulatory bodies to provide flexibility when reviewing medical devices.

Manufacturing of medical devices also requires a level of process control based on the classification of the device. In general, the higher risk of the device, the more controls require during its manufacturing process. In the initial R&D phase, manufacturers are now beginning to design for manufacturability, which means products can be more precisely engineered for production to achieve shorter lead time, tighter tolerances, and more advanced specifications and prototypes. Nowadays, with the aid of CAD systems or modeling platforms, the work of designing a new medical device is even much faster.

It is widely known that failure to meet cost targets will lead to significant losses for a company. Moreover, in a globally competitive environment, the R&D of new medical devices is not just necessary but imperative for medical device manufacturers. The realization of a new design can be very costly, especially with the shorter product lifecycle. However, as technology advances, the quality, safety, and reliability of new medical devices typically increase exponentially over time.

For example, initial models of the artificial cardiac pacemaker were external support devices that transmit electrical pulses to the heart muscles via electrode leads on the chest. The electrodes contact the heart directly through the chest, allowing stimulation pulses to pass through the body. Since recipients of this initial model of pacemaker always suffered infection at the entrance of the electrodes, manufacturers of pacemakers then tried to design and examine the first internal pacemaker with its electrodes attached to the myocardium by thoracotomy. When we look to the future, the isotope power source that would last for the whole lifespan of the patient or the no battery device which acquires energy from the kinetic energy of the heartbeat may replace the lithium-iodine battery used in the pacemaker now. In that way, patients will no longer need to have an operation every few years to replace a new cardiac pacemaker due to the low battery of the old one.

We know from its definition that medical equipment is designed to aid in the diagnosis, monitoring, or treatment of medical conditions. Therefore, there are several basic types of medical equipment:

- Diagnostic equipment includes medical imaging machines that are used to aid in the diagnosis, such as ultrasound and MRI machines, PET and CT scanners, and X-ray machines.
- Diagnostic medical equipment may also be used in the home for certain purposes, for example, equipment for the control of diabetes mellitus.
- Medical monitors allow medical staff to measure a patient's medical state, these monitors may measure a patient's vital signs and other parameters including ECG, EEG, and blood pressure.
- Treatment equipment includes infusion pumps, medical lasers and LASIK (laser-assisted in situ keratomileusis, commonly referred to as laser eye surgery or laser vision correction) surgical machines.
- Life support equipment used to maintain a patient's bodily function. Examples are medical ventilators, incubators, anesthetic machines, heart-lung machines, ECMO, and dialysis machines.
- Physical therapy machines like the continuous passive range of motion (CPM) machines.
- Medical laboratory equipment which automates or helps analyze blood, urine, semen, and dissolved gases in the blood, etc.

In this section, we have a comprehensive understanding of the definition and classification of medical devices. Starting from the next part of this chapter, we will explore some examples of user innovation in the medical field, particularly the ones that doctors or clinicians act as innovators.

3.2 Examples of Radical Innovations for Modern Medical Equipment – User Innovators' Different Roles and Contributions

In this section, we focus on examples of the radical innovations in the medical field that emerged in the late 20th and early 21st centuries. Cited from the article by Lettl et al., we will have a comprehensive understanding of the application of user innovation in the early development phase of modern medical equipment, particularly these innovations with a high degree of newness of the technology and can be called radical. Moreover, according to the cases, Lettl and his colleagues presented an in-depth analysis of the observed phenomena for us, including the different roles played by user innovators in different cases and their corresponding characteristics, as well as how manufacturing firms can benefit from innovative users in the early phases of radical innovation projects.

3.2.1 Radical Innovation and Research Approach

Before conducting case studies, firstly, we need to better understand the term "radical innovation". In general, radical innovation involves new products or services with a high degree of innovativeness. While previous studies show that innovativeness can be best understood as a multidimensional phenomenon that relates to technology, market, organizational change, as well as environmental alterations.

- Technological dimension – an innovation can be called radical in the technological dimension if the knowledge about the product architecture or its components differs significantly from existing knowledge. These innovations are often based on completely new technological principles, new architectures, or new materials.
- Market dimension – innovations are radical in the market dimension if they satisfy unmet needs for the first time and lead to a quantum jump in customer value. The new product may require potential consumers to considerably change their attitudes and behaviors. Predictably, an entirely new market may be created. But the market risk is also high because large market investments are needed, and many unknown competitors may enter the market.
- Organizational dimension – organizational innovativeness relates to the internal changes experienced by the innovating organization. Changes may happen in organization's strategy, structure, processes competences, incentive systems, or culture. Besides, organizational innovativeness may also refer to the firm's possible inexperience in the field of the specific innovation, as well as the organizational risks that it faces.
- Environmental dimension – it relates to environmental alterations such as the requirement of establishing a new infrastructure, the changes of regulation, or the changes of societal value systems.

Considering these four dimensions, in order to better assess the innovativeness of an innovation, Lettl et al. listed a detailed table (see TABLE 2) that consists of a series of measurements. The degree of these measurements determines innovations' innovativeness and whether they are radical or not. Lettl selected specifical radical innovation cases in his study by applying this conceptualization of the degree of innovativeness, ensuring the selected radical innovations are both from the users' and the manufacturers' perspective.

What's more, the selected cases should help to gain an in-depth understanding of the characteristics of users who are in an active position to contribute to radical

- (1) Market dimension
  - New benefit for the user
  - Higher benefit for the user
  - Degree of newness to users/Familiarity of users with technology
  - Degree of required behavior change for users
  - Degree of required learning by users
  - Degree of change in market structures
  - Degree of creation of new markets
  - Potential for competitive advantage
  - Degree of market uncertainty for manufacturers
    - Uncertainty about market acceptance
    - Uncertainty about market potential
    - Uncertainty about market growth
- (2) Technological dimension
  - Degree of newness of technological principle
  - Degree of complexity of technology
  - Degree of technological uncertainty for manufacturer
    - Uncertainty about feasibility of the technology
    - Uncertainty about the development time
    - Uncertainty about the development costs
- (3) Organizational dimension
  - Degree of newness to the manufacturer
  - Degree of required change in production process
  - Degree of required change of competencies
  - Degree of required change in organizational culture
  - Degree of required change in organizational structure
  - Degree of required change of (human) resources
  - Degree of required change in strategy
- (4) Environmental dimension
  - Creation of a new infrastructure
  - Alterations in regulation required in order to implement innovation
  - Critical debate of innovation in society

TABLE 2. Degree of innovativeness

innovations. Therefore, cases in which preliminary interviews and medical publications indicated that users had played an active role in the development phase were selected.

In the case selection, Lettl and his colleagues applied a two-stage filtering process. The first stage comprised nine expert interviews using a semi-structured interview guideline to identify medical disciplines in which radical innovations had occurred frequently and in which users exhibited intensive innovative activities. Finally, a sample of twenty innovations that roughly matched the characteristics of radical innovation was selected in the first stage. In the second stage, interviews with users, manufacturers, and industry experts were conducted to gain preliminary information about the role of users in the innovation process, as well as to assess systematically the degree of innovativeness of these innovations. Informants assessed the degree of innovativeness of the new products on a seven-point Likert scale that contained the four dimensions listed on TABLE 2. Innovations selected for the study sample included only those that matched the characteristics of radical innovation by exhibiting a high degree of innovativeness on all the four dimensions.

This filtering process resulted in the choice of four radical innovation projects in which preliminary research indicated that users had played an active role in the early phases of the projects. The final sample includes a medical robot system, a computer-assisted navigation system for neurosurgery, a computer-assisted navigation system for orthopedics, and a radically new biocompatible implant. A brief overview of the selected four radical innovations can be found in TABLE 3.

Case	Product description	Innovation success	Number of Interviews
URS	Robotic system for neurosurgery	MS: failure TS: high	8
SPOCS	Computer-assisted navigation system for neurosurgery	MS: medium TS: high	9
OrthoPilot	Computer-assisted navigation system for orthopaedics	MS: high TS: high	10
IMPLANT (acronym)	Biocompatible implant	MS : high TS: high	9

TABLE 3. Selected radical innovations in the study by Lettl et al.
(MS, market success; TS, technological success)

The corresponding medical equipment manufacturers of these four cases were visited. In order to collect the required data, in-depth interviews were conducted with users, as well as marketing, R&D, project leaders, and executive officers of manufacturing firms.

The semi-structured interview guideline for users included questions aimed at learning their roles in the innovation process; their specific knowledge and experience; their motivation for innovative endeavors; supportive contextual factors; interaction patterns with partners and manufacturing firms; the degree of innovativeness of their concepts; and the dynamics of the process.

While the semi-structured interview guideline for manufacturing firms included questions that assessed the innovations in various stages of the innovation process (degree of uncertainty on the market and technological dimension, and fit with strategy and core competencies); the role of the firm in the innovation process; the adoption decision and adoption process of the radical innovation (why and when the firm had adopted the user innovation); the degree of innovativeness of the new concepts; the market and technological success of the innovations; the users' characteristics, roles, and contributions; and the knowledge transfer and learning effects at the user-manufacturer interface.

Totally, 36 in-depth interviews were conducted by Lettl and his colleagues. Then, a content analysis framework was applied in coding the data, whereby category systems were developed for user characteristics, user activities and corresponding roles, interaction patterns between users and manufacturing firms, and learning effects for manufacturing firms.

The information from the interviews was validated carefully by using several sources of verification. Including interviews with three experts from the medical equipment industry; an analysis of the users' personal development records (education, career, interest fields, etc.) for validating the qualification profiles of users; and an analysis of users' publications to validate the users' roles and contributions in the radical innovation projects. Furthermore, internal reports of manufacturers were also analyzed to validate the interview data.

Market data related to goal achievement with respect to profits, competitive advantage, customer satisfaction, customer acceptance was used to validate the market success of the radical innovations. While the technological success was assessed by asking whether the radical innovations met the technical specifications.

Finally, by using the information collected from interviews for the selected four cases, Lettl et al. conducted a multiple case-study analysis to get the valuable research findings that we will discuss later. Because of the application of multiple case-study analyses, the validity of the insights is facilitated by comparisons across cases.

3.2.2 Cases Details

CASE 1 URS – Universal Robot Systems

In the early 1990s, Volker Urban, a German neurosurgeon, began questioning conventional surgical techniques for neurosurgery. Based on his experience in the operating room, Urban realized that there was a gap between the needs to operate at submillimeter precision and the comparatively low-precision performance of current surgical equipment. This realization triggered his search for new solutions.

Urban looked for technologies outside the medical field that met high-precision requirements, such as the nuclear power plants and aircraft cockpit technology. Based on his exploratory research, Urban developed the vision of utilizing for neurosurgery the new technologies that were incorporated into microcomputers and robotics. The key element of this vision was a medical robot system for neurosurgery, and a complementary element was an operating cockpit that enabled tactile feedbacks for the operating neurosurgeon.

In September 1995, at a medical conference entitled "Medical goes Electronic", Urban presented his concept and met representatives of Siemens. At that time, Siemens was preparing for its 150th anniversary celebration and was looking for feasible visions in medical technology that was presented at this event. Therefore, Urban contacted Siemens and obtained agreement that Siemens would finance the development of the first prototype of his vision.

However, Siemens had no technological knowledge or core competence to enable it to develop a medical robot at that time, hence, Urban had to search for a suitable technology partner. Then, he identified the Fraunhofer Institute in Stuttgart as a worldwide leading competence center in robotics. He contacted the engineers of that institute and convinced them to develop a first prototype. While the entire budget for the project was provided by Siemens.

After a year and a half of intensive development and experimentation, in October 1997, the first functioning prototype of a medical robot was presented. Urban then engaged in additional networking activities. Firstly, he identified leading medical institutes at where the medical robot could undergo clinical tests. Secondly, as a partner and scientific advisor of Universal Robot Systems (URS), the newly founded firm that was created as a spin-off from the Fraunhofer Institute, Urban actively marketed his concept and promoted the new advice at medical congresses and conferences.

CASE 2 SPOCS – Surgical Planning and Orientation Computer System

This is another case that happened in the neurosurgery domain. It related to a major problem in neurosurgery that conventional mechanical procedures could not solve and was the inability of surgeons to navigate their instruments in the depths of brain antrums. In the 1980s, Prof. Reinhard, the neurosurgeon from the University of Basel, was searching intensively for new solutions to this problem.

He developed the idea of a computer-assisted navigation system that would be capable of guiding the surgeon by providing three-dimensional information in real time. To achieve this idea, Reinhard recruited a number of neurosurgeons who had the required complementary technological competencies, including a neurosurgeon with computer programming skills and a neurosurgeon with a background in electronics. Besides, before becoming a neurosurgeon, Reinhard himself was a clock maker, and therefore had profound knowledge of fine mechanics.

The development team was established in 1983, and the first prototype was completed by the team 2 years later without requiring any additional external knowledge. Subsequently, the first human patient trial was successfully conducted in 1985. This new computer-assisted navigation system was constituted as a radical departure from conventional medical equipment technology in neurosurgery. It leaded to the feasibility of controlled navigation in the depths of brain antrums and significantly improved the capabilities of neurosurgeons.

However, the development team lacked the essential financial resources and marketing and sales know-how to transform the prototype into a marketable product. Consequently, Reinhard contacted Aesculap, a German medical equipment manufacturer that he believed could provide the missing resources. Because Aesculap had founded a task force in 1987 to explore the potential for using robotics and navigation systems in surgery and was therefore aware of the emerging technologies.

Aesculap agreed to cooperate with Reinhard in 1990. But at that time, the company was weak in the ability to provide additional technological input for the development of the navigation system because they did not have any specific core competence in the field of sophisticated computer-assisted systems. In 1993 -1994, Aesculap put this project on hold because of doubts about its market potential but restarted it by the end of 1994. Finally, in 1995, the first navigation systems were introduced to the market, and the existing mechanical navigation system applied in the medical field was born.

CASE 3 OrthoPilot

One of the major problems that the orthopedic surgeons met in the early 1990s was the anatomically accurate positioning of knee endoprostheses. If the implants not positioned accurately, they may cause severe pain to patients and needed to be replaced after several years. Another primary drawback of the conventional procedure was the needs for patients to be exposed to radiation-intensive computed tomography scanning to obtain images before surgery. These preoperational examinations were time-consuming and expensive and were complained by patients.

For these reasons, Prof. Saragaglia, an orthopedic surgeon from the University of Grenoble, started to search for new solutions. Based on his knowledge of orthopedics and technological advances achieved in neurosurgery, Saragaglia developed his vision of a computer-assisted navigation system for orthopedic surgery.

Due to the lack of relevant technological knowledge, Saragaglia contacted engineers at the University of Grenoble who were experts in the field of programming and identified another orthopedic surgeon, Frederic Picard, who had a strong background in anatomy. This additional know-how was crucial in developing the required biomechanical solution for the navigation system.

In 1994, before the development of the first prototype of his vision, Saragaglia realized that extensive funding would be required. So, firstly, he contacted with the European Union for financial support. The EU acknowledged the great potential of his idea and agreed to provide kick-off funds. Thus, the project IGOS (Image Guided Orthopedic Surgery) was born.

However, Saragaglia found that the initial funds were not sufficient to finance the complete project soon, so, he sought for manufacturing firms that would be willing to participate in the project. At that time, Aesculap, the German medical equipment manufacturer, was aware of new technological advances in surgery and decided to invest limited funds on Saragaglia's project. In return, Aesculap acquired the commercialization rights.

With the kick-off funds from the EU and the financial investment of Aesculap, a first functioning prototype was finally developed in 1997. In the same year, after the prototype was successfully tested, Aesculap assumed management of the entire project. In 1999, after passing through a number of improvements in its user-friendliness, the navigation system was successfully introduced into the market. Then, the user inventors, Saragaglia and Picard, agreed to a licensing contract with Aesculap. Nowadays, the product has become a worldwide standard in orthopedic surgery.

CASE 4 IMPLANT

Patients of surgeons, especially those who had undergone hernia repair surgery, experienced severe problems after implants were inserted. They reported that the implants felt like a "board". The medical cause for this effect was that conventional implants were not biocompatible in the sense that enable optimal tissue regrowth. Conventional implants caused the growth of scar tissue that, in turn, led to the painful "board" effect.

In 1996, Prof. Schumpelick, a leading surgeon at the University Hospital of Aachen, developed the idea of a completely new implant with biocompatible characteristics. He intended to use polypropylene as the new material for the implant and propose a completely different implant design. The new and lighter material, as well as the new design of the implants were expected to support an improved process of tissue regrowth. This advanced idea emerged from Aachen's own research activities at the university labs.

In order to test the medical relevance of his idea, Schumpelick needed to develop a camera system that can be used to verify the specific characteristics of the abdominal wall. After realizing that engineers with specific know-how in camera technology were required for the development of the camera system, Schumpelick identified and cooperated with them to develop the new camera system. With the help of this camera system, Schumpelick and his team successfully validated the feasibility of the radically new idea about implants.

To develop the first prototype, due to the lack of related technical knowledge of textile engineering, Schumpelick contacted the leading institute for textile engineering, and within a short time, the institute developed the first prototypes of the new implants.

In addition, Schumpelick also approached a leading manufacturing firm in the field of medical implants who had substantial knowledge in the area of biocompatible materials and implants and an excellent reputation in the market.

In the end, Schumpelick established the innovation network for the prospective new implants, together with the specialists in camera technology, the research institute in textile engineering, and the leading manufacturing firm of medical implants. Schumpelick not only formed this network but also organized the cooperation within it, including the coordination of the network members' activities, the organization of face-to-face meetings, the creation of status reports, and the setting and realization of milestones.

The manufacturing firm successfully tested the biocompatibility of the implant, concluded a licensing contract with Schumpelick, and launched the new implants into the market in 2002. Today, this radical implant represents a state-of-the-art technique and is used worldwide for hernia repair surgery.

3.2.3 Research Findings and Insights

After a detailed comparative analysis of these four cases, Lettl and his colleagues extracted and summarized some interesting and valuable findings and insights about users' contributions to radical innovations in the field of modern medical equipment technology. These findings and insights focus on the following four aspects: users as inventors of radical innovations; the entrepreneurial role of innovative users; users as developers or co-developers; and benefits for manufacturers.

➢ *Users as Inventors of Radical Innovations*

It's obvious that in all the four cases, users were the originators and inventors of radical innovations. The question for us is what motivated them to do so and what factors enabled them to develop such innovative concepts. According to Lettl's research, there are several enabling factors that played an important role in the development of the radically new concepts, including:

- Problem-induced motivation

  Lettl found that all innovative users shared a major problem: they faced severe difficulties in their day-to-day work that could not be solved by conventional manufacturers' technology or existing medical equipment.
  For instance, the neurosurgeons in cases URS and SPOCS faced problems of

conducting surgeries with submillimeter precision, and the standard neurosurgical instruments could not satisfy this need. The fact is that innovative surgeons who encountered the limits of conventional technologies motivated themselves to search for other new and more workable solutions.

- Professionality and prior knowledge

  In addition to problem-induced motivation, Lettl et al. also found that all innovative surgeons were professional in their field and thus had in-depth knowledge within their domain of surgery. All of them had knowledge about the respective needs to improve the surgical process.
  This type of knowledge was acquired by extensive learning, experience, and experimentation, and was therefore difficult and costly to transfer to third parties. Furthermore, this type of knowledge, called "sticky" by von Hippel, served as a crucial basis for the search for solutions that met the specific medical needs.

- Openness to new technologies

  In all the four cases, the idea creation and concept generation processes of innovative surgeons followed a common pattern. The surgeons abstracted from their current use context by searching for appropriate technologies outside of the medical domain. Therefore, Lettl summarized that openness to new technologies became a key prerequisite characteristic that all innovative surgeons shared. Once recognized the relevant technologies, the innovative surgeons transferred these potential technical solutions to their medical domain.
  An example was the neurosurgeon in the URS case, who looked for solutions to prevent trembling of the neurosurgeon's hands and thus realized precision in the submillimeter area. In his search process for solutions, the neurosurgeon observed that employees in nuclear power plants needed a transmitter between them and the fuel elements. Therefore, he came up with the idea that a neurosurgeon could also use a transmitter between his hands and the patient to control trembling more effectively. Following this analogy, the neurosurgeon closely investigated various principles of kinematic solutions. Consequently, the concept of a medical robot arm system based on kinematics for neurosurgery was created.

Taking a closer look at these enabling factors, Lettl and his colleagues distinguished two types of innovative users.

- The first type of innovative users was considered in an environment with close access to interdisciplinary know-how.

  These users were surgeons at university hospitals that were affiliated with technical universities or that had access to departments of technical universities. This interdisciplinary environment inspired the surgeons' creative thinking as state-of-the-art technologies could be experienced. Furthermore, according to the concept of "absorptive capacity", access to interdisciplinary know-how conduced to increase the creative capacity of these users.

Moreover, this type of users had availability of essential resources for research, such as time, funds, and personnel. These resources enabled the innovative surgeons to perceive technologies outside of the medical domain and to think about possible technology transfers.

- The second type of innovative users did not have access to these interdisciplinary supports. However, they exhibited a strong intrinsic motivation.

  In addition to high problem pressure, this type of surgeons considered the search for radically new solutions as their personal hobby and spent a substantial amount of spare time on it. Lettl then pointed out that this finding was in line with research on creativity that highlighted the importance of intrinsic motivation for highly creative activities.

According to these findings, Lettl summarized that it was difficult to answer whether manufacturing firms had the capabilities to develop the radical new concepts like innovative users did. The key point was that the development of these concepts required a deep understanding of user needs and creative incorporation of relevant technologies outside of the medical domain. Whereas the in-depth knowledge about user needs was difficult to transfer to manufacturing firms. It meant that users had almost exclusive access to this type of knowledge. This reasoning might explain why users rather than manufacturing firms developed these radically new concepts.

➢ *Entrepreneurial Role of Innovative Users*

In addition to their inventor role, Lettl et al. also observed that the surgeons performed an entrepreneurial role as innovation network founders in the radical innovation projects. They established and managed the networks required to transform their radically new ideas into first prototypes and then into marketable products.

The innovative surgeons concerned themselves with the need for sufficient financial resources, therefore, invested significant time and efforts in convincing potential sources to provide such funds. Furthermore, they recruited experts from research institutes to provide the necessary technological know-how and expertise in specific fields. Also, they interacted with manufacturers to make them realize the commercialization potential of their concepts and convince them to participate in the development of the first prototypes. The FIGURE 1 illustrates this entrepreneurial role of innovative users in the four cases studied and the structures of these user-initiated innovation networks.

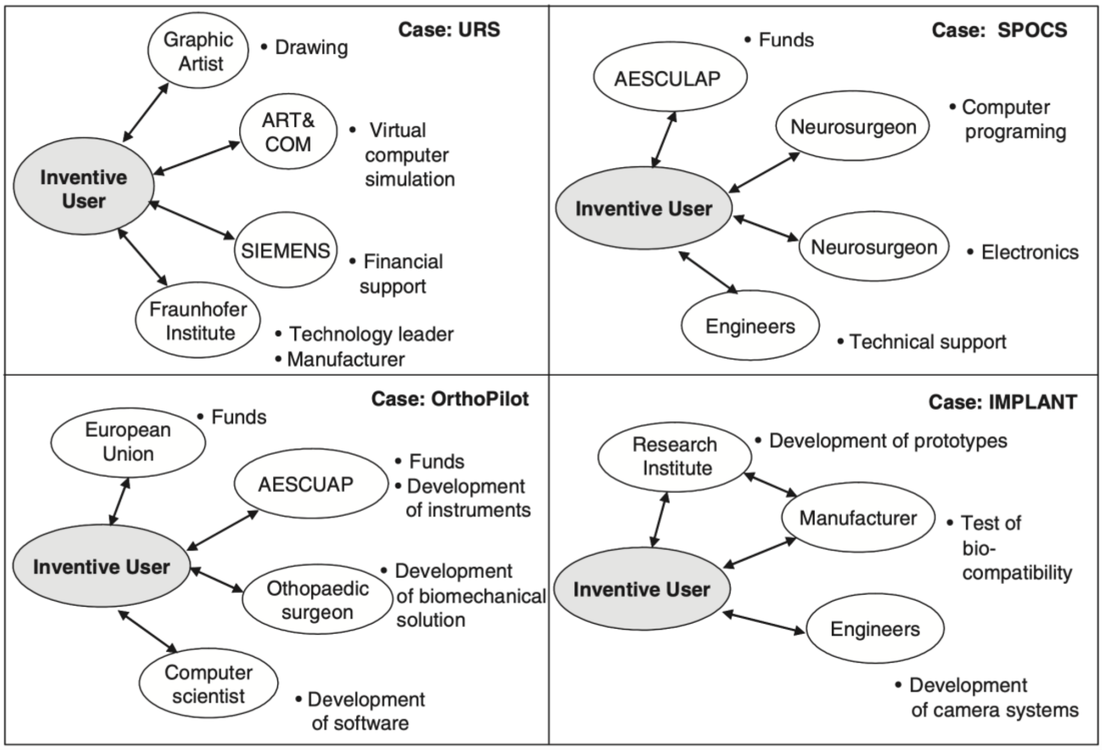

FIGURE 1. Entrepreneurial role of innovative users

Based on the four studied cases, Lettl and his colleagues identified that these networks built by innovative surgeons had a low degree of density or interconnectedness, as well as the user inventors were highly central within the networks. The interesting point was why did innovative users undertake such a challenging role? Lettl's analysis revealed that there were several factors can explain users' entrepreneurial role.

- First, these users faced severe problems in their daily work that could not be solved by conventional technology. The high problem pressure was the driving force not only for the development of radical concepts but also for the formation and management of the innovation networks.
- Second, the users developed the concepts independently, without any involvement of third parties like technological experts or manufacturers. Therefore, as the original inventors, users already had conceptual solutions for their problems at hand.
- Third, in the early phase of the radical innovation projects, potential manufacturers were not willing to adopt the users' radically new concepts. The reason might be the radical nature of these concepts, as a result, in all cases, the

new projects did not fit with the core competencies and technology strategies of the manufacturing firms.

In the early phase of these projects, an adoption of the users' radical concepts by a manufacturer might require it to build the necessary technological competencies, mostly start from scratch. In addition, the manufacturers were prevented by the high technological and market uncertainties associated with these innovations. they were faced with a situation in which the respectively technological application in the medical field was just emerging and that the volume, market share, and growth rate of prospective markets were yet unknown. Therefore, the degree of innovation became a key factor that explained why manufacturers did not become actively in the early phase of the innovation projects, as well as why the user inventors had to fill this gap. Because the manufacturers did not adopt the innovative concepts, the user inventors needed to take over the entrepreneurial role, at least temporarily.

- Fourth, the innovative users did not have all the required competencies and lacked the essential resources needed to transform their concepts into the first prototypes and marketable products. These missing competencies included the technological competencies and marketing knowledge that were required to implement radical innovations into the market successfully. In fact, this required set of competencies had exceeded the "bounded rationality" of a single user or even a team of users.

  Moreover, the innovative users did not have all the necessary financial, human, and marketing resources needed to develop prototypes and marketable products. So, they were dependent on external supports from technological experts, development partners, and medical equipment manufacturers.

Eventually, Lettl summarized that the observed entrepreneurial role of innovative users was because of the high problem pressure of users, the conceptual solutions at users' hands, an unwilling position of manufacturers, as well as missing competencies and resources of these innovative users.

➢ *Users as Developers or Co-developers*

Except for networking, the user inventors also took over another typical function of manufacturers, they became developers or co-developers during the development phase of their new concepts. In order to study the characteristics that enabled user inventors to perform such a developer role, Lettl and his colleagues conducted a case comparison of user characteristics and associated development contributions and came up with a swell model with separate layers. Each layer can be considered as a critical activity level, and the higher layers were associated with more ambitious and challenging contributions. FIGURE 2 illustrates this swell model in detail.

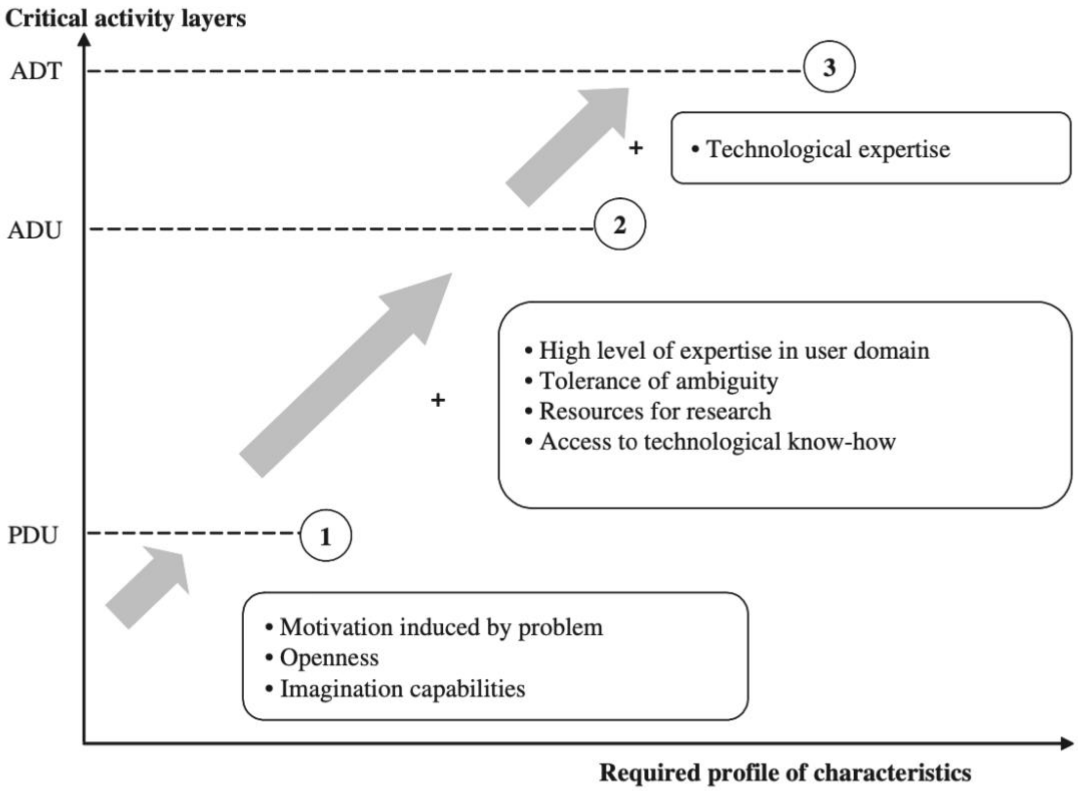

FIGURE 2. Swell model of development contributions by users for radical innovations (ADT: Active development contribution in technological domain; ADU: Active development contribution in user domain; PDU: Passive development contribution in user domain)

- The first layer – passive development contributions in the user domain

  The contributions of user inventors in this layer include the articulation of needs and/or problems and the evaluation of concepts and prototypes. Lettl's analysis revealed that in radical innovation projects, even this type of contribution required distinct user characteristics compared with ordinary users. The four studied cases showed that users needed a motivation caused by a current problem, by openness to new technologies, and by imagination capabilities.

  This finding explained why the so-called opinion leaders were not necessarily suitable informants in radical innovation projects, because they may lack one of these three prerequisites. In particular, the openness to new technologies was not necessarily associated with opinion leaders since their status was often based on conventional technologies. For instance, In the URS and IMPLANT cases, opinion leaders were opponents of the radical innovations, and were therefore incapable to validly evaluate the concepts and prototypes.

- The second layer – active development contributions in the user domain

In this layer, the user inventors' contributions involved the development of users' own solutions. According to Lettl's studies, in order to perform well on this layer, users needed an additional set of characteristics.

First, users needed to have a high competence in their own domain. In order to develop solutions for radical innovations, one must have a profound understanding of the elements, the causes, and the effects of a certain domain.

Second, users must have a tolerance for ambiguity or the ability to handle uncertainty. It meant that users who actively engage in the development of radical innovations must be able to handle a great deal of uncertainty related to the final output and benefit of their development efforts.

Third, users needed to have access to technological know-how. This resource was critical for providing immediate feedbacks to user inventors regarding the technological feasibility of their solutions. Through an iterative process, user inventors can leverage the feedbacks to improve their own solutions. For example, in the OrthoPilot case, an innovative orthopedic surgeon developed the biomechanical solution of the computer-assisted navigation system for orthopedics. By having access to the technological knowledge of computer science possessed by the co-developer, the innovative surgeon was able to improve his solution iteratively.

Fourth, users need resources for their own research activities. It was a critical characteristic for users at this layer due to the high complexity of such a development task. Users must have required intellectual free space and resources such as time, facilities, and funds to deal intensively with the specific subjects at hand.

Finally, Lettl summarized that the specific characteristics enabled users to achieve active development contributions in their own domain were needed at this layer of swell model.

- The highest layer - active development contributions in the technological domain

At this layer, innovative users also needed technological competencies. In the SPOCS case, a team of innovative neurosurgeons developed not just the radical concept but also a first prototype of computer-assisted navigation system for neurosurgery.

This development was possible because the surgeons possessed all the essential complementary technological knowledge on mechanics, computer programming, and electronics. The inventor of the concept was a professional watch maker before he became a neurosurgeon, therefore, had the technological know-how associated with mechanics. While another surgeon in the innovative team trained himself autodidactically in computer programming until he had sufficient computer programming skills. A third team member, at that time, had a strong background in electronics. Users with a diverse set of technological capabilities founded this attractive group as development partners for radical innovation projects.

In most cases, users primarily focused their development activities on the user domain. Therefore, innovative users who were able to perform on this highest layer of the swell model were an exception. Lettl attributed this finding to the nature of radical innovations, particularly in a high-technology field. The innovations in his studied cases incorporated new and highly complex technologies, therefore, separate educational tracks of inventors were required to develop sufficient technological know-how. However, most surgeons did not have enough time and energy to build up such technological competencies.

This swell model proposed by Lettl et al. provided a framework that explained the characteristics that enabled distinct development contributions by innovative users in radical innovation projects. Moreover, Lettl's analyses regarding the surgeons' active development contributions revealed that surgeons applied knowledge that they already had rather than actively searched for new knowledge.

➢ *Benefits for Manufacturing Firms*

Manufacturing firms who adopted the innovative users' concepts and prototypes in later phases of product development benefited from the users' contributions on the following three dimensions:

- Product innovation dimension

  Cooperating with innovative users, manufacturers learned about concepts that meant a significant change of the "standard of care" in the medical field. It was not capable for leading manufacturers of medical equipment to develop these radical concepts themselves since the concepts were far away from their core competencies. Medical equipment manufacturers who wanted to absorb these radically new concepts must keep close contact with the small circle of highly creative surgeons.

  Besides, by cooperating with surgeons, medical equipment manufacturers also learned to improve the quality of the radical innovations substantially. This benefit was derived from the surgeons' active development contributions in the medical and technological domains.

- Process dimension

  Manufacturers benefited from innovative surgeons with respect to the efficiency of the innovation process.

First, the surgeons' active development contributions enabled manufacturers to decrease development time and costs. In all the four studied cases, the surgeons dominated large parts of the innovation processes and delivered the complete prototypes to manufacturers. Therefore, manufacturers did not have to invest in the cost-intensive early phases of the radical innovation projects and were able to introduce the medical equipment into the market in a comparatively short time.

Second, the relevant innovation information provided by the surgeons enhanced the decision quality of the manufacturers' decision process. Thanks to the surgeons' information, the medical equipment manufacturers were able to select the most promising prototype versions.

- Technology dimension

  Manufacturers also realized benefits of cooperating with innovative surgeons on the technology dimension.

  First, manufacturers were able to acquire new technological competencies. There were two different modes in which technological knowledge transferred from surgeons to manufacturers. A direct mode that happened in the SPOCS case. Innovative surgeons had technological competencies and therefore transferred this knowledge to the manufacturers' engineers. An indirect mode that happened in the URS, OrthoPilot, and IMPLANT cases. In these cases, innovative surgeons identified the leading research institutes and developed their first prototypes with these institutes. By taking over these prototypes later, manufacturers were able to acquire the underlying technology.

  Second, manufacturing firms learned about relevant technological trends in the medical equipment industry by cooperating with the innovative surgeons. Since the surgeons' concepts and prototypes contained the leading-edge technology for the specific medical domain, manufacturers obtained information about the technological trends and received early signals of emerging technological discontinuities. In the four cases studied by Lettl, these technological trends were robotic systems in surgery, computer-assisted navigation systems, and bio-compatible implants.

  Third, by linking up with the user-initiated networks, manufacturers knew about the leading technological research institutes related to radical innovations in their business divisions. Therefore, they were able to extend their networks of innovation and technology.

All these findings and insights extracted and summarized by Lettl and his colleagues are valuable for users and open innovation research as well as for corporate practice. According to their case study analysis, we can easily find that the profiles of users who are able to contribute actively and substantially in the early phases of radical innovation projects are significantly different from the profiles of users who are typically involved in conventional marketing research.

The innovative users in cases studied by Lettl do not exactly meet the classical definition of lead users. The problems and needs that the user innovators faced were commonly faced by the mass of surgeons in the respective surgical fields. Therefore, the user innovators did not show the leadership of the market trends. However, the user innovators in the studied cases shared some characteristics that lead users possess. For instance, the innovative surgeons were highly motivated to develop new solutions. Moreover, in the two cases where innovative users were neurosurgeons, as they faced the need for extremely high-precision technology, these neurosurgeons can be categorized as extreme users. While previous studies have shown that lead users frequently appear among extreme users. Lettl summarized that the innovative users in his sample had close similarities with lead users. Besides, additional user characteristics such as being open to new technologies, being embedded in a supportive environment, and having strong intrinsic motivation are required to contribute substantially to the development of radical innovations.

On the other hand, these innovative users can be considered as lead users because they recognized the relevance and benefit of new technologies far earlier than manufacturers and peer users. They identified the technological opportunities because of their specialized knowledge and experience. Subsequently, these new technologies became the medical standard in many different medical applications. Lettl called these innovative users “technology lead users”, who are trend leaders on the technological dimension.

It is crucial for firms that seek to benefit from users in the early phases of radical innovation projects to identify these “technology lead users”. Lettl emphasized the relevance of users from a technological perspective in his study. Usually, the user innovation approach and the lead user approach are applied to identify the market needs and market trends. But Lettl highlighted the technological dimension of user innovations and emphasized the value of innovative users for identifying technological trends.

Furthermore, Lettl observed the entrepreneurial role of the user innovators and gave another explanation from the dominant design theory perspective. Radical innovations are usually considered as technological discontinuities in an industry and let the existing dominant designs obsolete. Therefore, there is a turbulent phase in which high uncertainties exist with respect to the emerging dominant design. Because of these design instabilities, manufacturing firms are unwilling to invest in new product development in this phase of the industry life cycle. On the contrary, users might obtain a direct benefit from the new technologies by way of tailored solutions for their needs. Thus, user innovators may derive innovative and entrepreneurial benefits due to the absence of manufacturers.

Lettl also found in his cases that users involved manufacturing firms in the development process at a time in which they lacked the required competencies and resources to proceed on their own. It's necessary for manufacturers to establish an ability to differentiate between promising and less promising user innovations.

With respect to corporate practice, Lettl et al. recommended that manufacturing firms systematically leverage capable users for radical innovation projects. The capability of identifying this group of highly creative and entrepreneurial users is an important dimension to measure the organizational competence for radical innovations. The identified characteristics of innovative users in Lettl's study can be applied by manufacturing firms to identify highly creative users more systematically. As well as the swell model proposed by Lettl can be used for the identification of users who can play the role of developers or co-developers for radical innovation projects. Assumed that the number of users decreases with higher layers of the swell model, since higher layers are more challenging and require additional characteristics, the swell model can be identified as "user pyramids". It means the difficulty for manufacturing firms to identified users on top of the pyramid (users capable of active development contributions in the technological domain) is significantly higher than to identify users at the bottom of the pyramid (users capable of passive development contributions in the user domain).

As few users are able to deliver substantial contributions for radical innovations, manufacturers need to conduct the user selection process frequently. Once innovative users are identified, manufacturing firms need to cooperate intensively with them in order to effectively learn from them. In particular for small and medium size firms who are under research and development budget restrictions, it is a suitable strategy to identify innovative users who take over large parts of the development process and cooperate with them.

Observing the cases studied by Lettl and his colleagues, manufacturing firms were passive in participating in the development process until the first prototypes had been developed. Although manufacturers realized the radically new technologies, they did not adopt them in the early stages. Lettl's study revealed that manufacturing firms were initially unwilling to adopt concepts that subsequently turned into successful both on the technological and market dimensions. However, it did not imply that manufacturers took improper actions in the early phases. Instead, manufacturers' passive behavior minimized the risk of their own investments. As the benefits of the radical innovations became more apparent, the manufacturing firms took over complete prototypes from the user innovators and then introduced the radical innovations to the market in a relatively short time.

Finally, Lettl suggested that the user innovators' networking activities also had implications for corporate practice. It was crucial for manufacturing firms to identify these user-initiated innovation networks. By connecting with these networks, manufacturing firms can participate in radical innovation projects and access to the exclusive rights for commercialization. It was an effective way to reduce manufacturers' investments and risks in radical innovation projects. Moreover, manufacturing firms can identify leading research institutes and extend their own innovation networks by linking with user-initiated innovation networks. Lettl et al. recommended manufacturing firms to create an organizational department that systematically scans the relevant environment for users who work on the leading edge of their domains and for innovation networks that establish for their innovative activities.

3.3 Examples of User Innovation in Techniques in the Field of Medical Devices

In previous cases, we discussed innovations developed by clinicians and surgeons in the field of medical equipment. Also, application examples of user innovation in different fields exhibit that the users have been an important source of innovation in products and services. However, in this section, we will focus on user innovations in techniques in the medical devices' field. Based on the research of Hinsch et al., we analyze users' generation and diffusion processes of new techniques as well as the interdependencies between user-generated techniques and subsequent changes to product use and product innovation.

3.3.1 Introduction and Research Methodology

Different from products and services, techniques mean skillful or efficient ways of doing something. They often involve the use of physical products and significantly affect the perceived value of the physical products. Therefore, innovations in techniques are likely to have an effect on products, the existing products may have new usages when employed in new ways. In some cases, the application of new techniques may require changing the existing products or even developing new products. For instance, a new operating technique or surgical procedure usually requires adjusted or new surgical instruments or medical devices to realize.

Techniques often refer to specific ways in which products are employed. The use benefit acquired from a product or service, especially for tools and equipment, may largely depend on the techniques that are employed during its use. Thus, techniques are important for users, and innovations in techniques may have significant effects on both existing products and product innovations. The techniques employed by users have become an important source for new ideas of tool design and usage.

techniques may be carried out with or without physical objects such as tools, instruments, and equipment. In the field of medical devices, techniques are surgical procedures to treat a certain disease. They include a sequence of different steps such as cutting, sewing, holding, suction, etc., some of which employed instruments. Furthermore, techniques should be observable and describable so that can be learned by others, they need to be repeatable in the same way.

There are various procedures and methods can be observed in the field of medical devices. According to their aims, they can be differentiated as surgical, therapeutic, or diagnostic procedures and methods. Innovations in medical techniques may offer substantial benefits such as moving from treating symptoms to treating causes, reducing treatment and healing times, as well as lower risks for patients and fewer side-effects.

In their research, Hinsch and her colleagues conducted multiple case studies in the medical devices field to investigate the development and diffusion processes of new techniques and the impact they have on new product development. They chose four cases from different surgical areas and different stages of development and diffusion. In this way, Hinsch et al. can identify differences and patterns of user innovations in techniques. Meanwhile, selecting cases at different stages of development and diffusion allowed Hinsch and her colleagues to recognize the key steps in these processes.

Cases were chosen based on interviews with surgeons from different disciplines, experts working in hospitals and the health system, as well as manufacturers of medical devices. Besides, medical publications and conference summaries were studied to find interested areas and identify new techniques. The cases were selected based on the following criteria:

- Technique developed by surgeons;

- Technique developed within the last 10 – 15 years to assure that development processes could still be followed, but also allowed enough time for the technique to spread among other surgeons and influence product development;
- Technique treating an at least common indication, to assure number of patients and interventions;
- At least first signs of diffusion among other users;
- Related product changes or even development with or without manufacturers.

For all cases, Hinsch and her colleagues collected data from different sources. They conducted interviews with the inventors of the surgical techniques, surgeons who adopted these techniques later and specialists who involved in the development of new products based on the new techniques. Each interview was conducted following an interview guideline, and the interview contents were recorded and transcribed for evaluation. Besides, secondary data such as publications, procedural statistics and instrument sales were also analyzed by Hinsch.

3.3.2 Cases Details

CASE 1 Endoscopic Approach to Treat Nerve Compression Syndromes

This technique was developed by a German hand surgeon who was unsatisfied with the results of his surgeries. Then he used the knowledge acquired in other interventions to innovate a minimally invasive route to an anatomic area treated by open surgery previously. Following the advice of a nurse worked in different surgical fields, the doctor initially used instruments from other surgical fields. He employed the same point of access to the anatomic area as previous open approach and iteratively developed and refined this new technique in his daily surgeries with the agreement of patients that he operated on.

The hand surgeon first conducted the technique in 2004. Then, in the next two years, he developed and refined the technique and experimented with different existing instruments. After realizing the potential business opportunity and the help for the diffusion of the technique that a commercial product could bring, the doctor approached a medical device manufacturer with his new product ideas. The new product proposed by the doctor only needed to change existing products slightly and arranged in a new special instrument set for this intervention.

The surgeon actively promoted his technique and the related product. He started providing courses about this new technique at his hospital in 2004. Later, in 2006, the courses were sponsored by the manufacturing firm of the instrument set, since the firm considered the courses as an important marketing tool. Furthermore, the doctor published articles, held presentations at conferences, and gave mini workshops at congresses to facilitate the diffusion of this technique. The marketing brochures delivered by the manufacturer also focused on the technique rather than the product.

Many early adopters became diffusion agents later and also provided courses to other surgeons. Research conducted by the manufacturing firm showed that most surgeons interested in buying the instrument set had participated in courses provided by either the doctor himself or one of the early adopters.

In 2008, the technique became the recommended approach to treat the corresponding nerve compression syndromes by the relevant association of specialized surgeons. It had spread in the community of hand surgeons and neurosurgeons by 2012.

CASE 2 Endoscopic Approach to Treat Neuro Conditions

Another case for user innovations in medical technique is a German neurosurgeon refined the ETV in the beginning of the 1990s. ETV – endoscopic third ventriculostomy is a surgical procedure that creates an opening in the floor of the third ventricle using an endoscope placed within the ventricular system through a burr hole. The only existing alternative for this surgical procedure to treat certain forms of obstructive hydrocephalus, such as aqueductal stenosis, is the placement of a cerebral shunt.

The surgeon said that in the early years of his career, he came across ideas for minimally invasive surgery of the skull which started from the 1910s. However, before he could perform his technique, he needed a lot of experience with the delicate anatomy of the brain and the formal structure. Until the doctor became the head of neurosurgery in his clinic and was no longer obliged to follow the rules and standards set up by his former chief surgeon, he was able to finish the development of the technique and actually use it. The hierarchical structures in the hospital hindered the development of the technique as well as the development of new products in this case.

This technique developed by the neurosurgeon led to several different developments of products in the range of neurosurgery. In the beginning, urological equipment was used to conduct the technique. Nevertheless, the rise of regulatory issues and the necessity of changing the equipment prompted the doctor to contact manufacturing firms. The firm that developed the related equipment was not active in the field of neurosurgery at that time. While a new market for the company was opened up when they started to develop specialized instruments for the technique and further neurosurgical instruments.

The promotion of the instruments was mostly done by the doctor through his innovative technique. However, with the instrument innovation became more general, manufacturer shifted more attentions to promote the instruments and perform promotional activities.

The neurosurgeon offered courses and taught the technique to the visiting clinicians at his clinic, therefore, promoting the diffusion of the technique among neurosurgeons worldwide. Moreover, two of the inventor's former surgical students took the innovative technique with them and taught it to their assistants and colleagues when they became heads of departments in other hospitals. Also, the inventor and his two students had been involved in the development of further equipment innovation.

CASE 3 Minimally Invasive Approach for the Thyroidectomy

An ENT (ear, nose, and throat) surgeon developed this new approach to remove the thyroid gland based on his expertise in the anatomical area of the mouth. This endoscopic minimally invasive approach was developed between 2005 and 2009 in anatomical studies to demonstrate its safety and feasibility and was first conducted successfully in humans in March 2009.

The ENT surgeon wrote papers and gave presentations at conferences to diffuse his technique. Although there was considerable interest in the technique, it had not yet spread widely. A main reason was that a comprehensive study with cadavers and many cases would be necessary before hospitals would be allowed to conduct this approach in German and European health systems.

The doctor termly conducted the technique with patients' approvals and started to provide courses in some Asian and Eastern European countries like China and Hungary, where surgeons had shown interest in the technique. Different regulatory settings and patients' needs in different geographical areas led to different diffusion processes in these areas.

The surgeon realized that the existing instruments could not properly reach the surgical area in the early phase of the development of the innovative technique. However, the medical devices' manufacturer that cooperated closely with the doctor when he first developed the technique was unwilling to pursue product development, unless a broader diffusion of the technique was achieved. Therefore, the ENT surgeon contacted another manufacturing firm and developed instruments with them during the anatomical studies. Due to the rather slow diffusion of the technique, the new products were not yet widely used.

CASE 4 Transvaginal Cholecystectomy

The natural orifice transluminal endoscopic surgery (NOTES) had been one of the most discussed topics at medical conferences and in medical publications worldwide. It had become an area in which a lot of new techniques had been developed.

In 2007, a German general surgeon developed a NOTES approach to remove the gallbladder. This technique allowed a surgeon to conduct a cholecystectomy using laparoscopic instruments with a combined transvaginal and trans-umbilical approach. It used both an approach and instruments that the surgeons were already familiar with to achieve the goal of the NOTES – less injury to the abdominal wall, consequently less pain, and a better or ideal cosmetic result.

The doctor closely cooperated with a gynecological surgeon to make sure proper access to the surgical site and iteratively developed and refined the technique. But he never interacted directly with a product manufacturer to develop special instruments, even if his innovative technique benefited from the general development in this area. Many manufacturing firms developed general instrument sets for the new NOTES approach, and almost all of them could be used for various techniques.

As this technique is one among many treatments for cholecystectomy and is only applicable for female patients, its diffusion process is rather slow. With the ongoing development of complete technical systems for the NOTES approach, it had been used in many clinics, but only for some of the cases.

3.3.3 Cross-Case Analysis and Insights

In order to identify patterns across the four cases and acquire some valuable insights for user innovation in techniques, Hinsch and her colleagues compared them and conducted a cross-case analysis. Analysis and insights can be summarized into the following four aspects.

- *Development of Techniques*

Although the development time varied, all the development processes for surgical technique innovations generally followed the steps of the ideal process and showed an iterative property that characterized by feedback loops, adaptions, and trial-and-error, thus exhibiting patterns similar to product development.

However, Hinsch observed there were several differences between cases. In cases 2 and 3, the development of the technique was addressed in anatomical studies and only applied into real surgical circumstance when the technique was fully development. While techniques in cases 1 and 4 were developed during daily surgical procedures. These differences were caused by the interdependencies between technique development and related product innovation as well as the complexity and newness of the technique.

The techniques differed in their degree of newness. Hinsch and her colleagues considered the surgical access point, the anatomical structures, and the steps used during the technique as indicators of technical newness, while the availability of other techniques and the improvement over previous techniques as indicators of newness of use benefits.

Cases 1 and 2 showed a relatively low degree of technical newness since the surgical access points and anatomical structures in these two cases did not deviate from previous approaches. Besides, there was only one inferiorly alternative approach respectively for both cases to conduct the same surgeries. The alternative one in case 1 inflicted more significant damage to the tissues on patients, while in case 2, the alternative approach had a much higher risk of infection. Therefore, both cases offered new use benefits.

On the other side, cases 3 and 4 involved new surgical access points and operated in new anatomical structures. So, they exhibited a higher degree of technical newness. However, both innovative techniques in these two cases showed limited newness of use benefits since there were many other techniques that were not inferior to these new developments.

- *Diffusion of Techniques*

Hinsch et al. also observed that the techniques in cases studied had different degrees of diffusion. Techniques in cases 1 and 2 had already diffused broadly, while the diffusion was slower in cases 3 and 4 and did not reach the same extent as the first two cases. In general, the speed of diffusion of techniques was influenced by whether the technique offered significant use benefits or was merely an alternative to many other approaches. Moreover, the number of indications, potential patients, complexity of the technique and other factors also influenced the diffusion of techniques.

Then, Hinsch summarized that different from the diffusion of products, the inventor of the new technique played a key role in its diffusion. Classical tools for diffusion of products, such as publications, speeches at congresses, demonstration videos, theoretical courses and other materials had only limited impacts on the diffusion of a technique. The most important influence factor for the technique diffusion was the personal contact with the technique under the supervision of someone already familiar with it. Therefore, the diffusion of new techniques was a much more social process than the diffusion of new products. Besides, it depended on the inventors' diffusion efforts and their ability to gain further diffusion agents from among early adopters.

As all inventors of new techniques presented their innovations at congresses or wrote papers about the new ideas, their further involvement in spreading the technique varied greatly, leading to different levels of diffusion.

In the first two cases, the inventors of technique offered courses for other surgeons to spread their techniques. The inventors organized the workshops which included theoretical and practical trainings by themselves. The first participants were mostly part of the inventor's professional network, but the audience extended to other surgeons who were interested in the new technique soon. Later, with the involvement of manufacturers, participants in these workshops may come from all over the country or even worldwide. In both cases, manufacturers did not pay any tuition for courses to inventors. But they provided the instruments and other equipment, supported the courses with technical staff, and sometimes sponsored a meal during the courses. On the other side, the courses were not offered for free, since basic fees were needed to cover administration costs, presentation rooms, catering, etc. However, the courses were not profit-making, suggesting the inventors aimed for reputation, fame, and surgical improvement rather than financial gains.

While in case 3, the inventor offered no workshop in Germany but in other countries due to some regulatory reasons. In case 4, the innovative surgeon only offered training in his operating room and did not organize any courses.

As analysis above, the diffusion of a technique and its relevant products significantly depended on the activities of the inventor and other experienced users such as early adopters. Besides, workshops also played an important role in the diffusion of new techniques since they enable potential adopters to try the technique in a secure circumstance with the option of receiving help and advice from the inventor. On the contrary, existing methods for the diffusion of products such as presentations, brochures, word-of-mouth, and demonstration videos were much less important for the diffusion of techniques. Therefore, Hinsch and her colleagues proposed that:
"Interaction between potential adopters and diffusion agents, as well as personal contact of potential adopters with the technique itself, are of utmost importance for its diffusion. This is true for the diffusion of the technique and any related product

innovation."

Furthermore, comparing with the diffusion of products, the diffusion of techniques needed much more inventors' personal efforts and social connections. Early adopters were exclusively workshop participants and also members of the inventor's professional network. Consequently, the diffusion of techniques was a much more social process than the diffusion of products, which typically did not require close relationships between the inventors and adopters. Additionally, extra diffusion agents are required to achieve the widespread diffusion of techniques, because the inventors' available time and professional network were limited. So, Hinsch et al. proposed that: *"The diffusion of new techniques resembles a snowball scheme, involving personal contact with the inventor or other diffusion agents and the technique. Diffusion primarily follows personal relations as viral diffusion does not work."*

➢ *Interdependencies between User-Generated Techniques and Product Innovation*

Moreover, Hinsch and her colleagues observed and highlighted several interdependencies between user-generated techniques and product innovation.

- First, the availability or lack of compatible instruments influenced the development activities of new techniques.
  In case 2, the development of the new endoscopic approach was theoretical and only conducted on cadaver tests until instruments from urology were identified that satisfied the needs of the innovative surgeon. Later, with the involvement of the manufacturer, the specialized instruments were further developed and allowed the technique to be carried out in humans.
  In case 3, the development of the specialized instruments also happened during the cadaver tests to allow the technique to be performed in humans.
  While in case 1 and 4, the techniques were developed during daily surgical procedures as the technique could be performed with existing instruments (case 1) or benefited from the parallel development of common NOTES-related products (case 4). Therefore, in these two cases, the development of the new technique showed a much weaker connection with the parallel development of the respectively specialized instruments.
- Second, the characteristics of a technique drove the needs for subsequent product innovations.
  Case 1 illustrated that slight changes to existing products may be sufficient to perform the technique successfully even in a long run. While in case 2, the identification of existing instruments in other medical areas and the legalization

of off-label use initially satisfied the inventor's needs. However, as the refinements in the technique increased, the transfer of existing products from other areas was no longer sufficient, and new instruments had to be developed. In case 3 and 4, the development of new products was necessary. Technique in case 3 required the development of new products specific to it, while technique in case 4 benefited from the parallel development of common NOTES-related products. These facilitated the use of the new techniques.

Overall, the extent of technical newness of the technique and lack of compatibility with existing approaches drove subsequent product innovations. techniques with low technical newness typically put existing products to new, innovative uses and no or little subsequent product development took place. The more changes a new technique required regarding access points and anatomical structures, the more likely new products are developed following the technique innovations.

- Third, the diffusion of the technique and related products was closely interwoven. Hence, the users played an important role not only in the diffusion of the technique but also the diffusion of the product. Because of the importance of interpersonal exchange, the widespread diffusion of both the technique and the product may only be achieved with the help of the inventor and additional diffusion agents who also engaged in instructional activities.

  Except the diffusion of the techniques was important for the diffusion of the related products, Hinsch et al. also pointed out that the availability of a product influenced the diffusion of the technique. As soon as the specialized products became available, the diffusion of the techniques accelerated.

According to the analysis above, Hinsch and her colleagues summarized that the innovations in techniques were interlinked with products in two ways. Firstly, techniques with low technical newness generally put existing products to new, innovative uses, thereby enhancing their functional values. Although no or little product development took place, but new application areas for the existing products were explored. Secondly, with the increasing of degree of technical newness of the innovative techniques, parallel or subsequent product innovations were required. In these cases, the development of the techniques may slow down or even stop because of the lack of instruments. However, once the solutions had transferred from other medical areas or entirely new instruments had been developed, the development processes of the innovative techniques could go on. So, Hinsch proposed that:

"The development of user-generated techniques is interlinked with the development or adaption of related products. The degree of technical newness of a user-generated technique increases the likelihood of subsequent product innovations."

In addition, Hinsch et al. also summarized that user innovation in techniques influenced product use and product innovation by users as well as manufacturers. It meant that in order to assess the innovative performance of users and their economic contributions properly, one had to consider not only user innovations in products, services, and techniques, but also the stimulative effect of these techniques on sales of existing products as well as manufacturer-based product innovations. This suggested that users' contributions to total innovation output were much higher than previously considered. Therefore, Hinsch proposed that:

"User-generated techniques stimulate new product uses and product innovation by users as well as manufacturers. Consequently, even more product innovation has its roots in user innovation than has been previously considered."

- *Managerial Implications for Manufacturers*

Finally, Hinsch and her colleagues proposed some important implications for the marketing strategies of product manufacturers according to their studies, especially for these manufacturing tools or equipment.

New products which required specific knowledge of techniques to be used effectively would not diffuse unless the related techniques diffused. Besides, the more difficult the technique, the less likely the product would diffuse by itself. Even though manufacturers already frequently cooperated with key opinion leaders and worked with users in many ways, they may find that it was not sufficient if the product was specifically designed to be used for a certain technique, especially if it was a very complex one.

Therefore, instead of putting an ever-higher emphasis on selling their products, manufacturers should consider stimulating the innovative users to diffuse the technique. They should involve themselves in the diffusion of the techniques to market their products. Consequently, marketing messages, types and contents of marketing materials, communication channels, etc., needed to be adapted because of the changes of marketing strategies.

Moreover, Hinsch also suggested that product manufacturers should get involved in technique development as early as possible. Manufacturers were not often aware of innovation activities occurred among their users. Therefore, they needed to build their own market research competencies to actively scan for and track the development of user innovations in techniques. In this way, attractive opportunities may be sought out proactively.

Building up such competencies required manufacturers to develop a deeper understanding of use-related or need-related knowledge. It may influence the hiring and training decisions of manufacturers because these decisions must ensure their sales staffs who interacted with users identified and were capable of transferring users' knowledge to the product specialists inside the company.

Additionally, manufacturers also needed to rethink their warranty policies for unintended use of products so that provided more incentives for innovative users to freely reveal how existing products could be used in new techniques.

Chapter 4 Doctors Versus Patients When Acting as User Innovators

In chapter 3, we have deeply discussed how clinicians act as user innovators in the radical innovations for modern medical equipment, including the different roles they played and contributions they made. Except focusing on innovations in equipment, we also studied user innovations in techniques in the field of medical devices, in other words, the innovative approaches developed by surgeons to conduct surgical procedures to treat a disease. Surgeons developed these techniques and engaged in the diffusion of the techniques.

In this new chapter, we will pay attention to patients and their caregivers, who act as user innovators, especially these patients with rare diseases and chronic needs. Based on the research of Oliveira et al., we explore the extent to which patients develop innovative solutions, whether these solutions have a positive perceived impact on the patients' overall quality of life, and the factors associated with patient innovation development and sharing of the solutions. Furthermore, a brief comparison between doctors and patients when acting as user innovators will discuss in the end.

4.1 Examples of Innovation by Patients with Rare Diseases and Chronic Needs

Based on the data from previous studies, there are 5000 to 8000 rare diseases which afflict up to 8% of the world's population. Most of them are generic and chronic, and causing significant difficulties in the daily life of patients and their caregivers. Besides, rare disease patients are often underserved both clinically and scientifically. This is because the prevalence of each rare disease is low. Therefore, the market size for new products of rare diseases is small, and it is commercially unattractive for pharmaceutical firms and other medical suppliers to invest in corresponding projects.

Due to the high needs of patients and low initiatives of commercial activities in rare disease marketplaces, patients and their caregivers are motivated to innovate for themselves to help them solve problems and improve their quality of life. This corresponds to the view that individuals with high and unmet needs for a solution often tend to develop a product for their own use until a producer introduces an improved version of the product to the market.

Previous studies have found that patients and caregivers have invented a number of valuable solutions to improve their own personal medical situations. These solutions contain simple tools for daily use, discoveries of unknown therapies, and highly sophisticated solutions such as a textile mesh support for dilated heart aorta developed by a Marfan syndrome patient. Furthermore, emergence of innovation intermediaries in healthcare and initiatives to discover and share patients' solutions both suggest that more and more institutions have realized the innovative capacity of patients.

Patients and their caregivers who develop innovative solutions to solve the problems related to their diseases can potentially give valuable contributions to the stock of knowledge about their diseases and ways to cope with them. With the diffusion of solutions, their general value also increases. Cited from the research of Oliveira and his colleagues, we will have a deep understanding of user innovations by patients and their caregivers.

4.1.1 Data Collection and Analysis

To get a comprehensive analysis result, Oliveira and his colleagues administrated a rigorous data collection and analysis process. They conducted a survey of rare diseases patients with the support of a European-based association of mental deficiencies and rare diseases. The association ran a helpline to support patients inquiring about administrative and disease related questions and had about 800 registered members. Together with the individuals who had contacted its helpline before, the association recorded about 5000 individuals' contact information in total and randomly selected a sample of 1000 individuals for Oliveira to conduct their survey.

Besides, four social workers with rich experience in working with rare diseases patients were appointed by the association to administer Oliveira's survey. The interviewers contacted individuals on the list provided by the association in sequence until 500 completed questionnaires had obtained.

Interviewers started each telephone interview by identifying the participating individuals and explaining the purpose and topic of the survey. They proceeded to the questionnaire only if they received the agreement to participate from the interviewees. In the end, the interviewers made 546 calls to the patients on the contact list and received 506 responses of which 500 were usable for further processing. All the information collected and included in the database for analysis was de-identified which meant patients' data was analyzed as a group with no individual information disclosure.

The questionnaire contained 67 questions in all and was divided into 7 sections:
1) in the first section, interviewers identified the respondents as patients or caregivers and adapted the language of the questions for following interviews. Next, questions about the limitations imposed by the disease upon both patients and caregivers were asked, as well as questions about perceived needs for related solutions. Finally, interviewers asked whether the patient or their caregiver had developed a solution that helped them cope with the diseases;
According to their answer, respondents were branched to one of four sections:
2) no solution developed;
3) equipment or technical aid development;
4) therapy development;
5) a behavioral change developed;
Respondents with developments were then asked to describe what they had developed in detail. Moreover, they were also asked to estimate their overall quality of life (measured by a single-item, 7-point Likert Scale) before and after using their solutions to better evaluate the value of their solutions. If the respondent was a caregiver, quality of life changes for both the caregiver and the patient were asked about.
6) questions about respondents' demographics;
7) asked about respondent's use of the Internet and medical community memberships.

To assess the novelty of the solutions, first, Oliveira et al. removed these ones that were obviously mismatched with the aim of the study. After the initial screening, two medical professionals, who had both clinical and research expertise, independently assessed the novelty of all the solutions developed by respondents. All the information about the patients' gender, their diseases and disease durations, and collected descriptions was available to these experts. Additionally, there were two research assistants collected information about common therapeutic practices for the diseases to them.

Each professional independently read the descriptions of patients' solutions and evaluated whether respondents' solutions were novel, or whether the solution was already known to them or the medical practice, based on their specialized medical knowledge. During their evaluating, they also checked the medical literatures and the information collected by the research assistants.

A solution was classified into a patient innovation only if both evaluators agreed that it was novel. If the solution was already known to medicine, although not to the respondent, it was classified as a redevelopment. Redevelopments were valuable to individual patient developers, but not to the stock of medical knowledge.

The evaluators were also asked to assess whether in their opinion the solutions are useful or helpful for the patients. The assessment of the solutions' usefulness or helpfulness was based on the following three criteria: 1) it helped the patients or caregivers in their daily activities 2) it may help in coping with the disease and 3) it was a cost saving alternative to something that already existed. In addition, the evaluators were asked to indicate which of the solutions were dangerous for respondents in their point of view.

After all these data collections and assessments processes, in the statistical analyses phase, Oliveira and his colleagues built and tested two multivariate discrete choice models to explore what motivated respondents to innovate and what drove them to share their solutions.

In the first model, Oliveira set the validated innovation as the dependent variable, and independent variables were: 1) socio-demographic variables 2) disease prevalence (obtained from external databases and categorized into 5 categories: higher than 1/1,000; 1 to 9/10,000; 1 to 9/100,000; 1 to 9/1,000,000; or lower than 1/1,000,000), which allowed to test whether lower prevalence implied higher needs for solutions and higher likelihood of patients' innovation 3) disease burden (measured on a 5-point scale, from 1 – the disease imposed no limitations on patient's life, to 5 – the disease imposed extreme limitations on patient's life), to realize the extent that patient's disease impose limitations on their life 4) medical patient community memberships which indicated whether the respondent belonged to any formal organization of patients with the same disease. Besides, the squared terms of the respondents' age and their disease duration were also included as variables to test their non-linear effects on innovation.

In the other model built by Oliveira and his colleagues, except for the variables from the first model, they added another one to test the respondents' likelihood of information disclosure. The added variable was the difference in the overall quality of life before the innovation and after using the solution. The quality of life for the two periods was measured on a 7-point scale, from 1 – extremely low, to 7 – excellent. Oliveira et al. conducted the analysis using two data samples: 1) sample with all 263 reported solutions and 2) restricted sample with 182 solutions that passed the prescreening. This was because that whether the respondents believed that they had developed something was important to study their solution sharing activities.

Therefore, analysis of restricted sample was conducted to check the robustness of the results.

4.1.2 Research Results

The statistical analysis showed that the majority of the 500 respondents in the sample were caregivers, they constituted 59% of the entire sample. Moreover, 85% of the respondents were women, and women also made up 65% of all the patients in the sample. The average age of patients in the sample was 33 years old with the average disease duration of 12 years. While the average age of the respondents was 45 years, and most of them (65%) were between 18 and 45 years old. One-third of the respondents held university degrees, 51% were employed, and 64% were married.

53% (263 of 500) respondents claimed that they had developed a novel solution to assist them in managing their diseases. The prescreening of researchers removed 81 solutions that were mismatched with the aim of the study, leaving 36% (182 of 500) of the sample as potential solutions. Further evaluation by the medical professional evaluators suggested that 8% of the respondents' solutions in the sample were evaluated as novel which meant "new to the world". While the remaining claimed innovations were assessed by the evaluators to be redevelopments – novel to the patient developer, but already known to medicine. To get a robust result, Oliveira and his colleagues used the restricted sample of 182 solutions that passed the initial screening for further analysis.

Almost all the reported solutions were evaluated to be relatively safe by the expert evaluators, only 2% (4 of 182) of the restricted sample were assessed to be potentially detrimental to patients' health. Besides, 40% (73 of 182) of the patients' innovations were evaluated to be useful without considering their novelty.

Oliveira et al. divided the patients' developments into two categories – products and services. Developments were classified as products if there was a description of a medical equipment or an assistive product. While developments were defined as services in other cases, where there was a description of an activity or a plan of activities that related to treatments or changes in strategies or behaviors related to the disease. In the restricted sample, 90% (163 of 182) of the reported solutions were categorized as services.

Most of the solutions in the restricted sample were technically simple, but they offered significant value to patients. Some examples of these solutions are described as follows:

- The first case considers a mother who takes care of her son who is an Angelman syndrome patient. The Angelman syndrome causes patients to have ataxia, making them unable to walk, move or maintain balance well. Although the mother had experimented with many strategies recommended by the doctors or therapists, her son obtained little gain from them.
  By chance, at a neighbor's child's birthday party, the mother observed that her son jumped excitedly for strings to catch a floating balloon. This gave her an idea and she experimented at home by filling a room with floating balloons. She found her son started jumping and reaching for the balloons and amused by this challenge. Besides, the mother also used bands to support her child's knees and keep him in an upright position.
  This training significantly improved her son's physical abilities. The mother introduced this balloon strategy to other parents whose children had Angelman syndrome, they tried the solution on their children, and most had positive results. This was assessed as a novel innovation by the professional evaluators.
- Another example is about a mother of a child with cerebral palsy. One of the symptoms of this disease is hypersalivation. It is not only uncomfortable for the patients and a potential source of disease but also a cause for social exclusion. The medical solution for this problem is removing the salivary glands by surgery. However, the mother considered this solution was drastic and with limited benefits.
  Instead, the mother tried to solve the problem by considering ways that allow her child to socialize with others more easily. Therefore, she designed "the cute turtle collar" for her son. It is a kind of turtle collar made by a material that absorbs the saliva well and is both stylish and suitable to use in all weather conditions.
- Several reported solutions in the sample included descriptions of intensive physical activity which, in respondents' opinion, led to improvements in their overall quality of life. An example is the case considering a Thrombocytopenic purpura patient. Rather than following the advice of health professionals not to engage in physical activities that could hurt the body, the patient practiced martial arts, Muay Thai and kickboxing up to 5 hours a day. The respondent reported significant decrease in frequency of hemorrhages and credited it to the intensive practice of material arts.
- Another case also involves intensive physical activity is a boy afflicted by Charcot-Marie-Tooth disease. The disease makes the patients progressively lose their muscle tissues and touch sensation, and usually, the first visible symptoms appear in legs and hands. However, the boy's daily practice of playing piano slowed down

the disease's development on his hands and masked some of the symptoms, which made the diagnostic process harder. With continuing playing piano, the boy's hands remained fully functional, only a little or no sign of the disease on his hands. While his foot may need surgery to maintain the desired level of functionality.

It is well-known that physical exercises have many benefits for patients, but in this case, the intensity of the exercise may have changed the development of the disease. This information may be useful for clinicians to establish a correct diagnosis earlier for similar cases, as well as for other patients and their caregivers to solve their problems.

- Most of the innovations in the sample were developed to increase the patients' autonomy. The fifth case considers a patient with myasthenia gravis, an autoimmune neuromuscular junction disorder. The respondent reported that she had designed several customized products according to her specifications.

  An example was a metal two-hook button aid that helped her button pants with others' assistance. Although there was a variety of button hooks available on the Internet, the patients often experimented with the design to make the one that better fit their specific conditions and needs.

  Other solutions that involved the design of elements commonly found in any household were also reported. Such as optimization of the height and width of stairs to improve mobility, or design of tables and chairs with extra features to increase the safety of hyperactive children with cognitive limitations, etc.

Most of the respondents who reported a solution described significant improvements in their overall quality of life as a result of using their solutions. According to the statistical analysis of Oliveira et al., the mean improvement in quality of life of the patients was 1.6 on a 7-point Likert scale for solutions that were novel to the patient but not to the world. While for solutions that were new to the world, this corresponding number was 2. Caregivers reported mean improvements in the quality of their lives of 1.4 for non-novel and 1.9 for novel solutions.

Other than the significant improvements in quality of life resulting from using the innovations, the difference in the quality of life improvements was not significant for solutions that were only novel to the individual respondents compared to new to the world.

Besides, Oliveira et al. matched the medical evaluators' perceptions of the solutions' usefulness with the patients' perceptions of their overall quality of life improvements due to the use of their solutions. In the 115 solutions that the patients reported as beneficial for their quality of life, 68 (59%) were assessed as not helpful by the professional evaluators. On the other side, the evaluators judged as useful 23 (44%) of 52 solutions that patients reported no improvement in quality of life.

Of all the 263 respondents who reported developing a novel solution, 84 (32%) of them also reported putting effort into sharing their solutions with others. While of the restricted sample of 182 solutions, 55 (30%) respondents reported engaging in the sharing activities.

Oliveira and his colleagues asked respondents about seven types of diffusion effort that they might have undertaken (see TABLE 4). Respondents in the restricted sample reported engaging in 1.5 of these diffusion activities on average, and 71% (39 of 55) of them reported engaging in only one of the seven possible diffusion activities. Moreover, in the non-restricted sample, diffusion effort was significantly higher in the case of innovations that were new to the world than in the case of redevelopments that were only novel to the individuals. However, in the restricted sample, the difference between the same groups was not statistically significant.

Solution sharing activity	Non-restricted sample (n = 263)		Restricted sample (n = 182)	
	New to the world (n = 19)	New to the respondents (n = 65)	New to the world (n = 19)	New to the respondents (n = 36)
Shown it to other patients	89%	88%	89%	92%
Shown it to medical professionals	5%	6%	5%	2%
Shared the info on a website/blog/social network	37%	22%	37%	28%
Shared it through media	16%	5%	16%	8%
Shown it to commercial entities	11%	2%	10%	3%
Spent time and/or money to help others (people, companies) use the solution	11%	3%	10%	5%
Made a manual or documentation that helps using the solution	5%	3%	5%	5%

TABLE 4. The patients' solution sharing activities

Considering the non-restricted sample, the most common mode of sharing was patient-to-patient, 88% (74 of 84) of respondents shared their solutions to other patients. On the contrary, only 6% (5 of 84) of the respondents shared their solutions with their doctors and 3.5% (3 of 84) shared with commercial entities. In four cases, patients or caregivers spent time or money to help diffuse their solutions. And in three cases, the inventors also made a manual or documentation to help others use their solutions.

While exploring factors that were associated with patients' likelihood of developing and sharing their novel innovations, the first multivariate discrete choice model conducted by Oliveira et al. showed that two factors might help predicting patients' likelihood to innovate: 1) Disease burden – the patients' perception of limitation on life imposed by their disease was positively and statistically significant for their likelihood of innovating. With other coefficients held constant, a 1-point increase in perceived limitations increased odds of patient innovating by a factor of 1.3, and 2)

Academic degree – having a university degree also increased likelihood of patient innovation, with an increase of odds of patient innovating by a factor of 2.

In the second (included the full sample of 263 reported solutions) and the third (included the restricted sample of 182 reported solutions) multivariate discrete choice models, Oliveira and his colleagues explored the factors associated with the diffusion of innovation. The strongest predictor of respondents' sharing activities was the difference in the respondents' overall quality of life before and after using a solution, in both models. In model 2 with the full sample, a 1-point increase in the perceived difference increased odds of sharing the solution by a factor of 1.7, with other coefficients held constant.

Besides, in model 2, Oliveira et al. found an inverted U relationship between the respondents' age and the likelihood of sharing a solution, the effect of age on the diffusion of innovation became negative after the age of 55. While in model 3 with the restricted sample, this non-linear effect of respondents' age on the solution sharing was not statistically significant. The other difference between models 2 and 3 was that disease duration had positive and non-linear relationship with the diffusion of solutions in model 3, but this observation did not hold in model 2.

4.1.3 Discussions and Insights

In the end, based on their research results, Oliveira and his colleagues suggested that their study results have significant implications for all stakeholders in the delivery process of healthcare related to rare diseases. 36% of the sample of rare disease patients and their caregivers had developed novel solutions to manage their diseases, and the use of these solutions significantly improved their quality of life. 22% (40 of 182) of these claimed novel solutions were assessed as new to the world by the professional evaluators. Therefore, 8% (40 of 500) of rare disease patients and their caregivers in Oliveira's study sample had developed valuable, new to the world innovations to improve their own care. Considering an estimated 6% to 8% of the world's population are afflicted by rare diseases, and the commercial innovation efforts associated with these patients are negatively affected by small market sizes, there exists a massive and non-commercial source of medical innovations – patients and their caregivers. Although this valuable source is hidden due to the lack of diffusion efforts by innovating patients, efforts could be made to change this situation.

Furthermore, Oliveira et al. found the significant positive relationships between the limitations caused by a disease, as well as educational level and the patients' likelihood of innovation. Besides, they also found that the difference in the patients' quality of life improvements before and after using their novel solutions was significantly positively associated with efforts to diffuse their innovations to others.

Oliveira and his colleagues also revealed a potential problem of their study: the patients' systematical assessments of their innovations were different from doctors, as suggested by the observed differences between patient and clinician evaluations of the usefulness of novel solutions. A possible explanation was that clinicians assessed the usefulness of innovations, primarily considering whether they affect the clinical course of disease in beneficial ways. In contrast, patients might evaluate useful innovations that had no impact on the course of their disease but improved their comfort or other aspects of their quality of life when living with their disease.

Another finding was that most development efforts of patients and their caregivers were considered as the reinvention of known solutions of which they were not aware. Oliveira's research data showed that in the restricted sample, only 22% (40 of 182) of the solutions developed by patients and caregivers were assessed novel to the world by the professional clinician evaluators. It suggested that the information on known solutions was poorly diffused or that the information provided by clinicians was barely absorbed by many patients. One possible reason was the duration of medical appointments was quite limited. It might also be a reason for Oliveira's other finding – only 6% of patients reported sharing their innovations with their clinicians.

According to the research results, the most common diffusion mode of patients' innovations was the direct patient-to-patient information sharing activity. Up to 88% (74 of 84) of respondents who shared their solutions participated in patient-to-patient sharing activities. The second most common diffusion mode was via blogs, websites, or social networks, reported by 25% (21 of 84) of those who shared solutions. Rare disease patients and their caregivers were known to actively use the Internet and social networks to find and provide help and connect with other patients and caregivers. However, considering 85% of the respondents in the full sample used the Internet of which 71% used social networks, the reported level of solution sharing through the Internet was low.

Oliveira and his colleagues suggested associations to develop and experiment with systems to collect and medically evaluate novel solutions developed by patients and to identify solutions that are worth further test, improvement, and diffusion. They also suggested further research on the topic of patient-developed innovations should be conducted.

4.2 Comparison between Doctors and Patients in User Innovation

Based on Lettl and his colleagues' research on radical innovations by clinicians in the medical field and the research of patient innovation by Oliveira et al., we can roughly summarize the similarities and differences between doctors and patients when they act as user innovators, respectively.

First, as highlighted by Eric von Hippel in the definition of user innovation, one of the most important reasons for users to innovate is the existing products are unable to satisfy their specific demands, so they have no choice but to modify the existing products or develop a new one to solve their problems. Therefore, problem-induced motivation plays an important role both in innovations by clinicians and by patients. In all the cases studied by Lettl, clinicians faced severe difficulties in their daily work that could not be solved by conventional technology or existing medical equipment. The limitations of conventional technologies motivated these innovative surgeons to search for other new and more workable solutions. While in cases of patient innovation, patients and their caregivers developed novel solutions to manage their diseases better and improve their overall quality of life by using these solutions. They are motivated to innovate for themselves because the diseases they have are rare, and the medical suppliers' initiatives of commercial activities in such rare disease marketplaces are low.

Besides, the innovative surgeons in Lettl's study who developed radical innovations for medical equipment and surgeons in Hinsch's study who developed novel techniques in the field of medical devices are all professional and have in-depth knowledge within their domain of surgery. Correspondingly, in Oliveira's research, patients with a university degree are more likely to innovate. The factor "academic degree" is statistically significant for patients' likelihood of innovating, with an increase of odds of patient innovating by a factor of 2. Therefore, innovators' specific knowledge for innovation plays an important role in user innovations both for clinicians and patients.

However, there are some differences between clinicians' user innovation and patients' user innovation. Although patient-developed innovations can be technically advanced, but most of them are relatively simple in technics. It does not mean these novel solutions offer little value to patients. On the contrary, the majority of the respondents of Oliveira's survey who claimed that they had developed a novel solution described substantial improvements in their overall quality of life as a result of using their solutions. Nevertheless, most of the user innovations developed by doctors are complicated, technically advanced, and based on professional knowledge in a specific medical domain.

Besides, comparing with that most of patients' innovations are categorized as service innovations, the innovations developed by clinicians are multiple categories, they can be radical innovations for medical equipment, novel innovations in surgical techniques, innovations for public health systems and medical services systems, and so on. A possible reason for this difference is that innovative clinicians have more extensive and specialized medical knowledge related to innovations in the medical field.

Furthermore, due to the complexity and technological sophistication of clinicians' innovations, the innovative surgeons tend to cooperate with other experts who can provide the necessary technological know-how and expertise in specific fields for their innovations. In radical innovation projects, surgeons even perform an entrepreneurial role. They establish and manage the required innovation networks that transform their radical ideas into first prototypes and then into marketable products. But most of the patient innovations are developed by patients or their caregivers independently because they often don't know who or where to turn for help when innovating. It is also another reason why patients' innovations are often relatively technically simple.

Innovative clinicians more actively engage in the diffusion of their innovations. In most clinician innovation cases, the surgeons put significant time and effort into its diffusing activities once their innovation developed. Especially for innovations in techniques, although the speed of diffusion is influenced by many factors, the inventors of the new techniques still actively diffuse their innovative techniques to other surgeons through publications, speeches at congresses, offering courses, etc. While in cases of patient innovations, Oliveira and his colleagues observed that the proportion of patient innovators who actively diffused their innovations was low. Only about 30% of respondents who claimed to develop a novel solution also reported engaging in the sharing activities. Besides, most of the patients' sharing activities are patient-to-patient, the diffusion of their new solutions to medical professionals or commercial entities is even fewer.

Therefore, different from the exploration and commercial application of clinician user innovations are relatively mature, further in-depth study about the patient user innovations should be conducted. It is valuable to continue researching how rare disease patients and their caregivers can be helped in their innovation activities, how their innovations can be evaluated professionally, and how these patient-developed innovations can be diffused more widely and benefit the public healthcare systems.

Chapter 5 The Application Prospects of User Innovation in the Medical Field & Conclusions

So far, we have discussed many examples of application of user innovation in the medical field, including radical innovations for modern medical equipment developed by clinicians, user innovations in surgical techniques, as well as innovations by patients with rare diseases and their caregivers. When we talk about the latest cutting-edge applications of user innovation in the medical field, some interesting cases raise.

With the rise of emerging technologies such as artificial intelligence, big data, and cloud computing in recent years, these advanced technologies are also applied into the medical field by user innovators. Because of the high risks of long detailed operations, the 3D operating models co-developed by surgeons and medical device manufacturers are used by a growing number of surgeons to practice complex operations before they walk into the operating room. The 3D operating models not only help the surgeons to perform the operations more quickly but also allow them to test their innovative techniques and to be more confident of their success.

Another example is an advanced AI miniature robot co-developed by clinicians and researchers at Carnegie Mellon University that can perform heart treatments. Surgeons make a small incision and then navigate the robot to particular areas of the heart, where the robot sticks to the organ and performs therapy. This AI miniature robot significantly improves traditional heart therapy procedures since it is more precise, less invasive, and safer.

Except for the advanced technologies mentioned above, cutting-edge technologies in biomedical and biochemical fields are also applied by innovative clinicians in their user innovation development. For instance, genetic editing technology and drug design and delivery.

According to these cases of the latest application, it’s easy for us to find that more and more new technologies from different fields are searched and applied by doctors when they meet problems that can’t be solved by existing products and try to develop novel solutions. Sometimes, these innovations developed by clinicians can be technically complex, and the development processes can be costly. Therefore, innovative doctors tend to cooperate with experts in different fields and medical device manufacturers who can provide the necessary technological support, funds, and other resources to clinicians' innovation activities. Innovative users become an important resource of innovation activities. They play the role of inventors, co-developers, or even entrepreneurs.

In summary, my thesis started from the definition and the key premises of user innovation. According to Eric von Hippel who developed the concept of user innovation, it is the "one that a firm or individual makes to use themselves". Then, based on the definition of "user innovation", we discussed in depth the concept of "lead users" – the innovating users with needs ahead of the general market and are an important information source for innovating companies in the development process of new products.

Because of the importance of user innovation for commercial success, more and more producer firms have an interest in their customers' innovations. Therefore, in the first part of my article, we also discussed the lead user method which is a market research tool that has been developed to help companies identify the newest user-developed innovations and analyze their commercial potential. This methodology developed by Eric von Hippel is widely applicated in research for user innovation in different fields, as well as in the real business world.

In the second chapter, we discussed the three most representative examples of the application of user innovation to deeply understand how the lead user methodology works. Including the first empirical application of the lead user method – the PC-CAD system case study, the application of user innovation in relatively new sports equipment field, and the case study of the LEGO Ideas platform. Through these three case studies, we also identified the value of lead users and their novel innovations for manufacturers, as well as the challenges for companies to collaborate with user communities.

Next, we went in-depth into the application of user innovation in modern medical equipment. After a concise introduction to modern medical equipment, we discussed examples of radical innovations for modern medical equipment developed by clinicians. Based on the research of Lettl and his colleagues for four radical innovation projects screened by a rigorous process, we observed that except for acting as inventors, user innovators might also play a role as entrepreneurs or co-developers in different cases. Moreover, we also identified that manufacturing firms that adopted the innovative users' concepts benefit a lot from the users' contributions on several dimensions.

Also, we discussed examples of user innovation in surgical techniques developed by clinicians and surgeons. According to another four cases studied by Hinsch et al., we identified the different development processes for surgical technique innovations. Besides, rather than the previous study of the application of user innovation in medical equipment, when researching the application of user innovation in surgical techniques, we were more focused on the diffusion of techniques and the role of innovative surgeons in diffusing activities. Furthermore, we also discussed the interdependencies between user-generated techniques and product innovation.

In the fourth chapter, we studied examples of innovation by patients with rare diseases and their caregivers based on the research of Oliveira and his colleagues. In the same chapter, we also made a comparison between innovations developed by clinicians and patients.

The topic of user innovation is extensive. Users have been found playing the role of innovators in almost all the different fields. They develop innovative products and services for themselves since their needs are unsatisfied by the existing products. My thesis only concerns the application of user innovation in the medical field, more precisely, the innovations developed by clinicians related to modern medical equipment. However, of many aspects and in different domains, the user innovation is worth further studying by not only researchers but also manufacturing firms. In this way, the hidden value of user innovation can be better explored and utilized, bringing significant benefits to the innovation process of companies and industries.

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