

Patients as Innovators

An Empirical Study of Patients' Role in Innovation in the Healthcare Industry

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PATIENTS AS INNOVATORS: AN EMPIRICAL STUDY OF PATIENTS' ROLE IN INNOVATION IN THE HEALTHCARE INDUSTRY

PhD Series 01.2024

Marija Sarafinovska

**PATIENTS AS INNOVATORS:
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IN THE HEALTHCARE INDUSTRY**

Department of Marketing

PhD Series 01.2024

CBS COPENHAGEN BUSINESS SCHOOL
HANDELSHØJSKOLEN

Patients as Innovators: An Empirical Study of Patients' Role in Innovation in the Healthcare Industry

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I would like to express my utmost gratitude to every chronic disease patient who participated in this study. This thesis is for you! For all of your inspirational innovations, which not only ease your own but also the lives of others battling the same disease.

Thank you for making this world a better place!

ABSTRACT

This dissertation investigates two distinct but interrelated phenomena of user innovation and user co-creation in a healthcare context. We explore the role of patients (end users of healthcare products and services) as both co-creators in the pharmaceutical and medical technology industries and their role as patient (user) innovators. To do this, we utilize both qualitative and quantitative research methods.

This dissertation is divided into six chapters. Chapter 1 introduces the topic of the PhD dissertation. In Chapter 2 we discuss the theoretical background, identify research gaps, and present the specific research objectives and methodologies that will be addressed in the articles that constitute chapters 3, 4, and 5. Chapters 3, 4, and 5 present the three papers. Chapter 6 concludes on the overarching theme and provides an integrated discussion of theoretical contributions, managerial implications, limitations, and future research opportunities examined in the articles that compose chapters 3, 4, and 5.

In Chapter 3, we examine ethical challenges that arise during the co-creation process analyzed through 42 semi-structured interviews with both patient co-creators and managers with long-term co-creation industry experience. Co-creation can be defined as “an active, dynamic, and social process based on interactions and relationships between firms and external stakeholders, oriented toward new product generation”. However, ethical challenges arise when firms engage in co-creation with external stakeholders. We focus on the pharmaceutical and medical technology industries as these industries have been slower in adopting co-creation practices than other sectors, mainly due to stricter legal and compliance regulations. Based on our data analysis, we develop a framework that characterizes the ethical challenges posed by co-creation, proposing an extension to Schwarz's universal moral standards for corporate codes of ethics, with additional moral standards emerging as relevant for co-creation: equality, inclusivity, and diversity. Furthermore, by exploring both patients and managerial perspectives, we reveal the discrepancies in the expectations between patients and managers. The findings are followed by recommendations to address these challenges.

In Chapter 4 and Chapter 5, we study the factors influencing patients' intention to innovate and their willingness to share innovations. Patients and their non-professional caregivers, as end users of healthcare products and services, invent valuable solutions to improve their own and their communities' health. Their main motivation for doing this is not for profit, but to address their own unmet needs and the needs of their close networks, reflecting the fact that this represents a social process. Based on data collected by surveying more than 300 patients living with a chronic disease accessed through patient organizations and social media communities, we study patient innovators' social consciousness on their intention to innovate. Additionally, we explore the moderating effects of patients' ahead-of-trend behavior and treatment burden on the relationship between socially conscious behavior and intention to innovate. The findings confirm the positive impact of patients' socially conscious behavior on their intention to innovate. Moreover, the fact that patients are ahead of trend strengthens the relationship between their social consciousness

and intention to innovate. Even though this research does not find evidence that supports the moderating effect of burden of treatment, it does show the importance of considering burden of treatment as a factor influencing intention to innovate, suggesting the need for future research.

Social welfare benefits from user innovation can only be achieved when valuable user-developed innovations are shared with others who can benefit from them. Therefore, the willingness to share user innovations becomes a relevant factor to investigate. To explore the impact of innovation-related resources (technical expertise and community-based resources) on users' willingness to share innovations, we analyze data collected by surveying 318 chronic disease patients through various patient organizations and patient communities on social media. The study also explores the moderating effect of legal barriers on the relationship between innovation-related resources and users' willingness to share. Our empirical findings support the following hypotheses: firstly, that technical expertise and community-based resources positively influence users' willingness to share innovations; secondly, that legal barriers weaken the positive effect of community-based resources on willingness to share. Our study lays the groundwork for further research on the impact of legal barriers on user innovation diffusion. The insights gained from this study are valuable for advancing the field of user innovation as well as for manufacturers and policymakers seeking to leverage user-developed innovations.

RESUMÉ / SUMMARY (DANISH)

Denne afhandling undersøger to distinkte, men indbyrdes forbundne fænomener knyttet til bruger-innovation og brugermedskabelse i en sundhedsfaglig kontekst. Vi undersøger patienternes rolle (slutbrugere af sundhedsfaglige produkter og-tjenester) som både medskabere i de farmaceutiske og medicinalteknologiske industrier og deres rolle som patient (bruger) innovatører. For at gøre dette vil vi anvende både kvalitative og kvantitative metoder.

Denne afhandling er inddelt i seks kapitler. I kapitel 1 introduceres emnet for ph. d.-afhandlingen. I kapitel 2 drøftes den teoretiske baggrund, der identificeres huller i forskningen og der præsenteres de specifikke forskningsmæssige mål og metoder, som vil blive håndteret i de artikler, der udgør kapitel 3, 4 og 5. Kapitel 3, 4 og 5 præsenterer de tre artikler. Kapitel 6 konkluderer på det overordnede tema og giver en integreret diskussion af teoretiske bidrag, ledelsesmæssige implikationer, begrænsninger og fremtidige forskningsmuligheder, der undersøges i de artikler, der indgår i kapitlerne 3, 4 og 5.

I kapitel 3 undersøger vi de etiske udfordringer, der kan opstå i forbindelse med medskabelsesprocessen analyseret gennem 42 semistrukturerede interviews med både patient-medskabere og ledere med langsigtet erfaring med medskabelse i industrien. Medskabelse kan defineres som "en aktiv, dynamisk og social proces baseret på interaktioner og relationer mellem virksomheder og eksterne interessenter, orienteret mod generering af nye produkter".

Der opstår dog etiske udfordringer, når virksomheder inddrager eksterne interessenter i medskabelsesprocessen. Vi har fokus på de farmaceutiske og medicinalteknologiske industrier, da disse har været langsommere i at udvikle medskabelsespraksisser end andre sektorer, primært på grund af skærpede juridiske og compliance-regler. Med udgangspunkt i vores dataanalyse udvikler vi en ramme, der karakteriserer de etiske udfordringer, som medskabelsen medfører, og foreslår en udvidelse af Schwarzs universelle moralske standarder for virksomheders Codes of Ethics, idet yderligere moralske standarder fremkommer som relevante for medskabelse: ligebehandling, inklusion og diversitet. Desuden afdækker vi gennem en undersøgelse af både patienters og ledelses perspektiver, at der er uoverensstemmelser i forventningerne mellem de to parter. Resultaterne efterfølges af anbefalinger til at imødegå disse udfordringer.

I kapitel 4 og kapitel 5 undersøges de faktorer, der påvirker patienternes intention om at innovere og deres villighed til at dele innovationer. Patienter og deres ikke-professionelle omsorgspersoner opfinder, som slutbrugere af sundhedsprodukter og-tjenester, værdifulde løsninger til at forbedre egen sundhed, samt sundheden i deres nære netværk. Deres primære motivation for at gøre dette er ikke for profit, men for at adressere deres egne ikke-opfyldte behov og deres nære netværks behov, hvilket afspejler, at der er tale om en social proces. Med udgangspunkt i data indsamlet ved en undersøgelse af mere end 300 patienter med en kronisk sygdom, som vi har fået adgang til gennem patientorganisationer og fællesskaber på sociale medier, studerer vi patientinnovatørernes sociale bevidsthed om deres intention om at innovere. Derudover undersøger vi de modererende effekter af patienternes fremadrettede adfærd og behandlingen (burden of treatment) på forholdet

mellem socialt bevidst adfærd og intention om at innovere. Resultaterne bekræfter den positive effekt af patienternes socialt bevidste adfærd på deres intention om at innovere. Desuden styrker det faktum at patienterne er foran udviklingen forholdet mellem den sociale bevidsthed og intentionen om at innovere. Selv om denne forskning ikke finder evidens, der understøtter den modererende virkning af behandlingen (*burden of treatment*), viser den vigtigheden af at overveje denne som en faktor, der har betydning for at innovere, hvilket understøtter behovet for yderligere forskning på dette område.

Sociale velfærdsydelser fra brugerinnovation kan kun opnås, når værdifulde brugerudviklede innovationer deles med andre, der kan få gavn af dem. Derfor bliver viljen til at udveksle brugerinnovationer en relevant faktor at undersøge. For at undersøge effekten af innovationsrelaterede ressourcer (teknisk ekspertise og netværksbaserede ressourcer) på brugernes villighed til at udveksle innovationer, analyserer vi data indsamlet ved at inddrage 318 patienter, der lider af kronisk sygdom, gennem forskellige patientorganisationer og patientfællesskaber på de sociale medier. Undersøgelsen udforsker også den modererende effekt af juridiske barrierer på forholdet mellem innovationsrelaterede ressourcer og brugernes villighed til at dele. Vores empiriske resultater understøtter følgende hypoteser: for det første, at teknisk ekspertise og netværksbaserede ressourcer har en positiv indflydelse på brugernes villighed til at udveksle innovationer. For det andet, at juridiske barrierer svækker den positive effekt som fællesskabsbaserede ressourcer har på brugernes villighed til at dele. Undersøgelsen lægger op til yderligere forskning om, hvordan juridiske barrierer påvirker udbredelsen af brugerinnovation. Den opnåede indsigt fra undersøgelsen er værdifuld med henblik på at fremme feltet om brugerinnovation, samt for fabrikkerne og politikere, der søger at udnytte brugerudviklede innovationer.

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1. INTRODUCTION

1.1. Introduction to the Topic of the PhD Thesis

Over the past decades, growing evidence suggests that firms no longer rely exclusively on their internal R&D activities to maintain technological innovativeness (Narula, 2001). The rapid evolution of technology and global communication enables firms to be closer to their stakeholders and to facilitate co-creation with external stakeholders (Ind et al., 2013; Merz et al., 2009). Consequently, more and more firms are adopting strategies that allow co-creation with external stakeholders in new product development (NPD) to improve their competitiveness (Prahalad & Ramaswamy, 2004; Roser et al., 2013). Co-creation is defined as an active, dynamic, and social process based on interactions and relationships between firms and their external stakeholders towards new product generation (Markovic & Bagherzadeh, 2018, p. 173). Co-creation with external stakeholders may enhance innovation and unlock sources of competitive advantage (Frow et al., 2015).

However, firms often encounter ethical challenges when engaging in co-creation with external stakeholders (e.g., relating to intellectual property rights, confidentiality of information, the negotiation process) (e.g., Ind et al., 2017; Lindfelt & Törnroos, 2006; Markovic et al., 2018, 2022; Sierra et al. 2017; Singh et al., 2012; Stanislawski, 2011; Williams & Aitken, 2011). This highlights the necessity for further research on the intersection between co-creation and ethics. Even though Stanislawski has linked co-creation with universal moral standards of corporate code of ethics (Schwartz, 1998; 2002), her work remains conceptual.

To deal with this research gap, the first overarching research objective of this PhD thesis is to empirically investigate ethical challenges that could arise during the co-creation process, both from managerial and patient perspectives.

Our research was conducted in the pharmaceutical and medical technology industries which offer unique perspectives. Firstly, they operate under stringent regulations and have been relatively slower in adopting co-creation compared to other sectors. This is primarily due to the guidance provided by their legal and compliance teams, who often advise R&D teams to maintain a certain distance from patients, the key stakeholders (Panchal et al., 2012). Furthermore, patients are inherently vulnerable and require a different approach when engaging with them. Given the specific context, co-creating with these industries can be particularly challenging. Therefore, studying the ethical principles in co-creation in these industries becomes particularly important.

The first overarching research objective of the thesis was to empirically investigate the co-creation process in the pharmaceutical and medical technology context. This was achieved by conducting semi-structured interviews with both chronic disease patients and managers, in order to capture both perspectives of the process. We applied the universal moral standards for a corporate code of ethics (Schwartz, 1998; 2002) as a basis to develop an extended ethical framework that identifies and characterizes the different ethical challenges posed throughout the different stages of the NPD process.

There is a mutually reinforcing link between co-creation and user innovation. While co-creation refers to a collaborative and interactive process of value creation between companies and their external stakeholders, user innovation refers to the phenomenon where users¹ actively participate in the innovation process by developing new ideas, products, or solutions.

The topic of user innovation will be discussed in depth in this thesis. User innovation not only competes with but may also substitute producer innovation in parts of the economy (Baldwin & von Hippel, 2011). An increasing body of literature aims to explain the user innovation phenomenon (e.g. Bogers et al., 2010; de Jong & von Hippel, 2009; Franke & Shah, 2003; Franke & von Hippel, 2003a; Herstatt & von Hippel, 1992; Hiennerth et al., 2014; Lüthje, 2003, 2004; Lüthje et al., 2005; Oliveira & von Hippel, 2011; Urban & von Hippel, 1988; von Hippel, 1976, 1988, 2006, and 2017). Previous research confirms that both the scope and scale of user innovation is substantial (von Hippel, 2011) and that user innovators often develop breakthrough innovations (Lettl et al., 2006; Lilien et al., 2002).

However, one of the main questions still remains: what motivates user innovation? User innovators primarily aim to generate value for themselves rather than the broad market (Bradonjic et al., 2019; von Hippel, 1986). By innovating, they try to fulfill their own and their immediate environment's unmet needs. Thus, users' incentives to innovate differ from producers' as the market potential of innovation is not as important for user innovators (Göldner, 2021; Pieper & Herstatt, 2018). Instead, user innovators are more likely to engage in innovation when they anticipate higher personal benefits from their inventions (Riggs & von Hippel, 1994). Some of them also perceive the innovation process as self-rewarding (Stock et al., 2015; von Hippel, 2006). Other potential benefits they can gain range from reputational to benefits from the network (Baldwin & Clark, 2006; Lerner & Tirole, 2002; von Hippel & von Krogh, 2003).

Patients and caregivers, as the most salient group of stakeholders in the healthcare value chain, are valuable sources of innovation, mainly due to their unique disease knowledge and experience. The research shows that they create solutions that vary from simple tools to help them with their everyday routine to highly sophisticated ones (Habicht et al., 2013; Oliveira et al., 2015; Shcherbatiuk, 2012).

The second research objective of the thesis is to empirically examine the factors influencing users' intention to innovate in healthcare by utilizing a sample of chronic disease patients (as end users of healthcare products and services). We developed and tested a model to explore the impact of socially conscious consumer (user) behavior, (being) ahead-of-trend characteristics and burden of treatment as potential drivers of patients' intention to innovate. To achieve this research objective, we applied quantitative research methodology.

Although research shows that millions of users innovate, a relatively small fraction of these innovations are shared (Canhão et al., 2017). However, social welfare benefits from user innovation can be considerable if user-developed innovations of general value are diffused to

¹ Throughout the thesis, the author uses the term “users” to refer to chronic disease patients and/or their non-professional caregivers as end users of healthcare products and services

others who can benefit from them (de Jong et al., 2015). The diffusion of user innovations within their communities and to the broader market is largely unexplored (Baldwin et al., 2006; Franke & Shah, 2003).

Therefore, an important question arises: how do we help the user innovators share their innovative solutions with a wider audience? (Canhão et al., 2017). Built upon previous research, our study aims to fill a gap in the literature, exploring factors that influence users' willingness to share their innovations.

In Chapter 5, this research paper investigates users' willingness to share their innovations. The authors study the direct effect of innovation-related resource constructs (users' technical expertise and community-related resources) on users' willingness to share, taking into account the moderating effect of legal barriers. More specifically, we examine whether legal barriers negatively moderate the relationship between technical expertise and community-related resources and users' willingness to share innovations with the community. To achieve this research objective, quantitative research methodology has been applied. To test the model, the authors collected data by surveying chronic disease patients (as the end users of healthcare products and services).

1.2. Structure and Content of the PhD Thesis

Overall, the present thesis addresses two interconnected phenomena: co-creation and user innovation in the context of pharmaceutical and medical technology industries.

Chapter 1 introduces the topic of the PhD dissertation.

In Chapter 2, we discuss the theoretical background, identify the research gaps, and present the specific research objectives and methodologies that will be described in the articles that constitute chapters 3, 4, and 5.

In Chapter 3, the co-creation process is investigated together with the ethical challenges that arise during the process.

In Chapter 4, we investigate the user innovation phenomenon. We examine factors that lead to user innovation to investigate how innovative users differ from their less innovative peers.

In Chapter 5, users' willingness to share innovations is investigated. We also examine factors that lead to user innovation diffusion among chronic disease patients.

Both qualitative and quantitative research techniques have been applied in the thesis, thereby adopting a comprehensive methodological approach.

In Chapter 6, we discuss the theoretical contributions, managerial implications, limitations, and future research opportunities of the articles that compose chapters 3, 4, and 5.

2. OVERARCHING FRAMEWORK

This chapter looks at the theoretical background, identifies research gaps, and presents the specific research objectives and methodologies that will be applied in the three articles that constitute chapters 3, 4, and 5.

2.1. Co-creation

2.1.1. Co-creation as Collaborative Innovation Process between Stakeholders

From the beginning of the 21st century, innovation literature has recorded a shift from a transactional to a collaboration-focused view of firm-stakeholders relations, where firms increasingly incorporate users' (and other external stakeholders) competences through dialogue (Prahalad & Ramaswamy, 2000; Sheth et al., 2000; Sawhney, 2006). This improved firm–stakeholder interconnectedness has given firms the opportunity to involve their key stakeholders in co-creating new products and/or services (Ind et al., 2017). The process of co-creation utilizes external stakeholders' insights as a means to better develop and market products which would better meet customer needs (Kristensson et al., 2004). This leads to the development of improved and more personalized products and enhances stakeholders' relationship with firms (Füller, 2010; Nambisan & Baron, 2007). Not only users benefit from greater personalisation and value as a result of co-creation, but it can also be used by firms to build a competitive advantage (Roser et al., 2013). As a consequence, more and more firms are adopting strategies that allow firms to co-create with external stakeholders in new product development in order to improve firms' competitiveness (Prahalad & Ramaswamy, 2004; Roser et al., 2013).

Studies on co-creation have been spread across various areas including entrepreneurship, firm boundaries, industry dynamics, innovation communities, measurement, and policy (Bogers et al., 2010). Despite an increased use of the term “co-creation” in innovation literature, there is little consensus among authors on how to define it (Alves et al., 2016; Galvagno & Dalli, 2014; Ind & Coates, 2013; Ranjan & Read, 2016; Saarijärvi et al., 2013; Zwass, 2010). The term “co-creation” is connected with various areas such as: new product and service development (e.g., Füller & Matzler, 2007; Hoyer et al., 2010; Mahr et al., 2014; Matthing et al., 2004; Nambisan & Nambisan, 2009; Sanders & Stappers, 2008; Sawhney et al., 2005), users as innovators (e.g., Bogers et al., 2010; von Hippel, 2006; Franke & Piller, 2004; Syam & Pazgal, 2013), co-production (e.g., Bendapudi & Leone, 2003; Etgar, 2008; Ramirez, 1999), participatory roles of consumers, communities, and crowds (e.g., Cova & Dalli, 2009; Ind et al., 2012; Kozinets et al., 2008), multi-firm partnerships (e.g., Ceccagnoli et al., 2012; Grover & Kohli, 2012) and open business models (e.g., Chesbrough et al., 2013; Ramaswamy & Ozcan, 2018).

In chapter 3 of the present thesis, the author adopts Ind et. al's definition (2013) of co-creation as "an active, dynamic, and social process based on interactions and relationships between firms and external stakeholders initiated by the firms and oriented toward generation of new products" (Markovic & Bagherzadeh, 2018, pp. 173).

Overall, co-creation is based on the concept that users' presence is essential in the process of innovation as they provide insights into what is valuable to them. This is collaborative work in which firms' R&D teams and users (as key external stakeholders) generate solutions together and take into account their different needs. The end goal of co-creation is to identify solutions that provide users with a better quality of life and firms with improved products and solutions (Bertini & Plumley, 2014).

Users are not passive recipients of innovations anymore but have the skills and expertise that enable them to undertake an active role in new product development processes from idea generation to implementation stage (Cova and Dalli, 2009; von Hippel, 2006; Mascarenhas et al., 2004; Payne et al., 2008; Prahalad & Ramaswamy, 2004).

Through interactions with external stakeholders, firms access valuable resources that are beyond their internal capabilities (Boselli et al. 2008; Ordanini & Pasini, 2008). According to the resource-based view (RBV), such external resources, combined with firms' internal resources, can lead to the generation of new and improved products (Ketchen et al., 2007; Markovic & Bagherzadeh, 2018). Therefore, firms must have the ability to recognize the value of new, external information and assimilate and incorporate this information into their development activities. This ability is connected with the concept of absorptive capacity (Cohen & Levinthal, 1990).

In the literature, most authors focus on co-creation practices relating to the early stages of the new product development process (Roser et al., 2013). However, in Chapter 3 of this thesis, we study co-creation in both early and later stages (pre-development and development stages vs. commercial deployment stage) of new product development processes.

2.1.2. Co-creation and Ethics

As co-creation is about mutual dependency and reciprocal exchange among co-creating parties, questions naturally arise about the ethical and moral imperatives and social consequences of using co-creation (Williams & Aitken, 2011). Firms should embed ethics in their business models, organizational strategy, and decision making and demonstrate ethical commitment when interacting with external stakeholders (Balmer, 2001; Carrigan & Attalla, 2001; Ind, 1997; Morsing, 2006; Rindell et al., 2011). This ethicality is of particular importance to those firms that recurrently involve external stakeholders in co-creation processes (Singh et al., 2012; Williams & Aitken, 2011).

Marketing ethics research has been defined as "the systematic study of how moral standards are applied to marketing decisions, behaviors and institutions" (Laczniak, 1993; Laczniak & Murphy, 2019, p. 401). Some authors make a distinction between ethics and morals, whilst others use these

terms as synonyms. Morals, according to Williams & Aitken (2011), is a set of underlying social norms that are concerned with notions of right and wrong, whilst ethics refers to the formalization of these fundamental principles into formalized rules or codes. We discuss ethics as statements regarding what firms should do to uphold the principles of morality (*ibid*).

Therefore, there is a need to investigate the ethical principles applicable to co-creation, such as: What reward systems are equitable and relevant? Who owns the intellectual property rights from co-created outputs?

Stanislawski's work (2011, 2022) provides the basis which marketers use to confront ethical issues in co-creation. According to Stanislawski (2011), six universal moral standards of the corporate code of ethics (Schwartz, 1998; 2002) are relevant in the co-creation process: trustworthiness, respect, responsibility, fairness, caring and citizenship. All stakeholders involved in the co-creation process should be treated equitably, respectfully and in compliance with human rights. Furthermore, it is also important that there are concerns about social and environmental implications (Schwartz, 1998, 2002; Stanislawski 2011, 2022). However, their work (2011, 2022) remains conceptual.

In Chapter 3 of this thesis, the authors investigate the challenges that arise during the co-creation process in the pharmaceutical and medical technology industries from both managerial and co-creator's perspectives. The findings build upon a framework which links co-creation with the universal moral standards described (UMS) (Schwartz, 1998; 2002).

Even though the phenomena of co-creation and user innovation overlap, there are differences between them (von Hippel 1988, 1994, 2006). User innovators are motivated intrinsically and innovate autonomously, without user-firm interactions.. Only subsequently do firms identify innovations of great value and commercialize them. On the other hand, co-creation is based on a firm-driven strategy which facilitates interaction with external stakeholders. Instead of screening the user base to detect any existing prototypes created or redesigned by users, with co-creation, the firm provides instruments and tools to actively involve users in a symbiotic process.

2.2. User Innovation

Previous research has shown that users not only have the ability to co-create products or solutions with firms (Lilien et al., 2002), but are also able to develop them on their own (Füller et al., 2007). Moreover, many commercially viable products are initially thought of by innovative users rather than by manufacturers (Piller et al., 2010).

The discussion on user innovation began in the 1970s when von Hippel demonstrated the central role played by users as innovators. In his study (1976), he investigated the role users played in the scientific instrument innovation process and found that approximately 80% of 111 innovations were invented, prototyped, and tested by users.

Quantitative studies on user innovation have been conducted documenting that users develop many novel products which are commercialized in a range of fields (Baldwin & von Hippel, 2011). For instance, user innovation has been studied in various areas such as printed circuit CAD software (Franke & von Hippel, 2003a; Lakhani & von Hippel, 2003), the construction industry (Herstatt & von Hippel, 1992), scientific instruments (Riggs & von Hippel, 1994), sporting equipment (Baldwin et al., 2006; Franke et al., 2006; Lüthje et al., 2005; Tietze et al., 2015), banking services (Oliveira & von Hippel, 2011), process equipment (de Jong & von Hippel, 2009; von Hippel & Tyre, 1995) and procedures' innovation (Habicht et al., 2013). Some scholars have conducted large-scale studies by using, for example, surveys (Bogers, 2009; de Jong & von Hippel, 2009; Lhuillery & Bogers, 2006) or patent data (Chatterji et al., 2008). However, so far, most research exploring user innovation has been based on case studies or other small-sample studies. This is in part because user innovations are often minor, especially when they are derived from learning-by-doing activities, making them more difficult to capture empirically (Bogers et al., 2010; von Hippel & Tyre, 1995).

After the recognition that users can be important sources of innovation, von Hippel (1978) came up with what he called the “customer-active paradigm” in which users develop new product ideas and take the initiative to transfer them to producers (de Jong & von Hippel, 2009). Firms can facilitate user innovation by providing “toolkits” for innovation (von Hippel & Katz, 2002) and by providing a platform for collaborative innovation, for instance, by hosting user innovative communities (Jeppesen & Frederiksen, 2006). The evolution of technology has also further facilitated the user innovation process (Piller & Walcher, 2006; Sawhney et al., 2005).

Even if manufacturers generally try to fragment a specified market with a high heterogeneity based on users' needs, they cannot come up with individual products for everyone (Lüthje & Herstatt, 2004). In cases where users need products not offered commercially, there are two possible scenarios: users' needs remain unmet or users create products or modify existing ones themselves according to their own and their community's needs (Franke & von Hippel, 2003b). Thus, the heterogeneity of users' unmet needs is a major driver of user innovation.

From that perspective, user innovation complements producer innovation in two ways. Firms may develop products that many people will want, capturing a large share of the surplus that these innovations create; or users may develop innovations serving their own and their close community's unmet needs, thereby creating a high consumer surplus for themselves. They use their unique “need” knowledge and expertise to create low-cost innovative solutions tailored to meet their unique needs (Franke & Shah, 2003; Lakhani & von Hippel, 2003; Slaughter, 1993). Moreover, users' expertise and experience in using products determines their ability to innovate, lowering innovation-related costs and increasing the likelihood of the innovation being successful (Lüthje, 2004; Bogers et al., 2010). User innovators' unique experiences can also provide firms with more creative ideas for products that even expert developers might have not thought of (Kristensson et al., 2004). Through user innovations, firms gain information about emerging market needs that would be difficult to obtain otherwise (Henkel & Hippel, 2004). Firms can then further develop users' work by turning valuable user innovations into robust products; they can further benefit from user innovation by adopting newly-developed user products that have been

tested for free. In this way, user innovation increases the efficiency of the innovation process (Bogers et al., 2010). That is why users, producers, and society are best served when both user and producer innovation paradigms are used simultaneously (Gambardella et al., 2017). The benefits for society as a whole can then be seen to be optimal when user and producer innovators focus on what they are best at (von Hippel, 2016).

Users develop different innovations as they expect to benefit from using the innovations themselves whilst drawing on a different knowledge base and expertise. There are, however, disparities between users' and producers' knowledge. Two types of knowledge are required for successful innovation: information about the existing problems ("need knowledge") and information about how to solve problems ("solution knowledge") (Schweisfurth & Herstatt, 2016; von Hippel, 1998). Most end users have "need knowledge" but lack "solution knowledge", while producers have "solution knowledge" but need to absorb external "need knowledge" if they want to better understand their users' needs (Block et al., 2016; von Hippel & Katz, 2002). Therefore, users are more likely than producers to innovate if the knowledge of user needs is "sticky", i.e. costly and difficult to transfer (von Hippel, 1994). More specifically, information stickiness is defined as "the incremental expenditure required to transfer that unit of information to a specified locus in a form usable by a given information seeker" (von Hippel, 1994, p. 430). The "stickiness" of information depends on the nature of the knowledge that needs to be transferred and the absorptive capacities of the firms (Cohen & Levinthal, 1990). User innovators are individuals who are living with the problem, and their specific knowledge and experience about this problem ("need knowledge") are key for successful innovation.

2.2.1. Factors Influencing Users' Intention to Innovate

Various factors facilitate the user innovation process such as users' expected benefits and their knowledge and expertise. Users' incentives for innovation differ from those of producers; for example, they are more likely to innovate if their expectations of innovation-related benefits are high (Riggs and von Hippel, 1994). There are also other kinds of motivation such as intrinsic benefits and career prospects (Bogers et al., 2010; Lakhani & von Hippel, 2003; Lerner & Tirole, 2002; Lüthje, 2004; Lüthje et al., 2005; Shah, 2006); users might even enjoy the innovation process for its own sake (intrinsic motivation) (Bogers et al., 2010; Lakhani & von Hippel, 2003; Shah & Tripsas, 2007).

It has been found that innovative users are often "lead users" (von Hippel, 1986, 1988, 2006). Lead user theory (von Hippel, 1986) posits that lead users might be used as a source of innovative and commercially attractive products or services (Franke et al., 2006; von Hippel, 2006). von Hippel defines lead users as individuals with two key characteristics: they face users' needs long before the majority of the market, and they expect to acquire high benefits from using these products (ibid). These two lead-user characteristics, known as: a) being ahead of trend (AOT) and b) expecting high benefits (HBE), are two independent dimensions of the lead-userness that are assessed separately in the literature (Franke et al., 2006).

Furthermore, several authors talk about lead users having made significant contributions to highly innovative and commercially attractive products (Bogers et al., 2010; Franke et al., 2006; Herstatt & von Hippel, 1992; Hiennerth & Lettl, 2011, 2017). Lilien et al. (2002) have demonstrated that lead users are able to develop novel solutions that are proven to be highly successful in the market. Therefore, integrating lead users into firms' R&D activities is a meaningful way to integrate sticky "need knowledge" which is located outside the firm's boundaries (Göldner, 2021; von Hippel, 1986).

In research, lead userhood is recognized as one of the major drivers of user innovation. However, a major challenge, according to current user innovation literature, has been to identify these lead users (Franke & Shah, 2003; Lilien et al., 2002; Lüthje and Herstatt, 2004; Lüthje et al., 2005; Morrison et al., 2000; Olson & Bakke, 2001; von Hippel, 1988).

Thus, to investigate which users are more likely to innovate, we include the construct of being ahead of trend (AOT) in our study as one of the factors that could potentially increase users' motivation to innovate.

User innovators typically focus on solving problems for themselves and their immediate environment (von Hippel, 2006). The main driving force behind user innovation is not monetary gain but a desire to help themselves and others who face similar challenges. Helping others in a community serves as a powerful motivator for user innovators, reflecting a social rather than a monetary incentive (Franke and Shah, 2003).

Community matters, not only in providing resources for innovation development, but in influencing the innovation process by which these resources are shared (Franke & Shah, 2003). Franke and Shah (2003) also highlight the benefits for user innovators of being part of a community, as they can receive valuable feedback and assistance from other community members. This support is often given freely, as user innovators willingly share innovation-related information within their community. Ultimately, community support positively influences user innovation outcomes (Hadjimanolis, 2000), leading to a form of social consciousness that arises from the conscious awareness of actively participating in an interconnected community with others. This sense of belonging to an innovative community enhances user engagement in innovation activities.

Consequently, our study explores the concept of social consciousness to investigate the impact of socially conscious consumer behavior on intention to innovate.

2.2.2. Patient Innovation

The concept of patient innovation follows general patterns of user innovation, involving patients and their caregivers who are end users of healthcare products and services (von Hippel, 2007). Patient innovators develop new products or solutions or modify existing ones with the intention of using them to better cope with their health conditions (Shcherbatiuk, 2012). These innovations

can vary from simple tools to help with everyday routines to highly sophisticated solutions (Habicht et al., 2013; Oliveira et al., 2015; Shcherbatiuk, 2012).

There is growing evidence that supports the benefit of a patient-centered approach to innovation in healthcare (Porter & Lee, 2013) and presupposes a system of healthcare designed around patients' specific needs (Chaudhuri et al., 2022). In the past, the relationship between patients and the healthcare industry was known to have significant information asymmetry. The healthcare industry perceived patients as passive recipients of healthcare products and services (Halabi & Richard, 2020). Since early 2000s, however, the patients' role in healthcare has changed from that of passive to knowledgeable end users of healthcare products and services (Anderson & Funnell, 2005; Bate & Robert, 2006; Berry & Bendapudi, 2007; Bitner & Brown, 2008; DeMonaco et al., 2020; Longtin et al., 2010; Nordgren, 2008; Oliveira et al., 2015; Pols, 2014). A greater change in this asymmetry has been noted in recent years with patients becoming more actively involved (Budych et al., 2012; Camerini et al., 2012; Hartzband & Groopman, 2010). In addition, healthcare experts are increasingly accepting the importance of patients' expertise, thereby encouraging patient collaboration (Bessant et al., 2012). Patients' own perceptions have also changed accordingly, as they began to perceive themselves as value creating actors, rather than simply patients in the traditional sense (Nordgren 2008; 2009).

There are several factors that facilitate patient participation in healthcare innovation. The world's population is getting older. Chronic diseases have taken over as the main cause of death (Suzman et al., 2015; World Health Organization, 2021). Chronic diseases are, in turn, associated with a decreased quality of life. As a consequence, patients are acting proactively and becoming experts in their own health conditions (Göldner, 2021; Hartzband & Groopman, 2010). Furthermore, digitalization has become increasingly accessible. The spread of the Internet (with its endless amount of medical information available online) and the fact that patients have easy access to more and more information and knowledge about their diseases, has led to greater patient empowerment (Orizio et al., 2010). Patients now have a considerable amount of knowledge about their healthcare conditions and many of them are well equipped to adapt and innovate medicinal solutions that could make their own and their community's lives better.

Another reason for an increase in patient innovation is the high cost of medical treatment, which creates further incentives for chronic disease patients to find innovative ways to meet demand (Göldner, 2021). Unmet medical needs combined with free access to medical information has served to accelerate patient innovation. However, the biggest incentive for patients to innovate and to share their innovations is that they generally expect to benefit from using the self-developed solutions themselves (Habicht et al., 2013). This incentive is often aligned with the outcomes as they are seeking to increase their quality of life and are prepared to invest in what they need to do so.

There is growing evidence that patients and their caregivers (as the end users of healthcare products and services) can be valuable sources of innovation. Thune and Mina in their review (2016) conclude that the role of the patient is now perceived as crucial in medical innovation. Patients are highly intrinsically motivated and have complementary knowledge to that of healthcare professionals about certain aspects of their diseases (Göldner, 2021). Therefore, they

can be valuable in the NPD process (Elberse et al., 2011; Göldner, 2021; Wilson, 1999). However, the topic of patient innovation has only recently gained popularity in research (DeMonaco et al., 2020; Habicht et al., 2013; Oliveira et al., 2015).

In contrast, an increasing number of non-profit initiatives have emerged actively supporting patients' innovation ability. Among these are patient communities, online platforms where patients offer mutual support, exchange knowledge, and share experiences on effectively managing and coping with illnesses (Frydman, 2009). These communities not only enable patients to share their personal experiences but also facilitate collaboration in the innovation process. Furthermore, it is common for patient innovators to share their innovations freely within these communities (Zejnilović et al., 2016).

For instance, during the COVID-19 pandemic, patients developed various innovative solutions to help chronic disease patients better manage their disease. The pandemic impacted healthcare systems and required urgent mobilization of all available resources. Healthcare systems were struggling to cope with the increased demand and costs. In addition to increasing morbidity and mortality, leading to high rates of community spread and various attempts to mitigate the effects of the disease, the pandemic also raised concerns about safely accessing healthcare (Czeisler et al., 2020) and reduced the ability to control chronic diseases. Thus, the pandemic crisis significantly increased the burden of treatment in patients living with chronic disease. This increased burden led to a significant increase in the number of patient innovations (<https://patient-innovation.com>). Therefore, we have decided to include the burden of treatment as a factor that could impact on the innovation activities of patient innovators.

2.3. User Innovation Diffusion

The current literature on co-creation distinguishes between different types of innovation: firstly, there are producers who develop innovations in their paid time and sell them for profit. Secondly, there are user innovators (individual users or user firms) who develop innovations for their own use, but do not reveal them freely (Adams et al., 2013). The third group consists of individual users who develop innovations for their own use during their paid work time (Oliveira & von Hippel, 2011), and the fourth group covers individual users who develop innovations in their unpaid discretionary time and benefit from the innovation themselves and reveal them to others freely. Finally, there are individual users who develop innovations in their unpaid discretionary time and reveal the innovations freely, but do not benefit from the innovation themselves (von Hippel, 2006).

Free innovation is defined as a functionally novel product, service, or process developed by users at private cost during their unpaid discretionary time that is not protected by its developers and could potentially be acquirable by anyone without payment, i.e. for free (von Hippel, 2017). User innovators are more likely than producers to freely reveal their innovations. When user innovations are freely revealed, positive welfare effects appear.

2.3.1. Factors Influencing Users' Willingness to Share Innovations

Research shows that even though many users innovate, very few of these innovations are shared (de Jong et al., 2015). However, to achieve social welfare benefits from user innovations, innovations of general value have to be diffused to other beneficiaries (de Jong et al., 2015). Prior research has revealed that users mainly share their innovations with people they already know within their communities or ask their communities to refer the innovations to others (Baldwin et al., 2006; Franke & Shah, 2003). They are mainly motivated by the enjoyment derived during the innovation process and by the feeling that their innovations will benefit the community, which is reflective of social processes (Raasch & von Hippel, 2013). Therefore, user communities are not only an important factor that fosters innovation, but they also positively affect sharing these innovations. By studying user innovation in the mountain biking community, Lüthje et al. (2005) introduced the term “innovation-related resources” consisting of: user innovator’s technical expertise (TE) and community-based resources (CBR). Technical expertise is users’ ability to actually make modifications or changes to existing equipment, while community-based resources (CBR) refers to the potential contacts which users can use at low or no cost when facing a problem with existing equipment (Franke et al., 2006, p. 307). Lüthje et al. (2005) empirically show that users with better technical knowledge and expertise are more prone to innovate. Community-based resources have also been shown to increase users’ innovation potential and their innovation tendency (Franke et al., 2006).

Although both technical expertise and community-based resources were studied to find out how they affected likelihood to innovate, to our knowledge, they have not yet been investigated to find out how they affect user innovators’ willingness to share innovations.

According to Svensson and Hartmann (2018), barriers in user innovation diffusion hinder user innovators’ ability to generate social welfare. Innovation barriers are defined as factors inhibiting user innovation-related activities over a certain period of time (Raasch et al., 2008). Braun and Herstatt (2007; 2008; 2009) were the first researchers to classify user innovation barriers into economical, technological, social, and legal barriers. They argue that legal barriers (LB) negatively affect user innovation as users have to overcome barriers such as warranties or guarantee rights on products and components or deal with problems related to patents, copyrights or secure codes (Braun & Herstatt, 2007, 2008; Morrison et al., 2004; Pieper & Herstatt, 2018).

However, user innovators themselves rarely decide to protect or restrict access to their innovations (Raasch et al., 2008). Instead, more than 90% of users make their innovative designs available to everyone for free (Demonaco et al., 2020), so the role that intellectual property plays merits further investigation (Harhoff et al., 2003; von Hippel & von Krogh, 2003).

As the evidence of the impact of legal barriers on users’ willingness to share innovations is scant, we employed the construct of legal barriers to study their effect on users’ willingness to share innovations.

2.4. References

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3. EXPLORING AND COPING WITH THE ETHICAL CHALLENGES OF CO-CREATION IN THE PHARMACEUTICAL AND MEDICAL TECHNOLOGY INDUSTRIES: PATIENT AND MANAGER PERSPECTIVES

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3.1. Abstract

Enhanced firm-stakeholder interconnectivity has made the environments they operate in more transparent, giving rise to ethical issues that are not always considered. Ethicality should be a concern for firms that recurrently involve external stakeholders in co-creation, due to the mutual dependency these interactions and relationships imply. In the pharmaceutical and medical technology industries, firms have been slower to adopt co-creation, mainly due to legal and compliance regulations. Considering the inherited vulnerability of patients as key stakeholders, these industries are a relevant context in which to study the ethical challenges throughout the co-creation process. Therefore, the aim of the research was to empirically investigate ethical challenges arising throughout the co-creation process and find ways to overcome them. The data were collected via 42 semi-structured interviews with chronic disease patients and managers working within patient co-creation and analysed using NVivo 12 software. Based on the results of the analysis, we developed a framework that identifies and characterises the different ethical challenges throughout the co-creation process. Using Schwarz's universal moral standards for corporate codes of ethics as a framework, we identified additional moral standards (equality, inclusivity and diversity) that emerged as relevant for the process. Exploring both managerial and patients' perspectives, we revealed discrepancies in the expectations between managers and patients. Furthermore, we showed that external stakeholders' expectations are influenced by the stage in which they are involved in the co-creation. The findings are followed by recommendations to overcome such challenges.

Keywords: co-creation, ethics, universal moral standards, stakeholders, innovation, healthcare

3.2. Introduction

In an ever more competitive business environment, organisations are increasingly embracing co-creation to boost their competitive advantage (e.g., Iglesias et al., 2020; Nadeem et al., 2021; Wang et al., 2020). Co-creation can be defined as “an active, dynamic, and social process based on interactions and relationships between firms and external stakeholders, oriented toward the generation of new products” (Markovic & Bagherzadeh, 2018, p. 173). Research has shown that, through these interactions, firms can gain access to valuable external resources that they might not be able to develop internally (Boselli et al. 2008; Ordanini & Pasini, 2008). According to the resource-based view extended to capture firm relationships with external stakeholders (e.g., Eisenhardt & Schoonhoven, 1996; Kull, Mena, & Korschum, 2016), access to such external resources enables firms to combine them with their own resources, potentially leading to the generation of relevant, new or significantly improved products (Ketchen et al., 2007; Markovic & Bagherzadeh, 2018). This may result in increased customer trust and loyalty (Kirca et al., 2005), and decreased product development duration and costs (Helfat & Peteraf, 2003), and ultimately to a better innovation performance (e.g., Faems et al., 2005; Iglesias et al., 2020; Ferreras-Méndez et al., 2015).

Despite these benefits, co-creation can also generate some ethical challenges, due to its highly interactive, dynamic, and collaborative nature (Iglesias et al., 2020; Markovic et al., 2022; Williams & Aitken, 2011). When researching stakeholder–firm relationships, several scholars argue that ethics and moral standards ought to be at the heart of any firm’s behaviour (Abela & Murphy, 2008; Stanislawski, 2011; 2022; Williams & Aitken, 2011). There is a body of research linking firm-stakeholder co-creation and ethical concerns ranging from data privacy to environmental issues (e.g., Iglesias et al., 2019; Markovic et al. 2018; Sierra et al. 2017; Singh et al., 2012; Stanislawski, 2011; Schöler, et al. 2020; von Wallpach et al. 2018; Williams & Aitken, 2011). In spite of this, little research has been carried out into the ethical and moral issues that arise throughout the co-creation process (Stanislawski, 2011; 2022; Williams & Aitken, 2011). Such research includes works by Stanislawski (2011; 2022), who investigates the ethics of co-creation by applying Schwartz’s “universal moral standards for corporate codes of ethics” (Schwartz, 1998, 2002, 2005), but her work remains purely conceptual. To the best of our knowledge, there are virtually no empirical papers examining this link.

Based on the above-discussed research gap, our research objective is to identify and empirically investigate the ethical challenges of co-creation, and to find ways to overcome them. Our fieldwork is conducted in the pharmaceutical and medical technology industries. We have chosen these industries as extreme cases because co-creating in such highly regulated contexts can be especially challenging. These industries have been slower in adopting co-creation, largely because legal and compliance teams often advise R&D teams to maintain a distance with patients as external stakeholders (Panchal et al., 2012). Big pharmaceutical and medical technology companies are still predominantly using traditional market research methods, rather than co-creation with patients, and are still not realising the full potential of co-creation. Moreover, considering the inherent vulnerability of patients as key stakeholders, the pharmaceutical and

medical technology industries represent a relevant context in which to study the ethical principles involved in co-creation.

The data were collected via 42 interviews with patients and managers and analysed using the NVivo 12 software. Based on the results of the data analysis, we developed a framework that identifies and characterises the different ethical challenges, from both managerial and patient perspectives.

There are a few contributions from this study to existing literature. Firstly, we have empirically identified the ethical challenges that exist in the process of co-creation studying the context of the pharmaceutical and medical technology industries. Schwarz's universal moral standards for a corporate code of ethics (2002) emerged as the most suitable framework for analysis after the data coding process. Additional moral standards to the framework (equality, inclusivity, and diversity) relevant for the co-creation process also became apparent from our data. Secondly, exploring both managerial and patients' perspectives, we revealed discrepancies between managers and patients' expectations related to the co-creation process. Finally, we showed that external stakeholders' expectations are influenced by the stage from which they are involved in the co-creation. These findings are followed by recommendations to overcome such challenges by providing best practices for managers.

The remainder of the paper is structured as follows. Firstly, we review the literature on co-creation and universal moral standards. Then, we present qualitative data collection methods and how we have analysed the data. Thereafter, we present the findings that have emerged from our data analysis and conclude the paper with a discussion section where we present our theoretical contributions, managerial implications, and future avenues of research.

3.3. Theoretical Background

3.3.1. The Practice of Co-creation

Co-creation is an interactive process where firms can acquire new ideas, insights, and knowledge from organisational outsiders, which are then used for the development of new or significantly improved products (Cassiman & Veugelers, 2002; Frow et al., 2015, 2016; Markovic & Bagherzadeh, 2018). In line with the resource-based view (Eisenhardt & Schoonhoven, 1996), the increasing ability to draw on a wide array of external resources provides firms with access to a plethora of ideas, insights, and knowledge that they are unable to develop internally (Markovic & Bagherzadeh, 2018). However, in order to value, assimilate, and apply such external ideas, insights and knowledge, firms need to develop absorptive capacity (Cohen & Levinthal, 1990). Firms endowed with high levels of absorptive capacity are likely to be able to extract greater benefits from similar stocks of external resources, and therefore may outperform rivals in co-creation (Tsai, 2001).

Absorptive capacity has three key components: recognition capacity, assimilation capacity and exploitation capacity (Cohen & Levinthal, 1990). The firm's recognition capacity as an ability to identify the specific external resources needed for developing relevant innovations has a vital role in prompting the success of co-creation (Fosfuri & Tribó, 2008; Markovic and Bagherzadeh, 2018; Todorova & Durisin, 2007; Zahra & George, 2002; Zollo & Winter, 2002). Assimilation capacity consists of being able to analyse, process and use the identified external resources internally. Finally, exploitation capacity has to do with determining how to apply and combine the assimilated external resources with the internal ones (Faems et al., 2008; Cohen & Levinthal, 1990) to effectively develop relevant new or significantly improved products (Markovic & Bagherzadeh, 2018).

The traditional resource-based view literature focuses mainly on the firms' perspective. It is *the firms* that recognize, assimilate, and exploit external resources. While the firms are engaging with external stakeholders for pursuing their (*the firms'*) innovation needs, there is little consideration of the predilection and external stakeholders' desire to participate in the co-creation process. However, bringing a diverse group of stakeholders together may lead to divergent goals and interests, communication difficulties, distrust, or even conflict over value appropriation (Waligo et al., 2014). Therefore, co-creation entails socially complex interactions that can create different challenges for firms, raising the question of whether external stakeholders are involved in the process in a meaningful way (Iglesias et al., 2020; Markovic et al., 2022; Williams & Aitken, 2011).

To realise the full potential of co-creation, firms and the involved stakeholders must be equal partners in the co-creation process. Therefore, it is important to navigate the differences that might arise between the stakeholders, engage with each one of them in a meaningful way and combine competencies in co-creating products (Watson et al., 2018).

Overall, despite the significance of ethics and moral standards in co-creation, there remains scant research linking co-creation with ethics and moral standards. To provide a theoretical underpinning, we aim to establish a connection between co-creation, ethics and the universal moral standards proposed by Schwartz (1998, 2002, 2005).

3.3.2. The Link between Co-creation, Ethics, and the Universal Moral Standards

Co-creation requires both firms and external stakeholders to make necessary adjustments and recognize that interactions between the two parties must be built on four key pillars: dialog, access, risk-benefits, and transparency (DART) (Prahalad & Ramaswamy, 2004). *Dialogue* comprises deep engagement, interactivity, understanding and willingness of common agreement by both parties (Albinsson et al., 2016). However, dialog between the stakeholders is difficult if they do not have the same access and transparency to information. *Access* to information should be given at all stages of the process, starting from the design to the commercial deployment stage (Prahalad & Ramaswamy, 2004). With the right *access* and *transparency* at all stages of the process, stakeholders will feel more empowered and will prove better co-creators (Nagarethenam

et al., 2018). More importantly, access and transparency during the process lead to a better assessment of the *risk-benefits* of courses of actions and decisions (Prahalad & Ramaswamy, 2004). Otherwise, barriers to the efficient utilisation of external resources and capabilities during the co-creation might be created, which would hinder firms from achieving their full co-creation capacity.

Fassin (2000) identifies a number of ethical issues, relating to for example intellectual property, confidentiality of information and the negotiation process, and connects these ethical issues to different stages of the new product development process.

The work of Schwartz (1998; 2002) provides a ground from which firms can proactively confront the ethical issues of co-creation via six universal moral standards (Stanislawski, 2011; 2022). Firms ought to make sure that their co-creation processes are trustworthy, respectful, responsible, fair, caring, and that they promote citizenship. Below, we characterise each of the six universal moral standards and relate them to the co-creation practice.

Trustworthiness

The moral standard of trustworthiness is related to transparency, honesty, integrity, reliability, and loyalty (Schwartz, 2002). Trustworthiness has been identified as one of the most salient factors to successful interactions with stakeholders (Delgado-Ballester et al., 2003; Morgan & Hunt, 1994; Stanislawski, 2011; 2022) on which co-creation initiatives are based (Markovic & Bagherzadeh, 2018). The significance of trustworthiness derives from the highly interactive, dynamic, and collaborative nature of the co-creation process.

One important element of trustworthiness is the moral obligation of safeguarding confidential information (Schwartz, 2002, p. 30). Confidentiality applies to both co-creating parties: firms are concerned that co-creation “may lead to a leaking of valuable proprietary information”, and external stakeholders are concerned about the potential misuse of confidential information about them that the firms have access to (Stanislawski, 2011, p. 118).

Respect

Respect is considered as one of the most fundamental principles in ethics (Abela & Murphy, 2008). It is important for firms to adhere to the standard of respect when co-creating with stakeholders, act in accordance with human dignity and autonomy and respect stakeholders’ privacy. The aspects of human dignity and autonomy are at the very foundation of human rights (Bowie, 1999; 2017). The moral standard of respect relates also to the rights to privacy, defined by Goodwin (1991) as control over disclosure of information as well as to the environment in which interactions take place.

Furthermore, some authors have expressed concerns about adhering to the moral standard of respect from a labour rights perspective; whether all stakeholders’ rights would be met within co-creation (Banks & Humphreys, 2008; Ritzer & Jurgenson, 2010; Söderberg, 2007). For instance, firms may take advantage of co-creating stakeholders by exploiting their work as free labour or depriving them of their privacy rights (Herman et al., 2006; Stanislawski, 2011; 2022).

Fairness

The moral standard of fairness includes “notions of impartiality, equity and process” and implies not taking advantage of others in the co-creation processes (Schwartz, 2002, p. 29-30). It is achieved when both co-creating parties receive roughly proportional outcomes relative to their inputs (Ingram et al., 2005).

The moral standard of fairness calls for a balance of needs and interests of all stakeholders involved in co-creation (Iglesias & Ind, 2020). Co-creators should be perceived as equal parties with the employees (Banks & Humphreys, 2008). However, although external co-creating stakeholders invest their time, resources and efforts in the co-creation, firms often set terms to commercialise and distribute stakeholder-generated contents without providing them with adequate compensation (Hoyer et al., 2010).

Caring

The moral standard of caring is defined as avoiding causing unnecessary harm (Schwartz, 1998; 2002; Stanislawski, 2011; 2022). All stakeholders involved in the co-creation should be protected from abuse (Abela & Murphy, 2008). This holds particularly true for the vulnerable, such as children, the elderly, patients, or people stricken by poverty (Abela & Murphy, 2008; Miyazaki et al., 2001; Williams & Murphy, 1990).

The moral standard of caring is especially relevant in a health care context, where more vulnerable stakeholders such as patients are engaged in the co-creation process (Brenkert, 1998). Researchers studying patient involvement rank exploitation of vulnerable persons as one of the most pressing ethical issues (Bélisle-Pipon et al., 2018). In all interactions with patients, the human element of caring is needed (Varkey, 2021). Sometimes firms may even consider going beyond the regular user protection when engaging patients in co-creation. For instance, some European companies apply the codes of conduct for the pharmaceutical industry such as EFPIA (Code of practice on relationships between pharma and patient organisations, 2021) and their national guidelines (e.g., for Germany: FSA, AKG and for the UK the ABPI Code). Guidance from EUPATI (Warner et al., 2018), EMA (Engagement Framework: EMA and patients, consumers and their organisations, 2021) and PARADIGM ([PARADIGM](#), 2019) are also considered relevant.

Citizenship

Citizenship has to do with obeying laws and protecting the environment, and the term is sometimes used interchangeably with corporate ethics, sustainability, corporate social responsibility, and corporate conscientiousness (Valor, 2005; Stanislawski, 2011; 2022; Schwartz, 1998; 2002).

The standard of citizenship also relates to intellectual property (IP) rights on co-created products (Grimes, 2006; Herman et al., 2006; O’Hern & Rindfleisch, 2009; Stanislawski, 2011; 2022). IP rights are embodied in copyrights, trademarks, patents, trade secrets, and publicity rights that enable industries to exploit the value of their intangible assets in an increasingly global marketplace (Coombe et al., 2006; Litman, 2001; Herman et al., 2006). The controversial issue of

IP lies at the centre of co-creation, and copyright laws, in terms of both application and enforcement, should be considered (Grimes, 2006). Yet not all innovators wish to retain ownership over IP; some choose to freely reveal their ideas to others (Alexy, 2009; von Hippel, 2005).

Responsibility

The moral standard of responsibility includes “notions of accountability”, being answerable to one's behaviour (Mascarenhas, 1995; Schwartz, 2002; Stanislawski, 2011; 2022). “Morally responsible actors enter into actions aware of their risk and potential, willing to be blamed if they are performed faultily, and rightfully claiming credit for their probity” (Mascarenhas, 1995, p. 45).

Firm-stakeholder co-creation involves mutual obligation, and external stakeholders should understand that they have a responsibility for the risks they consciously accept. However, this does not take away responsibility from the firm (Prahalad & Ramaswamy, 2004). For instance, in cases of certain co-created products failing, it is generally the firms' and not the co-creators' responsibility. Nevertheless, if co-creating stakeholders engage themselves in ethically questionable co-creation activities, they may be held morally and even legally responsible (Stanislawski, 2011; 2022).

3.4. Methodology

3.4.1. Research Context: The Pharmaceutical and Medical Technology Industries

The pharmaceutical and medical technology industries are highly regulated, with many rules enforced by the governments to protect the health and well-being of the public (Handoo et al., 2012; Sheth, 2019). Traditionally, these industries were known for relying on closed innovation processes and imposing strict regulations on interactions with certain stakeholders (e.g., patients, caregivers) (Kazadi et al., 2016). Bureaucratic regulatory practices may restrict knowledge about new products being disseminated (Frow et al., 2016).

Therefore, pharmaceutical and medical technology industries have been slower in adopting co-creation, largely because legal and compliance teams often advise R&D teams to maintain a distance from patients (Panchal et al., 2012). In the past, industry, academia, healthcare professionals, regulators, and patient organisations have largely worked in silos. In practice, many decisions about medical research and service were made without meaningful patient involvement (Working together with patients, 2021). This has led to inefficiencies and low value in process and outcomes (Working together with patients, 2021). Traditional innovation models failed to create new products in an affordable and/ or profitable way (Barlow, 2016). More and more research has shown that patients and society need more effective, needs-based, and targeted medicine development (Hoos et. al, 2015). Amid rising health care costs and the increasing

demand for more personalised care, the pharmaceutical and medical technology industries have started to recognise the benefits of shifting away from the provider-centric model of care toward one that is more responsive to the needs of one of the key stakeholders - the patients (Janamian et al., 2016).

Effective collaboration between patients and the pharmaceutical and medical technology industries has the potential to co-create better health outcomes (Segev Shani, 2021). However, real patient empowerment necessitates a shift from a 'patients as testers' mentality to patients as equal co-creators, which can only be achieved by involving them in every step of the new product development process (Jacob et al., 2022).

Over the last decade, there has been a change in the regulations worldwide allowing the pharmaceutical and medical technology companies to engage patients in a more meaningful way. Regulatory bodies such as the European Medicines Agency (EMA) and the United States Food and Drug Administration (FDA) have started to consider co-creation with patients as one of their priorities (EMA News Release, 2014, EMA. Incorporating patients' views, 2014; Center for Drug Evaluation and Research, 2021). Many companies have developed new ways to incorporate patient insights and co-create with patients (Working together with patients, 2021). Nowadays, patient advocacy groups and associations are becoming more involved, not just in the clinical trial process, but also in co-creating new products (Pushparajah, 2017; Warner et al., 2018). For instance, AstraZeneca, Pfizer, GlaxoSmithKline, Novo Nordisk, and Amgen all have advisory boards that involve patient representatives (Boutin et al., 2017).

Even though there is increasing evidence for patient involvement in the co-creation process, there are many challenges that constrain such involvement. These challenges include traditional compliance with regulatory codes, internal bureaucratic processes, a lack of understanding of the advantages and disadvantages of collaborating with external stakeholders, unwillingness to share insights, and a lack of transparency or openness (Smith et. al, 2015). The pharmaceutical and medical technology industries are very risk averse, especially if compared to the voluntary sector, service providers, or big tech companies. Furthermore, considering the inherited vulnerability of patients as the key stakeholders, the pharmaceutical and medical technology industries represent an extreme case to study the ethical principles involved in co-creation.

However, co-creation in the pharmaceutical and medical technology industries share the same challenges as other industries, for instance, the need for transparency and clarity on compensation, privacy, misunderstandings between R&D teams and external stakeholders, and dependency on external stakeholders' views (Enkel et al., 2005; Schaarschmidt & Kilian, 2014; Smith et. al, 2015; Ulwick, 2002). Taken together, this makes pharmaceutical and medical technology a relevant context in which to study the ethical challenges of co-creation.

3.4.2. Data Collection and Sample

The data source consists of 42 semi-structured interviews with chronic disease patients² who have engaged in co-creation activities with pharmaceutical or medical technology companies and with managers that have been actively involved in co-creation initiatives in the biggest pharmaceutical or medical technology companies in the diabetes field worldwide. The patients and managers interviewed are based in 14 different countries. The study participants were chosen using a snowballing sampling technique. In snowball sampling (Noy, 2008), we accessed informants through contact information provided by other informants. The process was repeated: participants referred to others who we then contacted, and so on. Snowball sampling is arguably the most widely employed method of sampling in qualitative research in various fields across social sciences (Noy, 2008).

The patients interviewed were involved in recurrent interactions with the focal companies aimed at generating new or significantly improved products. The patients had been working with the industry on an ongoing basis. Many of them had also taken up various volunteer roles in patient organisations. The roles and the country of origin of the interviewed patients are presented in Table 2.

Whilst managers' roles varied, most of them had a middle to senior position and were involved in various tasks relating to patient co-creation. The companies these managers worked for were large multinationals operating worldwide. It is important to mention that many of the managers had been working with patients in more than one pharmaceutical or medical technology company.

The interviews were designed in a semi-structured way for two main reasons. Firstly, we wanted to ensure that the relevant concepts from prior literature on co-creation and moral standards were included in order to obtain empirical insights on them. Secondly, we aimed to provide respondents with enough freedom and flexibility to discuss their co-creation projects, and thereby allow theory to emerge (Eisenhardt & Graebner, 2007). The structure and the specific content of the semi-structured interview guide for patients and managers are presented in Appendix A.

²In this study we use European Federation of Pharmaceutical Industries and Association's definition of "Patients" as (EFPIA, 2019):

"Individual Patients" who are persons with personal experience of living with a disease. They may or may not have technical knowledge in R&D or regulatory processes, but their main role is to contribute with their subjective disease and treatment experience.

"Patient Advocates" are persons who have the insight and experience in supporting a larger population of patients living with a specific disease. They may or may not be affiliated with an organisation.

"Patient Experts", who, in addition to disease-specific expertise, have the technical knowledge in R&D and/or regulatory affairs through training or experience.

In addition, the principles can also be applied to:

"Patient Organisation Representatives" are persons who are mandated to represent and express the collective views of a patient organisation on a specific issue or disease area.

"Carers", who are persons supporting individual patients such as family members as well as paid or volunteer helpers.

Before embarking on the interviews, we conducted three pre-test interviews, two with patients and one with a manager. After revising the interview guides from their feedback, we conducted 42 interviews, which were used for the analysis.

The interviews were conducted in late 2020 and early 2021 and were online due to the COVID-19 pandemic. The interviews lasted between 40 minutes and 1 hour 45 minutes, yielding 342 pages of interview text. To ensure accuracy of the information, interviews were audio-recorded, transcribed verbatim, then proofed, and prepared for analysis. In accordance with Francis et al. (2010) and Mason (2010) the saturation criterion was taken into consideration. Saturation, in this case, was reached after conducting 42 interviews.

Each sample interviewee was assigned a code. P is used to represent patients and M is used to represent managers. The two digits represent the sequence of the sample interviewee. The letter B is used to indicate that the patients were involved in co-creation from the beginning of the co-creation process, while the letter L is used to indicate that the patients were involved in the later stages only.

Table 1. The current and prior positions of the interviewed managers

Code	Role	Prior role (if relevant to co-creation)
M01	Associate Patient Relations Manager at a multinational pharmaceutical company	
M02	Public Affairs Manager at a multinational pharmaceutical company	
M03	Chief Patient Officer at a multinational pharmaceutical company	Head of Patient Relations at a multinational pharmaceutical company
M04	International Trial Manager in Insulin and Devices at a pharmaceutical company	Patient Relations Intern at a multinational pharmaceutical company
M05	Medical Director at a multinational pharmaceutical company	Clinical, Regulatory, and Quality Director at a multinational pharmaceutical company; Regional Medical Head
M06	Senior Coordinator at a multinational pharmaceutical company	Patient Relations Intern at a multinational pharmaceutical company
M07	Professional Patient Insights at a multinational pharmaceutical company	Student Assistant Global Patient Relations at a multinational pharmaceutical company
M08	Associate Public Affairs Director, Global Public Affairs and Patient Relations at a multinational pharmaceutical company	
M09	Senior Lead – Patient Research and Alliance at a multinational pharmaceutical company	Associate Patient Relations Director at a multinational pharmaceutical company
M10	Director at a Medical Device Company	

Table 2. The country of origin of the interviewed patients

Code		Country
P01B	Patient Advocate (Diabetes and Obesity)	UK
P02L	Patient Advocate; Patient Organisation Representative (Diabetes and Obesity)	Canada
P03B	Patient Advocate (Diabetes)	US
P04B	Patient Advocate (Diabetes)	UK
P05B	Patient Advocate; Patient Organisation Representative (Diabetes)	US
P06B	Patient Advocate; Patient Organisation Representative (Diabetes)	Denmark
P07B	Patient Advocate (Diabetes) Healthcare Consultant	US
P08B	Patient Advocate; Patient Organisation Representative; Health Consultant (Diabetes)	Sweden
P09B	Patient Advocate (Diabetes)	UK
P10L	Patient Advocate (Diabetes); Healthcare Consultant	UK
P11B	Patient Advocate (Diabetes)	UK
P12L	Patient Advocate (Diabetes)	Serbia
P13B	Patient Advocate (Diabetes)	Austria
P14B	Patient Advocate; Patient Organisation Representative; Health Consultant (Diabetes)	UK
P15B	Patient Advocate; Patient Organisation Representative (Diabetes)	Portugal
P16L	Patient Organisation Representative (Diabetes)	Brazil
P17L	Patient Organisation Representative (Diabetes)	Brazil
P18L	Patient Advocate (Diabetes)	France
P19B	Patient Advocate; Patient Organisation Representative (Diabetes)	Australia

P20B	Patient Advocate (Diabetes)	UK
P21B	Patient Advocate (Diabetes); Healthcare Consultant	US
P22B	Patient Advocate; Patient Organisation Representative (Diabetes)	Germany
P23L	Patient Advocate (Diabetes)	UK
P24L	Patient Advocate (Diabetes)	Netherlands
P25B	Patient Advocate; Patient Organisation Representative (Diabetes)	US/France
P26B	Patient Advocate (Diabetes)	Germany
P27B	Patient Advocate (Diabetes)	US
P28L	Patient Advocate (Diabetes)	Germany
P29B	Patient Advocate; Patient Organisation Representative (Diabetes)	US
P30L	Patient Advocate; Patient Organisation Representative (Diabetes)	Brazil
P31L	Patient Advocate; Patient Organisation Representative (Diabetes)	Norway
P32L	Patient Advocate (Diabetes)	Germany

3.4.3. Data Analysis

The data analysis was conducted through an iterative and abductive process. While this approach follows the original analytical procedure of the Straussian version (Glaser & Strauss, 1967), the theory was developed from the abduction of existing theories to explain the relationships between emergent theoretical categories and articulate a coherent argument (Dick, 2007). We explored themes that were identified early in the interviewing process. This allowed us to explore the complex phenomenon of co-creation and the ethical challenges that arose during the process. Furthermore, it led to richer narratives and findings, which are key to understanding the complexities studied (Blaikie, 2018).

The researchers adopted Charmaz's (2006) coding technique, which goes through the steps of initial and focused coding. Initial coding entailed a close reading of the data with the goal of remaining open to all possible theoretical directions indicated by it. An initial list of codes was created and gradually refined during analysis. The initial phase involved naming each word, line,

or segment of data followed by a focused, selective phase that used the most significant or frequent initial codes to sort, synthesise, integrate, and organise large amounts of data (Hussain, 2015). While engaged in initial coding, researchers mined data for analytic ideas in order to pursue further data collection and analysis. Later, focused coding was used to pinpoint and develop the most salient categories in large batches of data. The themes (presented below) were compared with existing theory, which is something more akin to enable theorising (Dolbec et al, 2021). The literature was revisited only after the initial codes were identified for comparison purposes. The authors used the NVivo 12 software for coding of the data.

We classified the patients according to the stage they were involved in the co-creation process, i.e., from early stages (the predevelopment & development) vs. in the commercial deployment stage only. We used Bosch-Sijtsema and Bosch's (2015) model which includes three stages of new product development (NPD) process: predevelopment, development and commercial deployment.

Table 3. Examples of Codes

Quotes (Examples)	Code: Compensation
<p><i>"<u>Compensation</u> is very <u>rarely fair</u>...I am a consultant in my day job, I know the general rate of fees for these sorts of things. I know that lots of people aren't paid fairly for their time or <u>expertise</u> when it comes to some of these activities."</i></p> <p>(Patient involved from the from early stages of NPD process)</p>	<p>Unfair compensation</p> <p>Lower rates than HCP</p> <p>Underappreciated expertise</p> <p>Undervalued knowledge</p>
<p><i>"The <u>expertise</u> coming from those living with an illness, in theory, should be equal to that of other <u>expertise</u>. In the US, <u>healthcare professionals</u> make an inordinate amount of money in any use of their time, and it is extremely well compensated. You see, a person living with diabetes being compensated at a rate that's infinitesimally smaller than other <u>expertise</u> towards the project..."</i></p> <p>(Patient involved from the from early stages of NPD process)</p>	

3.5. Findings

This section presents the main themes that emerged from the data analysis. We start off by identifying the ethical challenges the patients faced during the NPD stages (predevelopment and development stages *vs.* commercial deployment stage). After that, the challenges we identify are presented in relation to the universal moral standards (Schwartz, 2002; Stanislawski, 2011; 2022).

3.5.1. Patients' Perspective

Compensation

Compensation was the most frequently discussed topic. Overall, the interviewed patients perceived the compensation they received for participating in co-creation with the industry as a challenge. Patient experts engaged in co-creation from early on and across the entire NPD process believe that their compensation levels were significantly lower than those of other stakeholders (i.e., health care professionals).

A patient involved in co-creation for many years with both medical technology and pharmaceutical industries in Europe and the United States perceived that most of the time the compensation was not adequate compared with the amount of work they put in. He emphasised that patients provide the industry with unique expertise that the industry would not be able to obtain otherwise. Therefore, the industry has to compensate the patients at an equal rate as all other stakeholders.

Most of the time, I would say, it's not fair. Because the expertise coming from those living with an illness, in theory should be equal to that of other expertise. Where I'm living today (in the United States), healthcare professionals are extremely well compensated. So, it's hard when you are part of an initiative where you see a person living with diabetes being compensated at a rate that's infinitesimally smaller than other expertise towards the project. (P25B)

Similarly, a patient from Australia argued that in comparison with healthcare professionals, their rate is much lower even for longer engagements. Sometimes, patient experts are asked to participate for exposure only.

Many people are asked for their contribution for exposure. You would never ask a healthcare professional to be involved for exposure. (P19B)

A type-1 diabetic, professional athlete and patient from the US explained that in-person participation requires participants to take time off their daily commitments and that the industry should at least compensate them to make up for the lost days of work.

It's hard whenever I do need to have an in-person meeting, because then I have to take time away from work and be away from family and friends. And if I'm not receiving compensation to make up for the lost days of work, then I'm having to take time off to participate in these projects. (P05B)

In contrast, a retiree from the UK represented a small group of interviewed patient experts that felt grateful to be involved in the co-creation process even on a voluntary basis. Their desire to

share unique experiences and help others with similar conditions is the most important driver, showing their intrinsic motivation. This would be closely related to the moral standard of citizenship (Schwartz, 2002; Stanislawski, 2011; 2022).

The honorarium is the cherry on top of the cake. The work that I do as a patient and as a patient advocate is on a voluntary basis. I'm in a comfortable position, I am retired, I'm not doing this as a job. (P01B)

Additionally, we observed that the compensation is not so crucial for patients who are only involved in the later stages of the NPD process (commercial deployment stage). In contrast, the patients involved from the beginning of the NPD process when concepts and ideas are discussed (pre-development and development stages) had higher expectations regarding compensation. This could be because they perceive that they had co-developed the product together with the companies.

Only in the projects where I was involved very early on – I was compensated. And otherwise, I've always been involved too late and not considered worth the compensation. (P22B)

The compensation rights challenge relates to the universal moral standards of **fairness**, specifically with notions of **impartiality** and **equality** (non-equal compensation for the patients' expertise as compared with the healthcare professionals' expertise). However, notions of **citizenship** (Schwartz, 2002; Stanislawski, 2011; 2022) ameliorate this challenge, as patients are willing to provide free labour and share their knowledge, experience, skills and competencies in order to contribute to the common good.

Intellectual Property Rights

One of the challenges identified by our patient respondents was the intellectual property (IP) ownership of the co-created new product. The traditional school of thought posits that the industry, which contributes all the financial resources to the NDP process, owns the IP. Conversely, a co-creative perspective contends that anyone who contributes sufficient value should be entitled to (co)ownership of the NDP.

Most of our respondents believed that the company holds the IP rights of the NDP, even if patients are asked to give deep insights into the co-creation process.

Intellectual property always belongs to the company. So, it doesn't belong to us. Unless we design something that is ours, then I presume that we'd probably be okay. But it would still belong to the company. (P10L)

However, some of the patients involved in the co-creation from the beginning, including R&D and ideation, were concerned that their valuable ideas might be “used” by large companies without providing them adequate compensation or granting IPR for their contribution. The reasons for these patients' differences in attitude to IPR could be due to the fact that they perceive the initial concepts for the NDP as coming from the patients themselves.

A patient from Sweden, co-creating with the industry and actively engaged in the diabetes community for many years, stated that IP rights had not been addressed in the co-creation she had been part of.

No, I don't remember IPR ever being addressed, and I don't think it's because I've forgotten it. (P08B)

Furthermore, a patient from Germany considered that IP rights relating to the co-creation process constitutes a “grey area” and that companies do not clarify to whom the IP rights apply. The patient felt that IP rights should be addressed and agreed with the patients in advance. Otherwise, they are not comfortable discussing their ideas.

No, IP rights have not been addressed and it's definitely an issue. I've seen it happen to a friend of mine, that an idea from the workshop was taken. There was a talk about IPR and compensation, and then weird things happened. They should have levelled the playing field beforehand and made sure that everyone felt comfortable. That's why I get uncomfortable when we're supposed to brainstorm for cool ideas. Even though I do want to help those companies improve their products, I don't want to give them the idea for the next product for free. (P22B)

However, as one of the respondents stated, all co-creation work is focused on sharing experiences and ideas to help others living with similar conditions, which references the universal moral standard of *citizenship* (Schwarz, 2002; Stanislawski, 2011; 2022) that underlies patients' involvement.

I'm kind of thankful for the opportunity to share my thoughts with companies who can actually benefit. If somebody takes one of my ideas and makes millions of pounds doing it, they will be helping hundreds of thousands of people. (P01B)

The issue of IP rights could be associated with the moral standard of *fairness*. Patient co-creators must be understood as having agency by the industry, and the characteristics of that agency and the forms of power generated by this agency must be mobilised. Patient co-creators must be perceived as equal parties within the co-creation process. This would lead to long-term relationships, mutual understanding, and trust (Banks & Humphreys, 2008).

Patients as tokens/Tokenism

There was a difference in the responses related to tokenism depending on whether the patients were involved only in the late commercialization stage or already from the early stages of NPD.

The authors observed a shift in the patients' perception of the industry during the co-creation process: when they first became involved, they were sceptical as to whether the industry had their best interests at heart or were solely interested in profits. However, the more engaged they became, the more their perspective of the industry changed as they realised their input was taken seriously.

A patient and professional athlete from the USA described a change in his own perception of the motivation of the industry.

I think in the beginning, part of the motive was PR. But I also think as we started to bring value, they said: Okay, it's more than just a PR stunt. I feel like I saw that change where it's: “No, we really want to hear what you have to say’ and they asked me to participate.” (P05B)

A patient from Germany not involved in co-creation until the later commercialization stage felt that the industry collaborated with patients mostly as a marketing ploy and to maximise their profits.

I think they are doing so because they want to improve their products but also in that way maximise the profit, and that's why they do so. (P32L)

A patient from Australia expressed the same idea. However, she also thought that working with patients was still better than not involving them at all, as doing so brings patients' perspectives and opinions to the table.

Of course, it's all PR and marketing. Yes, absolutely! They look good when they talk to people with diabetes. And I have no issue with that because they are always going to do PR and marketing. I would prefer that they use people with diabetes, to make sure that they're getting their message across right and help promote the message rather than excluding us from the conversation. (P19B)

This is in line with the theme of *trust* as it builds up over time through continuous involvement. The more the patients are involved, the more there is mutual respect, understanding and trust between patients and the industry. This is in line with Prahalad and Ramaswamy's (2004) DART (dialog, access, risk–benefits, and transparency) principle.

The perceived challenge of potential tokenism relates to the universal moral standard of *fairness* (Schwartz, 2002, Stanislawski, 2011; 2022). The patients as co-creators show a high level of reflective and critical thinking. Even though they are aware that firms are in it for themselves, they believe that their voice is very important, showing that their assessment of *fairness* is holistic.

Long-term agenda, follow-up and feedback

Most of the interviewed patients experienced a lack of clarity in terms of long-term goals, follow-up and feedback in the co-creation process.

A patient from the UK involved in co-creation from the early stages of the NPD had difficulty understanding the long-term agenda, as the goals seemed vague and imprecise.

Take the project that we were giving experiences on hyperglycaemia, we knew it was to help that launch of a new product. But beyond that what are you trying to get? Are you trying to get marketing material? Are you trying to get quotes from us? Are you trying to give development teams direction? Are you trying to give marketing teams direction? That was very unclear. (P14B)

Similarly, one of the interviewees that had been collaborating with the medical technology industry for a long period, mostly in the later stages of product development, said that even years later, they did not have a clear idea of the projects' long-term goals.

To be honest, even today, I am not sure exactly what the goals were. (P12L)

The patients stated that they were often not aware of what their insights were used for even a long after their involvement in a project. Although the industry provided detailed formal procedures and guidance for patients before their involvement, there was no feedback on how their input was

subsequently used, nor any mechanisms to check if it was even considered in any part of the process.

That's something that's often very, very unclear; what are they going to do with this feedback - is it part of the process? So that's always the point of frustration. (P22B)

A patient from the United States, a board member in various international diabetes organisations, involved in co-creation from the beginning of the NPD, explained that receiving feedback about the output of the co-creation projects made a huge difference in the perception of the company and the motivation for future collaboration.

Recently, after five years of doing this, the company actually reacted – the patient experience liaison said: Here, we wanted to invite someone from R&D to tell you how your feedback was so helpful. That really meant a lot – that made all the difference. (P25B)

Improving the clarity on long-term goals, follow-up or feedback is associated with the moral standard of *trustworthiness*, particularly with the right of transparency and openness (Schwartz, 2002, Stanislawski, 2011; 2022). Notably, the patients expressed similar concerns regardless of the stage of product development they were involved in.

Lack of diversity when selecting participants

In addition to the issue of trustworthiness, there were interviewees that highlighted the issue of unequal patient inclusion in the co-creation process. Patients from some cultures or with certain ethnic backgrounds are not invited by the industry to participate in co-creation.

A patient from the United States, involved in co-creation from the early stages, referred to the unequal representation of different races and ethnicities, which could diminish or even compromise the significance of patients' input.

I speak up. Every chance that I get – there's 50 people in this room – I am the only black person. And there's only one Hispanic person, or two. So, this is the problem when the majority in the room is white. (P21B)

Likewise, patients not fluent in English or located far from the firms' headquarters were not invited to participate in innovation.

Most of them are people living in countries, where the headquarters are, not the global kind of population. There is sometimes a lack of consulting someone from a certain country in Asia or in Africa. (P30L)

When considering diversity and inclusivity in the selection of participants for co-creation, there were no major variations in the responses between patients involved in the different stages of innovation. The data points to a need for a new moral standard related to the **diversity** or **inclusivity** as many respondents identified these aspects as issues when co-creating with the industry.

Corporate Social Responsibility.

We investigated patients' awareness and their perceptions of any social contribution made by the industry's CSR activities. Firstly, we provided a brief description of what CSR activities are to ensure that the understanding of CSR was consistent across all respondents. Then, we asked the patients whether they were familiar with the company's CSR agenda. If respondents answered affirmatively, they were asked whether they thought the companies were adhering to this agenda.

We obtained different responses from the interviewees depending on the stages of the NPD process they were involved in. The more involved patients were in the entire process of NPD, the more informed they were about the firm's CSR.

A professional athlete and patient who had often been involved in co-creation from the early stages of NPD, believes that his positive perception of the pharma's CSR activities may be different compared to other patients who had not had the opportunity to work as closely with the company.

So, to be honest, my answer might be different than someone who hasn't had the opportunity to work with a pharmaceutical company, but I truly believe that they are (socially responsible), yes. (P05B)

The perception of the company's CSR varied depending on the country the patients came from. For instance, access to insulin is a challenge perceived by the patients from the United States, where not everyone can afford insulin or has access to treatment. The situation is different for participants from countries with more accessible healthcare (e.g., France, Austria and Denmark) as patients did not have to deal with similar challenges regarding access to insulin or treatment.

I do not perceive them (the pharmaceutical companies) to be specifically socially responsible due to ongoing concerns for environmental impact and pricing. They have not come out in any particular novel way to address these issues, particularly as they impact the US markets. (P03B)

I realise that this one company in Denmark and the company in the United States, operate differently, although they are the same company. The reality of it is people are dying in the United States because they can't afford their insulin and the company has not lowered their prices. (P07B)

Our data indicate that the evaluation of CSR is rather complex for patients (for instance, medicine pricing in the United States is a reflection on the complex healthcare system, not only the company's CSR). This could explain patients' doubts about whether the different companies were adhering to their CSR standards, even when they promoted themselves as socially responsible.

Furthermore, we observed that patient involvement from the early stages of the NPD increased their knowledge and interest in the firm. However, it seems clear from the data that access to medicines constituted the biggest single factor affecting how patients assessed a company's CSR standards.

3.5.2. Managers' Perspective

No follow-up

The patients' responses showed that, even though managers worked extensively with them throughout the projects, the managers appeared less interested in maintaining the relationship afterwards.

The managers we interviewed were also of the opinion that the industry should work more on sustaining long-term partnerships with the patients, by maintaining the relationship beyond individual projects. However, the managers also believed they had improved their approach and had become more responsive to patients' rights to be informed.

So, what we're trying to do now is to, even within those contracts, we leave a window open to follow up with them about what we are doing with their insights, how their insights are changing the root of a protocol in clinical trials or what is understood from what they said. (M07)

A manager working with patient relations at a multinational pharmaceutical company thought that the reason for the lack of clarity was due to legal compliance and specific terms of the contracts.

That's something patients provide a lot of input about: what did you do with my insights? That is because of compliance and contracting. Once the project is closed, we cannot reach them again. (M07)

Despite managers' increasing efforts to improve their approach in the co-creation process, there are **institutional and legal barriers** (meaning, for example, that they could not reach the patients once the project had closed) that undermined their relationship with the patients. This makes the context of pharmaceutical and medical technology industries an extreme case in which to investigate co-creation (Yin, 2003).

Although managers believed they were becoming more responsive, there was a disparity between patients' perceptions and managerial perspectives. Therefore, one of the key themes the industry needs to focus on is **aligning expectations** among the parties involved in the co-creation process. This would in turn make it necessary to build **long-term relationships**, understanding, and **mutual trust** among the parties (Prahalad & Ramaswamy, 2004).

The negative reputation of the industry

Managers identified the industry's negative reputation as one of the barriers to successful co-creation. This points to the fact that the two parties, when entering the co-creation process, have preconceived ideas of each other that affect the process. Corporate reputation can reduce patients' willingness to engage with pharma – largely due to past publicity about excessive pricing and a lack of transparency.

From a patient's side, they are very wary of traditional Big Pharma. (M05)

The industry in itself has always had a bad reputation. At least that's the thing that most people say. (M04)

However, our data reveals that patients were less critical of European health systems in comparison to health systems from other countries (e.g., the United States). Furthermore, patients' perceptions are not “set in stone”; rather, they are part of a dynamic process, which adds complexity to the ethical challenges.

Perceived adverse corporate reputations seem to be associated with the moral standing of the companies and are indirectly associated with the universal moral standards of **respect** and **trustworthiness** (Schwartz, 2002; Stanislawski, 2011; 2022).

Internal resistance towards co-creation and reluctance to perceive patients as experts

Another challenge, according to the managers, was that some teams in the company did not fully understand the concept of patient co-creation.

The main barrier is that from our internal colleagues' side, sometimes they invite patients too late. Or they don't consider them fully equal partners. (M02)

Managers acknowledged that sometimes they involved patients too late in the NPD process and when they did, it was difficult to achieve the maximum benefit from co-creation. They highlight the importance of patients being involved throughout the entire process of NPD, i.e., in the early, middle, and late stages – including launch and follow-up.

It is absolutely key to involve them as early as possible, because otherwise, you're not really co-creating. You are doing a tick mark exercise at the very end where you can't change anything. (M09)

The discussions with managers also brought up the issue of **mindset barriers** (e.g., employees' internal resistance towards co-creation, reluctance to perceive patients as experts), which can present challenges to achieving meaningful relationships with external stakeholders.

Intellectual property rights

The managers in our survey did not raise any concerns about the challenge of IPR in the co-creation process. They explained that in the industry, agreements usually include specific IPR clauses, which are addressed and resolved before the co-creation process starts.

Usually in the agreement there's clauses like IPR that are being addressed ahead of time. In my 12-year journey with the company, I have now generated more than 20 approved IPs. So that is typically addressed in the consent form as well. (M10)

Managers were not aware of patients' concerns regarding the IP of the co-created products. This represented another discrepancy between the patients and managers' expectations during the co-creation process.

Lack of diversity when selecting participants

Managers also identified a challenge related to a lack of diversity in patient selection that led to an underrepresentation of non-English speaking patients from different cultures, races and

ethnicities in the co-creation process. The managers described how the sampling process tends to target the same type of participants, which does not ensure diversity of the output.

The challenge that I see the most is when we are interacting with patients, we end up interacting with the patients that are English speakers, because that is what most of the industries work on.” (M04)

The themes of **inclusivity** and **diversity** are challenges that arose during the co-creation process, identified from both patient and managerial perspectives.

No clear guidance and regulations on co-creation; bureaucracy and compliance concerns

Most of the managers interviewed expressed concern about the lack of comprehensive and integrated guidance on patient co-creation. Very often, there is no strong legal framework on co-creation, especially in certain parts of the world (e.g., developing countries). Although some initiatives exist, they are so separate and disparate that they have resulted in a fragmented patient engagement landscape, with a lack of continuity, efficiency, and coordination (Deane et al., 2019).

The huge challenge is that it (patient co-creation) is not defined clearly. And even if you just search for all the buzzwords such as patient engagement, patient involvement, the academic literature that you find, which can guide you on how to do it properly or officially, it's very inconsistent. So, FDA, EMA, they are continuing to give guidance, but it's inconsistent. (M01)

Most of the managers identified internal bureaucratic processes and regulatory compliance as two of the biggest challenges in the co-creation process.

Obviously, the barriers are that the legal framework is often not completely in place. So, it's important that you get legal and compliance to do that, because then you ensure that both are safeguarded by a strong framework that's legally compliant. (M09)

So, the biggest barrier is ourselves. The big pharma companies are very risk averse, and obviously, for good reason because of compliance. (M05)

The managers identified the existence of internal bureaucratic and legal barriers concerning the process of patient co-creation. They perceived the big pharmaceutical companies as being very **risk averse**, mainly because of compliance. The theme of **institutional constraints** emerged again and again along with the **mindset barriers** that hinder transparency.

3.5.3. Ways to Overcome Challenges/ Best Practices

The managers were also asked to reflect upon best practices and suggest ways to overcome the challenges they face during the co-creation process.

The Chief Patient Officer at a Danish pharmaceutical company who had worked over twenty years with patient co-creation stated that it is important to generate value for both parties to ensure the best results. The intended outcome was that companies and patients create **shared value** throughout the process. It is not only important to help the company but also be on a mission to

help partners, patient organisations and/or patients. Having a **common purpose** was an important motivator for both parties.

At the end of the day, the desired outcome is that we make something that we didn't even imagine we could deliver to patients, a transformative solution. There must be value generated for both parties. Patients have a lot of challenges that they need to be dealing with, and we need to help them deal with it. Their business is our business. Our business is their business. (M03)

The managers observed that **aligning mutual expectations** during co-creation would lead to more successful value creation for both parties. Sharing experiences among the involved parties was needed if they were to align their mutual expectations in the co-creation process, which is in line with Prahalad & Ramaswamy (2004) DART principles.

Then the second one is having all the stakeholders understand why this co-creation is needed. (M04)

Awareness and **education** are other important aspects, so having internal training in the companies about what patient co-creation is and why it is needed was seen as vital.

Having a lot of conversations and internal training in the company about what it is to engage with patients and why this is needed. And really walk the talk and share examples, not just talk about how co-creation is needed, but start sharing experiences. (M02)

Managers also considered that teams working with co-creation in the companies would also need specific **soft skills** when working with people with diseases, taking into account the vulnerability of this particular group of stakeholders, which in turn is related to the moral standard of caring.

You need to be completely mindful that you're working with people with diseases. You cannot treat them like any other stakeholder- the approaches need to be different. The human connection needs to be even stronger when working in the co-creating processes. (M07)

A manager working in co-creation with various pharmaceutical and medical technology companies suggested that industry has to work proactively with regulators to move towards a more collaborative form of co-creation. Even though there has been a positive change in the last decade, a lot more needs to be done.

I've worked with government, with regulators, to say we can have interactions with patients, so that we move from this end user-asked them in a consultative way, and then have them involved in co-creation in a more collaborative way (an open-source model, crowdsourcing support group model), rather than just this consulting as a weak partner. (M05)

Another manager who had worked for over 15 years with patient co-creation talked about how the industry should address the **mindset barriers** that are still present during the co-creation process.

I think it is very important that we maintain an open mindset. We, as pharma, have been working in a very conservative way when we believe we know what patients need without asking them. (M07)

Furthermore, a manager working with patient insights in a Danish pharmaceutical company suggested hiring patients from within the company itself as a solution to reducing compliance, regulation and contracting challenges. This is a new concept of working with patients already used in a few pharmaceutical companies.

If you hire patients within your teams, then you avoid the compliance regulations and the contracting part. Because then they have different hats, and we can reach out to them at any point about any questions. (M07)

Managers explained that rare disease companies and nimble biotech are far ahead of the big pharmaceutical and medical technology companies, as they have already adopted agile methodology. There has been a shift from transactional to transformational methodology over the last decade in rare disease companies.

Have a think about personalised medicine, and the approaches for co-creation in that world, rather than this volume world of “one size fits all”. Understanding who a customer is/ who isn't/ who never will be, and what it takes to go from pre-patient, to diagnosis, to intervention, treatment, long term adherence–patient mapping – the patient journey. (M05)

3.6. Discussion and Conclusion

3.6.1. Theoretical Implications

Previous research investigating managers' perceptions has established that managers see a number of potential challenges when co-creating with external stakeholders such as loss of knowledge, misunderstandings between R&D teams and customers and dependency on customer views (Enkel et al., 2005; Schaarschmidt & Kilian, 2014; Ulwick, 2002). Additionally, they identified several barriers to patient co-creation, including internal bureaucratic processes, fear of being accused of promoting medical products to the public, limited understanding of the benefits and challenges of collaborating with other stakeholders, unwillingness to share information, and lack of transparency or openness (Smith et. al, 2015).

Building upon this existing body of knowledge, the present study makes several significant contributions. Firstly, studying the case of the pharmaceutical and medical technology industry, we empirically identify and explore the ethical challenges that arise during the co-creation process. This is followed by recommended ways to overcome such challenges, by providing best practices for managers. Adding to Schwarz's universal moral standards for corporate codes of ethics (Schwarz, 1998, 2002) (fairness, respect, trustworthiness, citizenship, caring, and responsibility), we extend this framework with additional standards of equality, inclusivity, and diversity. We found that these additional standards are very relevant in the co-creation setting.

Another important contribution is that the present study focuses on both managerial and patients' perspectives. The dual perspective highlights the complexity of the co-creation process while confirming the important ethical challenges that arise. This approach enabled the authors to reveal discrepancies in the expectations between managers and patients during the co-creation process. For both parties to be able to benefit from co-creation, it is important for managers and patients to understand and align their mutual expectations. Furthermore, we have shown that external

stakeholders' expectations are influenced by the stage from which they are involved in the co-creation process.

Finally, the present study emphasises the necessity of clear regulatory guidance on co-creation with patients, which would encourage the industry to engage patients without concerns about potential regulatory issues.

Equality, inclusivity, and diversity as emerging ethical challenges

One of the main theoretical contributions from the study is that we found that moral standards of equality, inclusivity and diversity are very relevant to co-creation, although they are not part of Schwarz's universal moral standards framework. Therefore, we propose extending the framework by adding the standards of inclusivity, diversity, and equality which emerged from our empirical data.

All patients interviewed perceived their compensation for co-creation as significantly lower than that of healthcare professionals. By sharing their personal experience of living with a disease, they provide the industry with unique insights. Patients (as the end-users of healthcare products) possess unique knowledge and experience ("need knowledge") that is crucial for a successful innovation process (von Hippel, 1986). However, managers seem not to value patients' knowledge and expertise *as highly* as knowledge generated by other stakeholders (e.g., healthcare professionals). The industry could benefit from compensating patients equally with other stakeholders (i.e., healthcare professionals) because their "need knowledge" is vital to realising the full potential of co-creation.

This challenge is associated with the standard of **equality**, which could hinder the co-creation process because co-creation is possible only between equal partners (Prahalad & Ramaswamy, 2004).

Furthermore, our data showed that patient co-creation activities might not truly reflect the perspectives and needs of a wider population because there is an unequal representation of participants from different races and ethnicities, geographical locations and socio-economic backgrounds. This observation raises concerns regarding the standards of **diversity** and **inclusivity** during the co-creation process.

To address these issues, the industry needs to make additional efforts and ensure the involvement of underrepresented populations in the co-creation process. By promoting diversity and inclusivity in patient co-creation, the industry can enhance the validity and relevance of outcomes, as well as promote equitable solutions that cater to the diverse needs.

Alignment of Mutual Expectations

A successful co-creation process is dependent on successfully aligning mutual expectations between the interacting parties (patients and industry). In the present study, we focus on both

managerial and patients' perspectives, which enables us to reveal the discrepancies in expectations between managers and patients during the co-creation process.

For firms to be able to benefit from co-creation in the NPD process, it is important for managers and patients to understand and manage expectations. This relates to the universal moral standards of trustworthiness and fairness, which are crucial in the co-creation process. In a similar vein, Ind and Coates (2013) state that firms engaging in co-creation need to move beyond the fact that co-creation exploits stakeholders but rather engages them in a reciprocally useful way.

In our study, managers are aware that the desired outcome of co-creation is to create a transformative solution, i.e., shared value for both parties. It is not only for the benefit of the company but is also a mission to help partners, patient organisations and/or patients. Both patients and managers should understand the benefits of the collaboration ("win-win") and have a common goal. This is in line with Prahalad & Ramaswamy (2004), who claim that only high-quality interactions between the external stakeholders and the firms are key to unlocking new sources of competitive advantage. It is the shift from a firm-centric to a co-creation perspective on value creation, co-extraction of economic value by empowered and active communities of consumers as external stakeholders that will enable companies to develop a competitive advantage over rival companies (*ibid*). Likewise, in our study, managers recognized the necessity of providing an environment in which patients can co-create unique experiences and shared value is jointly created by both the industry and patients.

However, patients' responses in our study showed that there is no regular follow-up or feedback in the co-creation process. Patients were sceptical as to whether the industry would actually ever go for the long-term cooperation and frequent follow-ups that patients wanted. Although managers stated that they had significantly improved their performance regarding follow-ups with patients, they also acknowledged the existence of **institutional and legal barriers** (e.g., not being able to reach patients once the co-creation process was finished).

Firms have traditionally benefited from exploiting the information asymmetry between them and consumers (Nayyar, 1990). Both transparency and access to information are critical to achieving meaningful interaction, which is difficult if external co-creators do not have the same access to information (Prahalad and Ramaswamy, 2004).

Additionally, the interviewed patients revealed that, at least to some extent, they perceive the process of co-creation as a marketing or publicity stunt. However, they continued to partake in co-creation as they believed that their insights were crucial to the co-creation. Although patients maintained a critical stance towards industry, they were still willing to share knowledge, experience, skills, or competencies to contribute to the common good, which is associated with the moral standard of **citizenship**.

Another challenge identified by patients was related to corporate social responsibility. Our data showed that perceptions towards the industry's CSR varied depending on which country participants were from. This could be due to countries having different kinds of health systems and different levels of patient support offered by those systems (e.g., lack of access to insulin was

one of the main issues in some countries, and this led to unfavourable perceptions of the industry in general).

No clear set of rules regarding ethicality in co-creation

Although some very general guidance and resources are available (e.g., EMA (Engagement Framework: EMA and patients, consumers and their organisations, 2021), FDA (Perfetto et al., 2015), and EUPATI (Haerry et al., 2018; Spindler & Lima, 2018), our findings show the necessity of establishing a clear set of rules regarding ethicality in patient co-creation,.

Key enablers for effective collaboration among different stakeholders include: having clearly defined rules, including those dealing with transparency, governing compensation; agreement and understanding about common goals, together with alignment of vision; establishment of appropriate governance/partnership structures and processes; resource alignment; agreement of roles, responsibilities, scope of collaboration; mutual respect and open and frequent communication (Gallin et al., 2013; Dewulf, 2015).

In our study, managers acknowledged that pharmaceutical and medical technology industries still largely function according to somewhat conservative principles; such industries believe they know what patients need without asking them. Managers explained that it was difficult for companies to incorporate patient insights in their agenda because companies saw themselves as experts in conceptualising a product from a purely R&D background; as a result, they believed they had the solutions to current product-related issues. Furthermore, there were strict institutional pressures for conforming to existing routines and behaviours.

This research reveals that managers are willing to move towards a more collaborative business model, directly involving patients in all phases of the NPD process. However, our study also uncovers significant barriers to this transformation (legal, institutional and structural), yet to be addressed by the industry, which would enable companies to move from the traditional market concept (as company-centric) towards an emerging market concept focused on patient/industry interaction.

Our study data show that managers recognize the need to cooperate and co-create with patients. They discuss the principles upon which this co-creation should take place, highlighting the necessity of identifying co-creative opportunities early on in order to achieve shared value for patients and the industry. However, some project teams within the firms do not recognise the real benefits of the concept of involving patients early on in the process and involve them too late. Furthermore, they do not perceive patients as equal partners in the co-creation process.

Our findings are in line with Bosch-Sijtsema & Bosch (2015), who call for changes to the R&D process, as external stakeholders need to be involved much earlier in the innovation process. Likewise, Lowe et. al. (2016) discuss how patients should be involved in the NPD from the very beginning. In line with previous research, we found that there are clear advantages of involving patients in the co-creation process earlier. These include the following fact that patients are more inclined to believe that the industries' interests are genuine and not solely for marketing and public

relations purposes. Patients also feel that their voices are heard, and that they are working for the greater benefit of the patient community.

On the other hand, our data show that patients involved earlier on in the co-creation process are less satisfied with the compensation and intellectual property rights they receive compared to patients not involved until the latter stages. However, despite their scepticism, the responses reveal a high level of patient commitment throughout the co-creation process. Through being involved in co-creation, they feel that they are affecting important decisions and making sure that their perspectives are heard by the industry.

3.6.2. Managerial Implications

Our research suggests that managers should change their perceptions about external stakeholders' ability to participate actively in the co-creation process by adjusting their practices and educating their employees (i.e., by raising awareness and organising internal training on the importance of external stakeholder involvement in the co-creation process).

It is crucial that both external stakeholders and firms understand the benefits of co-creation - to generate value and transformative solutions for both, ensuring the best outcome towards a common goal. Furthermore, managers should recognize that co-creation must be built on transparency, and therefore, the industry has to work on providing external stakeholders with long-term goals and feedback from co-creation. Follow-up during and after the process is important for a successful partnership and would guarantee mutuality and trust through a long-term partnership rather than just collaboration on a single project.

Additionally, there is a need for more clarity and transparency regarding compensation and the IP rights of external stakeholders. The industry could benefit from treating patients (external stakeholders) and other stakeholders (healthcare professionals) equally in terms of providing adequate compensation because patients' unique experience ("need knowledge") is crucial for new product development.

Our data show that the nature of the firm – stakeholder interaction differs depending on whether the co-creation starts from the beginning or stakeholders are included only in the later stages of a NPD process. It is important to involve patients as early as possible and throughout the entire NPD process to make sure of achieving the utmost benefit from co-creation.

Considering that compliance is one of the biggest barriers identified in our study, there should be a close relationship between teams working with co-creation and the legal and compliance teams in the company. To achieve successful co-creation in the highly regulated pharmaceutical and medical technology industries, despite the legal and regulatory obstacles identified in this study, the industry has to address barriers early on (for instance, by working closely with governmental and regulatory bodies on both national and international level).

More and better access to information about companies' corporate social responsibility could be one way to solve the issues related to patients' scepticism in this area.

The rare diseases model of patient co-creation could be exported to the chronic diseases model. This would translate not only into shorter development cycles and faster reallocation of resources to reduce time to market, but also result in more external collaboration with partners and key stakeholders (such as patients).

Lastly, our aim is to encourage managers and academics to move beyond perceiving ethics as an optional add-on and ensure that the standards of trustworthiness, respect, responsibility, fairness, citizenship, inclusivity, and equality are met throughout the co-creation process.

3.6.3. Limitations and Future Research

The current research contributes to filling a gap in the literature regarding the ethical challenges of co-creation in the pharmaceutical and medical technology industries. The authors intend to build upon this research and hope the findings will inspire other researchers to explore this topic in other industries. Moreover, even though the focus of this study is on healthcare, the findings could be applied to other industries engaged in co-creation with external stakeholders.

Although the fieldwork consisted of 42 in-depth semi-structured interviews with key players in the co-creation field in healthcare, the generalizability of the findings could still be perceived as an issue. As semi-structured interviews are the primary data source in qualitative research (Eisenhardt, 1989), double hermeneutics is an issue. This is because, firstly, participants interpret the reality, and then researchers interpret the participants' interpretations. To deal with this issue, future research could triangulate the interviews and validate the data quantitatively (for instance, with a survey instrument). Additionally, there are lots of opportunities for comparative and/or case study research including co-creators involved with different types of healthcare innovation, co-creators in different healthcare systems and co-creators across different industries.

The study is limited by its theoretical nature regarding marketing ethics in that the adopted framework is Schwartz's universal moral values for corporate codes of ethics (2002). Even though the framework has proven to be a fit for co-creation in the context investigated, future research could benefit from using other ethical frameworks to analyse challenges arising in the co-creation process.

While the authors have shed light on the importance of applying moral standards such as diversity, inclusivity and equality that have not been discussed in the existent literature in relation to co-creation, it is expected that more ethical issues are likely to arise as co-creation with external stakeholders/consumers evolves. Furthermore, the ethical challenges, and their relative level of importance, might differ if different industries and sectors are considered. Finally, the identified ethical challenges in this study and their causes could be studied more in depth in the future.

Another aspect that would be interesting to study is the cross-cultural ethical challenges in the co-creation process, especially if we consider the significant differences that exist between institutions, values, legal frameworks, and cultural practices. Differences in countries' healthcare systems also have an impact on patient expectations and their engagement in decision making. In

our study, we interviewed patients and managers based in 14 different countries. However, patient co-creation cannot be implemented using a “one-size-fits-all” approach, as healthcare systems are organised in very different ways across different countries and even in different ways within a given country (e.g., the USA). Some countries have healthcare systems operating within strong national support systems, while others consist mainly of independent private practices that are well coordinated. Countries and regions differ and a strategy that works well in one area may not transfer to another. Similarly, challenges that need to be improved in some regions might not be a priority for other regions. Therefore, further research on the topic is needed (e.g., a comparison between level of patient co-creation in developed vs. developing countries).

Table 4. Ethical issues related to co-creation in the pharmaceutical and medical technology context: Patients' perspectives

Moral/ ethical standard	Challenge	The stages of the new product development process, patients were involved in:		Note
		Predevelopment and development stages	Commercial deployment stage	
Fairness	Compensation	Higher expectations	Lower expectations	All patients perceive their compensation to be significantly lower than that of other stakeholders (e.g., health care professionals)
	IPR	IPR should be clearly addressed before the co-creation process	Patients perceived IPR as always belonging to the company	
Respect	PR strategy/ Tokenism	The patients' voice matters PR is not the main purpose for patient co-creation	Patient co-creation is mainly for PR purposes	Patients' perspectives shift with their level of involvement: the earlier they are involved, the more they perceive that companies have patients' best interests at heart.
Trustworthiness	No clear long-term goals, follow-up, and feedback	Regular follow up will make a huge difference	There is no follow-up	All patients have challenges understanding the long-term goals; no regular follow-up and feedback with patients
Citizenship	Corporate Social Responsibility	Generally favourable; depends on country where the patients come from	Not familiar with the company's CSR agenda	Access to insulin is stated as the main issue, leading to variations from country to country.
Inclusivity and diversity	Bias in identifying and recruiting participants	A lack of diversity in participant selection (e.g., participants from different cultures or backgrounds are left out; fewer participants far from a company's headquarters and who do not speak English.		

Table 5. Ethical issues related to co-creation in the pharmaceutical and medical technology context: Managerial perspectives

Moral/ ethical standard	Challenge	Description	Type of barriers	Ways to overcome
Trustworthiness (Transparency)	No clear long-term goals, follow-up, and feedback	Managers receive a lot of negative feedback about lack of clarity regarding follow-up, i.e., what has been done with patients' insights after the co-creation process	Institutional and legal barrier	Work on the long-term partnership with the patients, e.g., maintain continuity of the relationship beyond individual projects
Respect	PR Strategy/ Tokenism	Patients involved too late and used as a tick-the-box exercise by the companies rather than being part of a co-creation process.	Institutional and mindset barriers	Involve patients early on in the process and treat them as equal partners
Respect/Trustworthiness	The negative reputation of the industry	Negative corporate reputation can reduce patients' willingness to participate in co-creation	Mindset barriers	Build long and trusting relationships with patients
Respect/ Equality	Internal resistance and reluctance to perceive patients as experts	Some teams within the company do not consider patients as equal partners or invite them too late in the process.	Institutional and mindset barriers	Involve patients throughout the whole process. Educate managers across the company about the value of co-creation
Fairness	Intellectual property rights	IPR is addressed as a clause in the agreements in advance. In most cases, the company is the owner of the IP.	Institutional and legal barriers	Discuss IPR upfront with all collaborators (i.e., patients)
Diversity/Inclusivity	Lack of diversity when selecting participants	The companies interact with English speaking patients and do not include participants from different cultures or backgrounds.	Mindset barriers	Increase efforts to reach out to underrepresented communities and ensure their meaningful involvement in the co-creation process

Moral/ ethical standard	Challenge	Description	Type of barriers	Ways to overcome
Citizenship	<p>No clear guidance, regulations on co-creation</p> <p>Bureaucracy, compliance concerns</p>	<p>There are FDA and EMA guidelines, but they are not consistent. Strong legal framework is missing, especially in some parts of the world.</p> <p>The industry is highly regulated. The challenges are the traditional compliance with regulatory codes</p>	Legal and institutional barriers	<p>The industry should work closely with governmental and regulatory agencies to establish a legal framework</p> <p>Work with the legal and compliance teams</p>
Responsibility	Big companies have been slower to adopt agile methodology	<p>Pharmaceutical and MedTech companies are not considered agile enough especially when compared to rare disease and nimble biotech companies.</p> <p>They are still using traditional methods rather than design thinking with patients.</p>	Structural and mindset barriers	Export rare diseases model to chronic disease model (understanding consumers - mapping the patient journey)

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4. THE IMPACT OF SOCIALLY CONSCIOUS BEHAVIOR ON PATIENTS' INTENTION TO INNOVATE: THE MODERATING ROLES OF PATIENTS' BURDEN OF TREATMENT AND (BEING) AHEAD OF TREND

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4.1. Abstract

Recent research has revealed that patients and their caregivers, as end users of healthcare products and services, are not only drivers of institutional research, but also inventors of a multitude of valuable solutions to improve their own and their close community's medical conditions. The emergence of innovation intermediaries in healthcare and initiatives to share patients' solutions confirm that there is an increased awareness of the importance of patient innovation. However, there is still a dearth of quantitative research investigating patient innovation. In involving themselves in the innovation process, patients are trying to solve problems for themselves or their immediate environment (relatives, friends, or their community). This implies that one of their strongest incentives to innovate is the presence of community norms (that helping others in the community is what should be done), which is reflective of social processes and not of commercial benefits. Therefore, in the present study, we investigate the influence of patients' social consciousness on their intention to innovate. We also study the moderating effect of their lead user status (being ahead of trend) and the burden of their treatment on the relationship between socially conscious behavior and intention to innovate. We conducted the research by surveying over 300 chronic disease patients through various patient organizations and online communities. The findings confirm the significant and positive impact of socially conscious behavior on patients' intention to innovate. Furthermore, if patients are ahead of trend, this tends to strengthen the positive relationship between their socially conscious behavior and their intention to innovate. Although we failed to prove that the treatment burden moderates the relationship between socially conscious behavior and intention to innovate, this study is the first to consider the burden of treatment as a measure of patients' disease-related needs. It therefore paves the way for future research on the burden of treatment as a factor influencing innovation. Overall, we believe that this study enriches user innovation theory with a better understanding and predictability of the process, thereby making a significant contribution to the literature on patient innovation.

Keywords: User Innovation, Patient Innovation, Ahead of Trend, Burden of Treatment, Socially Conscious Consumer Behavior

4.2. Introduction

In the current business environment, firms no longer rely exclusively on their internal R&D activities to maintain competitive advantage (Bradonjic et al., 2019; Chatterji & Fabrizio, 2012; Cohen et al., 2002; Narula, 2001; Schweisfurth, 2017). In fact, users are often found to be the initial developers of what later become commercially successful products and services (Schreier & Prügl, 2008). Research has shown that between 19% and 36% of all innovations across various fields can be attributed to user innovators (Shah et al., 2000). User innovators are defined as “innovators who expect to benefit from their innovation via use rather than from production and sales” (von Hippel, 2017, p. 19). Several studies observe that such user innovators produce more original and more highly valued ideas than professional developers (Magnusson et al., 2003; Matthing et al., 2004).

With the help of technological development, user innovation has spread rapidly, and it is easier for users to design themselves what they need (Baldwin & von Hippel, 2011). The emergence of flexible manufacturing technologies (e.g., 3D printing) enables users to manufacture individual products directly from digital models at relatively low cost (Rayna et al., 2015; Schreier and Prügl, 2008; Weller et al., 2015). The steadily improving quality of information technology has facilitated the establishment of online communities where user innovators exchange ideas, have access to complementary skills of others, and share reliable solutions (von Hippel, 2006; 2017).

A growing body of research investigating user innovators' roles has emerged, including von Hippel's prestigious work from 1976, 1988, 2006, and 2017. Moreover, “user innovation” has become one of the hot topics in innovation research (e.g. Bogers et al., 2010; Bradonjic et al., 2019; de Jong & von Hippel, 2009; de Jong et al., 2015; de Jong, 2016; Franke & Shah, 2003; Franke & von Hippel, 2003; Franke et al., 2016; Herstatt & von Hippel, 1992; Hiennerth et al., 2014; Lüthje, 2003, 2004; Lüthje et al., 2005; Morrison et al., 2000; Oliveira & von Hippel, 2011; Urban & von Hippel, 1988). The phenomenon has been studied across various types of industrial and consumer products, such as printed circuit CAD software (Urban and von Hippel, 1988), construction products (Herstatt & von Hippel, 1992), library information systems (Morrison et al., 2000), medical equipment (Lüthje, 2003), sports-related product innovations (Lüthje 2004; Lüthje et al., 2005; Franke & Shah, 2003), and web server software (Franke & von Hippel, 2003). For example, Lüthje (2003) in his study on surgeons working at university clinics, found that 22% of the surveyed users had developed new products for in-house use.

The user innovation process differs greatly from producer innovation. For example, most user innovators make their designs available for free rather than seeking to protect the designs from imitators (using patents, copyrights and other protections) (Schreier & Prügl, 2008). Although differing from each other, the user and producer paradigms are complementary rather than competitive. The shift of innovation from producers to users offers some real advantages, such as contributing diverse and commercially attractive ideas, often at a low relative cost (Carbonell et al., 2009; von Hippel, 2017). It has also been shown to increase social welfare (Gambardella et al., 2017; Henkel & von Hippel, 2004).

Prior studies report that one of the main fields where user innovations are applied is healthcare (Cennamo et al., 2022; Habicht et al., 2013; Halabi & Richard, 2020; Oliveira et al., 2015; Zejnilović et al., 2016). The concept of patient innovation is built upon the user-innovation definition by von Hippel (2007), where patients (and their caregivers) are the largest, and most salient group of stakeholders in the healthcare value chain (Oliveira et al., 2017). Because of their unique knowledge about diseases, patients and their caregivers can potentially become valuable sources of innovation (Zejnilović et al., 2016). However, this unique knowledge is also sometimes difficult to transfer (Oliveira et al., 2017). Patient innovators are individuals who develop new equipment, medical devices, treatment, therapy, strategy, habits or behavior with the intention of using it (as opposed to for commercial purposes). They do this to treat or better cope with their health conditions (Shcherbatiuk, 2012). Driven by a sense of need, and often life-changing conditions, patients have become a promising source of ideas on how to improve products and medical devices (Lettl et al., 2006; Demonaco et al., 2020; Habicht et al., 2013).

Survey studies conducted in the US, Japan, Finland, and the UK suggest that approximately 0.5 % of the population have modified or created health-related products or services (de Jong et al., 2015; von Hippel et al., 2012). Indeed, research has already shown that patients and caregivers are not only the drivers of institutional research; they invent a multitude of valuable solutions to improve their own personal medical situations (Oliveira et al., 2015). These solutions vary from simple tools to help with everyday routines to highly sophisticated solutions (Frydman, 2009; Oliveira et al., 2015; Shcherbatiuk, 2012; Habicht et al., 2013). The healthcare system should identify these patients innovators and include them in a more collaborative healthcare research model, their innovations will reach a broader audience. Higher numbers of patient innovations could increase the overall capacity of the healthcare system. However, to date, there has been a lack of studies on large-scale and real-world data on patient-driven innovations.

Advances in information technology have enabled the emergence of many online communities where patients share their experiences (Frydman, 2009). Moreover, patient innovators share their solutions voluntarily within their patient community (Zejnilović et al., 2016). For example, the online platform PatientsLikeMe (<https://www.patientslikeme.com/about>) is a successful example of a user innovation model that brings patients to the center of the medical system (Kuenne et al., 2013). Another similar platform is Patient Innovation (www.patient-innovation.com), an open platform for patients (and caregivers) of any disease and geography to share solutions they have developed to help them cope with the challenges imposed by their disease or health condition (Oliveira et al., 2017; Cennamo et al., 2022).

When users (patients) innovate, they are driven by the desire to generate value, but predominantly for themselves rather than for the broader market. They try to solve problems for their immediate environment: for themselves, relatives, friends, or their community (Franke & Shah, 2003; Zejnilović et al., 2016). They invest in the communities to which they belong and are committed to driving positive social change. Studying user innovation in extreme sport communities, Franke & Shah (2003) show that user innovators have a stronger relationship to their community than do non-innovators. They further argue that one of the strongest motivations for participating in innovation is the presence of community norms (that helping others in the community is what

should be done), which is reflective of social processes and not of personal benefits. Users are socially conscious innovators as they have a purpose which is beyond profit. From this viewpoint, social consciousness indicates conscious awareness of taking part in an interrelated community with others (Wesley et al., 2012). Accordingly, one could argue that users' (patients') social consciousness could facilitate innovative activities.

To test the above hypothesis, we investigated the impact of socially conscious consumer (user)³ behavior on their intention to innovate.

Given the importance of patient innovation, several scholars have examined what drives users' intention to innovate (ITI) and have found that certain personal traits are strong drivers. For instance, lead userhood is recognized as one of the major characteristics of user innovators. Lead users are defined as members of a user population who (1) expect substantial benefits from finding a solution to meet their needs and so may innovate and (2) are ahead of trend (AOT) in a marketplace and currently have needs that many users in that marketplace will have at some later time (von Hippel, 1986, 2006; Schreier & Prügl, 2008; Franke et al., 2006). The "ahead of trend" characteristics are found to be positively correlated to both the likelihood of user innovation taking place and the commercial attractiveness of a user-developed innovation (Franke et al., 2006).

Considering the proven role of ahead of trend characteristic on users' innovativeness, we include it as a moderator in our study of patient innovation. Lead patient innovators not only have greater needs which are not met by commercially available products/services (before other patients), but also expect more substantial benefits from finding solutions to meet those needs. Therefore, we hypothesized that the impact of patients' social consciousness on their intention to innovate is likely to be higher if they also display more pronounced ahead of trend characteristics (i.e. identifying needs in their disease management that other patients will subsequently have).

Prior research also suggests a positive association between the expected benefits from an innovation and users' intention to innovate (von Hippel, 1986; 2006). The reality is that commercial healthcare products and services will never be able to deliver everything patients need, so innovative patients can fill many of the gaps in the healthcare market (Goldner, 2016; Göldner, 2021). Costly medical treatment creates further incentives for finding innovative ways of meeting demand (Zejnilić et al., 2016). In some cases, instead of waiting for market solutions, patients and informal caregivers start developing innovative solutions in order to overcome the limitations associated with their health conditions (Jacinto et al., 2021; Oliveira et al., 2015; Zejnilić et al., 2016).

To measure patients' disease-related needs, we include the burden of treatment (BOT) construct in our study. BOT represents challenges associated with everything patients need to do to manage their disease (e.g. adherence to complex treatment regimens, administrative tasks to access and coordinate care, visits to the doctor, laboratory tests, self-monitoring, lifestyle changes) (Gallacher et al., 2011, 2013, 2014; Eton et al., 2012, 2013; May et al., 2009). As von Hippel's study from 1986 shows, user innovators experience stronger needs for new products and services than non-innovators, and it is reasonable to assume that this higher burden of treatment would lead to a

³ We use both terms consumer and user interchangeably in the study

stronger need to innovate. Therefore, in our study, we include patients' BOT as a moderator affecting the impact of social consciousness on the intention to innovate. We hypothesized that the impact of the patients' social consciousness on their innovativeness will be greater when combined with a greater burden of treatment (representing stronger needs for new products and services).

Therefore, the present study employs two moderators: ahead of trend (AOT) and burden of treatment (BOT) and explores their moderating role on the relationship between social conscious consumer behavior (SCCB) and intention to innovate (ITI).

Accordingly, we developed a model to study patients' intention to innovate. To test the model, we collected data from 318 chronic disease patients through various patient organizations and online patient communities. The findings showed that socially conscious consumer behavior has a positive impact on patients' intention to innovate. Furthermore, the results indicated that being ahead of trend positively moderates the effect of community-based resources on patients' innovation intention.

In the following, we give a brief overview of the theoretical background of the concept of socially conscious consumer behavior. Afterwards, the concepts of being ahead of trend and burden of treatment as moderating factors are introduced and explained. Hypotheses with respect to factors influencing patients' innovation intention are then developed. This is followed by a description of the study method, after which the findings are presented. Finally, the article discusses the implications of the results as well as limitations and possible directions for future research.

4.3. Theoretical Background and Hypotheses Development

4.3.1. Socially Conscious Consumer Behavior and Intention to Innovate

According to Webster (1975), socially conscious consumers (users) are "consumers who take into account the public consequences of their private consumption or who attempt to use their purchasing power to bring about social changes". He further argues that socially conscious users are individuals who perceive themselves as active and socially involved in their community (*ibid*). Taking this concept a step further, Antil (1984) suggests that socially conscious users are "motivated not only by a desire to satisfy personal needs but also by a concern for the welfare of society in general". They are more aware of social issues than others, are involved in the community and are preoccupied by the social consequences of their behavior (Antil, 1984; Webb et al., 2008). Overall, socially conscious users act upon their concern for social issues (e.g., supporting companies that help the community, improving working conditions), environmental issues (e.g., buying products made from recycled material) and health issues (e.g., buying organic foods) (Antil, 1984; Webb et al., 2008). This positioning defines the individual users as members of a community and highlights the interactions that can result from their relationships with others (Davis et al., 2017).

Thus, community is at the center of the concept of social consciousness (Wesley et al., 2012). Community is also important in providing resources for innovation activities and influencing the process by which these resources are shared and exchanged (Franke & Shah, 2003). When users innovate, they try to solve or mitigate problems for themselves, their immediate environment (relatives and friends) and/or their community (von Hippel, 2006). The driver for these innovators is not making profit but helping themselves and others facing similar challenges (Shah & Tripsas, 2007; von Hippel, 2017). Therefore, user innovation is reflective of social processes and not of personal or monetary benefits. This is in line with Franke and Shah (2003)'s research showing that the idea of helping others in the community is one of the strongest motivators for user innovation. Hadjimanolis (2000) argues that if innovators have community support, the value of their innovative outcome is likely to be higher. From this viewpoint, social consciousness indicates conscious awareness of taking active part in an interrelated community with others (Wesley et al., 2012). Accordingly, user innovators' sense of belonging to a community and their socially conscious behavior can facilitate their innovative activities.

In the patient innovation domain, patients often form strong ties within their patient communities (e.g., <https://patient-innovation.com> or <https://www.patientslikeme.com/about>). They share their experiences, ideas and solutions and are actively and socially involved in their community. Building upon the previous literature, we hypothesize that patients' socially conscious behavior will positively influence their tendency to innovate. Therefore, in our study of patient innovation, we explore the impact of socially conscious consumer (patient) behavior on their intention to innovate.

We hypothesize that:

H1. Socially Conscious Consumer (User) Behavior will have a positive effect on Intention to Innovate.

4.3.2. The Moderating Role of Ahead of Trend

Previous research has shown that users have the ability to develop new products or services via co-creation with a firm (Lilien et al., 2002), and that they are even able to develop them on their own (Füller et al., 2007). Moreover, users are often the originators of major inventions in different industries and sectors, including the construction industry (Herstatt & von Hippel, 1992), library information systems (Morrison et al., 2000), printed circuit CAD software (Urban & von Hippel, 1988), medical equipment (Lüthje, 2003), web server software (Franke & von Hippel, 2003), and sports-related consumer products (Franke & Shah, 2003; Lüthje 2004; Lüthje et al., 2005). The use of external ideas for value creation is a key principle in the design approach called "democratized innovation", which considers users as an important source of innovation (Faullant et al., 2012; von Hippel, 2006). The basic assumption behind it is that users have skills and expertise to modify existing products or autonomously develop new products (Chesbrough, 2003; von Hippel, 2006).

User innovation theory describes the motivations, processes, and outcomes of user innovation. It focuses on individual end users (i.e., consumers) as opposed to companies (Morrison et al., 2004; Schreier & Prügl, 2008; von Hippel, 2006). Von Hippel (1986) developed the lead-user theory in order to understand what types of users trigger attractive user innovation. He found that “nuggets” of user innovation are concentrated in lead users who are able to develop solutions to products that commercial firms can take advantage of (von Hippel, 1986; 2006). Subsequently, a number of studies addressed lead-user theory quantitatively and provided strong empirical support for it (Schreier & Prügl, 2008). In these studies, lead userhood is recognized as one of the major drivers of user innovation (Franke et al., 2006; Hienrich & Lettl, 2017; Lilien et al., 2002; Lüthje & Herstatt, 2004; Lüthje et al., 2005; Morrison et al., 2004; Olson & Bakke, 2001; von Hippel, 1988). Urban and von Hippel (1988) studied software users and found that it was mostly (87%) lead users whose innovations were adopted. Morrison et al. (2000) confirmed that lead userhood is related to user innovation likelihood. Further evidence of the importance of lead users is presented by Lüthje (2003), who studied surgeon innovators, and by Franke and von Hippel (2003), who studied web server software. Franke and Shah (2003) observed the same pattern among end users in sports communities and showed higher lead userhood in innovators than in non-innovators. Similar results are reported for the field of consumer outdoor products (Lüthje, 2004). Lilien et al. (2002) show that lead users are able to develop both novel and useful problem solutions that have proven to be highly successful in the market. However, we still need more research to understand what factors impact users’ leading-edge status and to find out whether lead users can be differentiated from ordinary users by certain behavioral patterns.

Lead users are defined as “members of a user population who (1) expect substantial benefits from finding a solution to their needs and so may innovate and (2) are ahead of important trends in a marketplace and so currently have needs that many more users in that marketplace will subsequently have” (von Hippel, 2017, p. 38). The two dimensions of lead userhood are independent, i.e., not necessarily interrelated (Franke et al., 2006).

Being ahead of the market trend implies having up-to-date information and knowledge about major trends in products or services in the market and about future demand for such products and services (Hau & Kang, 2016; von Hippel, 1986; 2006). Von Hippel (1986) shows that innovators are not only ahead of trend but also experience greater needs for new products. If those users innovate in response to their own needs, the resulting solutions might subsequently become highly attractive to broader parts of the market (Schreier & Prügl, 2008; von Hippel, 2006).

Franke et al. (2006) developed scales for measuring users’ (being) ahead of trend characteristics in the kite surfer community. The users’ “ahead of trend” characteristics are found to be positively correlated to both the commercial attractiveness of a user-developed innovation and to the likelihood of users innovating (Hamdi-Kidar & Vellera, 2012).

Even though the concept “ahead of trend” has been studied in various contexts, it has not yet been researched in healthcare. Healthcare is an interesting sector in which to investigate the concept of “ahead of trend” as patients living with their disease possess unique experience (“need knowledge”) which enables them to foresee future needs in the management of their disease. The establishment of online communities makes it easier for patient innovators to exchange ideas,

access the complementary skills of others (to acquire “solution knowledge”), and to share reliable solutions (Zejnilovic et al., 2016). If those patients innovate to fulfill their own (or their immediate community’s) unmet needs, their solutions might be highly beneficial to other patients suffering from similar conditions. This was clearly demonstrated during the COVID-19 pandemic when patients who were “ahead of trend” from across the world were creating and sharing products and solutions through digital platforms (such as PatientInnovation.com.) before similar products or solutions were available on the commercial market.

Considering previous research in various communities showing that lead userhood is one of the major drivers of user innovation (e.g., Franke et al., 2006; Lilien et al., 2002; Lüthje & Herstatt, 2004; Lüthje et al., 2005; Morrison et al., 2004; Olson & Bakke, 2001; von Hippel, 1988), we postulated that this phenomenon would also be present in patient communities. In other words, lead-users patients who are ahead of trend (those who have up-to-date knowledge about healthcare products and can recognize future demand patterns in the market) will be more likely to develop innovations. Therefore, we include patients' (being) AOT characteristics as a moderator affecting the relationship between their socially conscious behavior and their intention to innovate, assuming that the impact of social consciousness on the intention to innovate is higher if patients possess stronger AOT characteristics.

In line with this discussion, we hypothesize that:

H2. Being Ahead of the Trend will positively moderate the relationship between Socially Conscious Consumer Behavior and Intention to Innovate.

4.3.3. The Moderating Role of Burden of Treatment

Chronic diseases are the leading cause of death in the world, associated with 74% of deaths globally in 2019, with the majority of deaths being attributed to cardiovascular diseases, cancers, chronic respiratory diseases and diabetes (World Health Organization, 2020). While the disease burden and symptom burden are well documented, the burden associated with chronic disease treatment has not yet been as well defined (Mathers et al., 2001; Gapstur, 2007). Treatment burden is a concept that is distinct from disease burden, symptom burden and other related terms (Spencer-Bonilla et al., 2017). It is not based on the natural history of the disease, but on the need to treat the disease in order to change its course or ameliorate its effects (May et al., 2014; Mair & May, 2014).

We consider the concept of treatment burden important for our research because it represents patients’ disease-related needs. Patient innovators develop novel solutions as a response to needs which are not met by the products and services available on the market. Indeed, Jacinto et al. (2021) demonstrated that the main motivation for patients to innovate (in over 80% of cases) is the fact that the commercially available products do not fully meet their disease-related needs. Their main goal is not to profit from the innovations, but to fulfill their needs and cope with the limitations they face every day (*ibid*). This is in line with von Hippel (1986) who showed that user

innovators have significantly greater needs for innovations compared to non-innovators. Therefore, in our study, we include the burden of treatment as a measure of patients' disease-related needs.

Treatment burden as a broad concept, involves many domains (Eton et al., 2013; Tran et al., 2015). Sav et al. (2013) identified four interrelated components of treatment burden: 1) financial; 2) time and travel; 3) medication; and 4) healthcare access. Tran et al. (2015, p. 1) defined treatment burden as "the impact of the 'work of being a patient' on functioning and well-being." It represents challenges associated with everything patients have to do to manage their disease (e.g. adherence to complex treatment regimens, self-monitoring, visits to the doctor, laboratory tests, lifestyle changes, and administrative tasks to access and coordinate care) (Gallacher et al., 2011, 2013, 2014; May et al., 2009; Eton et al., 2012, 2013). Spencer-Bonilla et al. (2017) also discuss burden of treatment, referring to the workload of healthcare and how it impacts on patient wellbeing. Burden of treatment takes into account problems caused by discontinuity of care, the potential psychosocial burden of becoming a patient, and indirect costs such as expenses incurred getting to clinic appointments, taking time off work, and paying for all or some of the treatment (Spencer-Bonilla et al., 2017).

Various researchers have developed instruments that measure burden without restricting its scope to a single condition or treatment context (Eton et al., 2010; Tran et al., 2014). In our study, we employed the Treatment Burden questionnaire developed by Tran et al. (2014) which includes three dimensions: pharmacological treatment, comprehensive healthcare and psycho-social-economic context. It assesses patients' burden in taking medicine, self-monitoring, undergoing laboratory tests, visiting the doctor, meeting organizational needs, carrying out administrative tasks, adhering to a diet, doing physical activity, and dealing with the social impact of their treatment. It also serves as a self-reported indicator of the effects that the treatment has on a patient's working life (e.g. having to repeatedly go to clinics for tests) and social life (e.g., having to reduce social activities because of treatment side effects).

Patients are often faced with complex administrative systems and have to cope with uncoordinated health and social care systems (Spencer-Bonilla et al., 2017). For instance, in the last few years, the COVID-19 pandemic crisis hugely impacted healthcare systems globally, presenting an unpredictable, large-scale health challenge that required urgent mobilization of resources and affected whole populations. The impact of the pandemic has been particularly profound for those living with a chronic disease (Rosenthal et al., 2020). Heart disease, diabetes, cancer, chronic obstructive pulmonary disease, chronic kidney disease, and obesity are all conditions that increase the risk of contracting a severe illness from COVID-19 (Centers for Disease Control and Prevention, 2021). In addition to affecting morbidity and mortality, causing high rates of community spread and leading to various efforts to mitigate the effects of the disease, including stay-at-home recommendations, the pandemic has also led to increased concern about safely accessing healthcare (Czeisler et al., 2020) and has reduced the ability to control chronic diseases. Therefore, the COVID-19 pandemic represents a significantly higher burden of treatment for chronic disease patients, especially considering the comprehensive healthcare domain. However, during the pandemic crisis, patients all over the world started all sorts of initiatives to develop

innovative solutions that the healthcare market is not yet providing to help chronic disease patients cope with the increased burden of treatment from the pandemic (<https://patient-innovation.com/>). The higher burden of treatment during the COVID-19 pandemic thereby increased the number of innovations available on the patient-innovation.com platform.

Therefore, we find it relevant to include the construct of burden of treatment and explore its moderating effect on the relationship between socially conscious consumer behavior and intention to innovate.

In line with this discussion, we hypothesize that:

H3. Burden of Treatment will positively moderate the relationship between Socially Conscious Consumer Behavior and Intention to Innovate.

4.4. Methodology and Data Analysis

4.4.1. Context for Empirical Research

Patients and their nonprofessional caregivers are the largest and most salient group of stakeholders in the healthcare value chain (Oliveira et al., 2017). Collaborative and interdisciplinary research has demonstrated that patients and their caregivers are valuable sources of product and service user innovation in healthcare (Oliveira & von Hippel, 2011; Oliveira et al., 2015; von Hippel 1988, 2006).

The importance of patient innovation motivated us to seek ways to understand how patients' characteristics (their social consciousness and being ahead of trend) and their treatment burden will influence their intention to innovate.

4.4.2. Data Collection and Sample

Data were collected through an Internet-based survey sent to several European chronic disease organizations. An invitation to participate in a survey was either posted directly on the patient organization's website or sent by patient organization leaders to the organization's members by newsletter or via email. Patient organization leaders were contacted to help distribute the survey as they have direct contact to all the members and have already established trusting relationships with their members. Whenever it was possible, at least one reminder was sent out.

The chosen chronic disease organizations were located in Europe due to the researchers' location and their network. As most of them are based in Denmark, it was mainly Danish patient organizations that were initially contacted. The survey was also distributed through the European

Patient Forum's newsletter, which enabled the researchers to reach a wider European audience. All the data were collected in the autumn of 2021 and early 2022.

The survey was pre-tested in the following way. Firstly, three experts from the fields of user and open innovation were asked to assess the conceptual adequacy of the questionnaire. Then, patient organization leaders pre-tested and provided feedback on the survey. Finally, several target respondents assessed the comprehensibility of the survey. After having answered the questionnaire, they provided feedback about the clarity, wording, and relevance of the items.

We obtained ethics approval from Copenhagen Business School Ethics Council before sending out the survey. In accordance with the regulations and guidelines, responses were de-identified and the data treated anonymously for the sole purpose of carrying out this research study. Patient data were analyzed as a group with no individual disclosure of information according to the Helsinki Declaration for human studies. The recruitment message outlined the purpose of the study and drew patients' attention to the fact that they were under no obligation to participate and that their aggregated results may be published. At the end of the survey, the respondents were given an option to sign up for a lottery with a chance to win various prizes. They were reminded of their right to withdraw from the project and to lodge complaints to relevant data protection authorities (i.e. Datatilsynet, www.datatilsynet.dk in Denmark and CNIL, www.cnil.fr in France). Following Copenhagen Business School's Ethics Council guidelines, participants were not asked about any sensitive data (e.g. type of chronic disease).

The data collection resulted in 318 responses, out of which 43 did not pass the attention check test or had missing data. We used attention checks as a simple way to find if the respondents had read the survey's instructions (Abbey & Meloy, 2017). The responses with missing data were likewise deleted and excluded from further analysis according to the most common approach for dealing with missing data (McKnight et. al, 2007; Schafer & Graham, 2002). This resulted in 275 responses that were used for further analysis.

4.4.3. Survey and Measures

The survey consists of 26 questions divided into four constructs that were measured by adapting existing scale items from the literature on innovation (see Table 6). These four constructs are: i) being ahead of trend (AOT); ii) socially conscious consumer behavior (SCCB)⁴; iii) burden of treatment (BOT); and intention to innovate (ITI) .

To measure the social consciousness of consumer behavior, we use the ethically minded consumer behavior (EMCB) scale developed and validated by Sudbury-Riley and Kohlbacher (2016), which consists of two factors: ecologically conscious consumer behavior (ECCB) and socially conscious consumer behavior (SCCB). In this study, we focus on the socially conscious consumer behavior

⁴The construct "socially conscious consumer behavior" was adapted in the patient context where patients are considered as end consumers (users) of healthcare products.

aspect. The questionnaire consists of statements to which the respondent chooses an answer based on a 5-point Likert scale according to how far they think the statement is never true (1) to always true (5).

The Burden of Treatment (BOT) measures treatment burden without restricting its scope to a single condition or treatment context (Eton et al., 2010; Tran et al., 2014). The instrument consists of three sub-dimensions: Pharmacological Treatment (BOT I), Comprehensive Healthcare (BOT II), and the Psycho-social-economic context (BOT III). There are 15 items in total rated on a Likert scale ranging from 0 (not a problem) to 10 (big problem).

The construct being Ahead of Trend (AOT) defines the degree to which users have ahead of trend needs and consists of five statements to which the respondent may choose an answer on a 5-point Likert scale (1=totally disagree to 5=totally agree).

The Intention to Innovate scale was adopted from Agarwal and Karahanna (2000) and measures the degree to which users believe that they will engage in creating products or solutions in the future. It is measured using a 7-point Likert scale anchored from “strongly disagree” (1) to “strongly agree” (7) (Kankanhalli et al., 2015).

Throughout the survey, we provided definitions and examples to familiarize respondents with some of the more technical terms (Meuter et al., 2000).

Table 6. Constructs and items used in the questionnaire

Construct		Items	Reference(s)	Note
Burden of Treatment (BOT) Pharmacological Treatment (BOT I)	BOT1	The taste, shape, or size of your tablets and/ or the annoyances caused by your injections (e.g., pain, bleeding, bruising or scars).	Tran et al. (2014)	Likert scale ranging from 0 (not a problem), to 10 (big problem)
	BOT2	The number of times you should take your medication daily.	Ysraelit et al. (2019)	
	BOT3	The effort you put into not forgetting to take your medications (e.g., managing your treatment when you are away from home, and preparing and using pillboxes).		
	BOT4	The necessary precautions when taking your medication (e.g., taking them at specific times of the day or at mealtimes, not being able to do certain things after taking medication such as driving or lying down).		
Comprehensive Healthcare (BOT II)	BOT5	Lab tests and other examinations (e.g., blood tests or radiology): frequency, time spent and associated nuisances or inconveniences.		
	BOT6	Self-monitoring (e.g., taking your blood pressure or checking your blood sugar): frequency, time spent and associated nuisances or inconveniences.		
	BOT7	Doctors' visits and other appointments: frequency and time spent for these visits and difficulties finding healthcare providers.		
	BOT8	The difficulties you could have in your relationship with healthcare providers (e.g., feeling not listened to enough or not taken seriously).		
	BOT9	Arranging medical appointments and/ or transportation (doctors' visits, lab tests and other examinations) and reorganizing your schedule around these appointments.		
Psycho-social-economic context (BOT III)	BOT10	The administrative burden related to healthcare (e.g., everything you have to do when being hospitalized, insurance reimbursements and/ or obtaining social services).		
	BOT11	The financial burden associated with your healthcare (e.g., out-of-pocket expenses or expenses not covered by insurance).		

	BOT12	The burden related to dietary changes (e.g., avoiding certain foods or alcohol, having to quit smoking).		
	BOT13	The burden related to doctors' recommendations to do physical exercise (e.g., walking, jogging, and swimming).		
	BOT14	How does your healthcare impact on your relationships with others (e.g., being dependent on others and feeling like a burden to them, being embarrassed to take your medication in public?		
	BOT15	The need for medical healthcare on a regular basis reminds me of my health problems		
Socially Conscious Consumer Behavior (SCCB)	SCCB1	I will not buy a product if I know that the company that sells it is socially irresponsible.	Sudbury-Riley and Kohlbacher (2016)	5–point Likert scale (1 = never true ... 5 = always true)
	SCCB2	I do not buy products from companies that I know use sweatshop labor, child labor, or have other poor working conditions.		
	SCCB3	I have paid more for socially responsible products when there is a cheaper alternative.		
Lead user characteristics: Being Ahead of the Trend (AOT)	AOT1	I usually find out about new products and solutions before other people.	Franke et al. (2006) Schweisfurth and Raasch (2015)	5–point Likert scale (1 = totally disagree... 5 totally agree).
	AOT2	I have benefited significantly by the early adoption and use of new products.		
	AOT3	I have tested prototype versions of new products for manufacturers.		
	AOT4	In my community I am regarded as being on the “cutting edge” regarding technical products.		
	AOT5	I have improved and developed new techniques or solutions for my type of disease.		
Intention to innovate (ITI)	ITI1	I will create a solution, a technical aid product, or a medical device.	Kankanhalli et al. (2015)	7–point Likert scale (1 = strongly disagree... 7 = strongly agree).
	ITI2	I am likely to develop a solution, a technical aid product, or a medical device.		
	ITI3	I am contemplating creating a solution, a technical aid product, or a medical device.		

4.5. Results

4.5.1. Construct Validation

The variables used to test the study's hypotheses: socially consciousness consumer behavior (SCCB), (being) ahead of a trend (AOT), burden of treatment (a second order construct consisting of: pharmacological treatment (BOT I), comprehensive healthcare (BOT II), psycho-social-economic context (BOT III)), and intention to innovate (ITI) were measured using a reflective complex construct measurement (Churchill, 1979).

Overall measurement quality was assessed by employing confirmatory factor analysis using AMOS 26 where maximum likelihood estimation was used to fit the model (Anderson & Gerbing, 1988).

Our initial analysis of model fit led to the dismissal of one item: BOT15 due to a low factor loading (lower than 0.5) (according to Babin & Boles, 1998).

All values were within the acceptable ranges (Bollen, 1989; Gerbing & Anderson, 1992). Global fit measures consistently support the study's measurement model $\chi^2/df = 1.484$; RMSEA = 0.042, 90% CI for RMSEA = (0.032; 0.051), CFI = 0.963 and SRMR = 0.0509, indicative of a well-fitting measurement model.

To establish convergent validity, the factor loadings of the indicators and the average variance extracted (AVE) were considered (Hair et al., 2011, 2017). We used the criterion of Fornell and Larcker (1981) to assess the degree of shared variance between the latent variables of the model. The values range from 0 to 1. AVE value should exceed 0.50 so that it is adequate for convergent validity (Fornell & Larcker, 1981; Ab Hamid et al., 2017). Initially, the AVE criteria ($AVE > 0.5$) were not met for the constructs AOT ($AVE = 0.431$), BOT III ($AVE = 0.432$) and SCCB ($AVE = 0.494$). To improve convergent validity (AVE) we removed items BOT13, BOT14 from the construct BOT III and AOT3 and AOT5 from the AOT construct as the loadings of these factors were lower than the others. After removing the four items, common quality requirements were met by all constructs, whose values were higher or equivalent to the threshold value of 0.5.

To test the reliability of the construct, composite reliability, maximum reliability and Cronbach's alpha were used. The reliability of each construct was satisfactory with a composite reliability value of at least 0.70 and a maximum reliability of at least 0.70 (Bacon et al., 1995).

Cronbach's α ranged from above 0.735 to 0.930, which is considered acceptable as it was between 0.70 and 0.95 (Cronbach, 1951; Nunnally & Bernstein, 1994). These results provide evidence for the composite reliability of the constructs used in this study.

We assessed discriminant validity using Fornell-Lacker criterion (1981).

Table 7. Factor loadings

Standardized factor loadings					
Items		BOT	SCCB	AOT	ITI
BOT1	The taste, shape, or size of your tablets and/ or the annoyances caused by your injections (e.g., pain, bleeding, bruising or scars).	0.571			
BOT2	The number of times you should take your medication daily.	0.815			
BOT3	The effort you put into not forgetting to take your medication (e.g., managing your treatment when you are away from home, and preparing and using pillboxes).	0.870			
BOT4	The necessary precautions when taking your medication (e.g., taking them at specific times of the day or at mealtimes, not being able to do certain things after taking medication such as driving or lying down).	0.804			
BOT5	Lab tests and other examinations (e.g., blood tests or radiology): frequency, time spent and associated nuisances or inconveniences.	0.759			
BOT6	Self-monitoring (e.g., taking your blood pressure or checking your blood sugar): frequency, time spent and associated nuisances or inconveniences.	0.509			
BOT7	Doctors' visits and other appointments: frequency and time spent for these visits and difficulties finding healthcare providers.	0.858			
BOT8	The difficulties you could have in your relationship with healthcare providers (e.g., feeling not listened to enough or not taken seriously).	0.782			
BOT9	Arranging medical appointments and/ or transportation (doctors' visits, lab tests and other examinations) and reorganizing your schedule around these appointments.	0.813			

BOT10	The administrative burden related to healthcare (e.g., everything you have to do when being hospitalized, insurance reimbursements and/ or obtaining social services).	0.780			
BOT11	The financial burden associated with your healthcare (e.g., out-of-pocket expenses or expenses not covered by insurance).	0.805			
BOT12	The burden related to dietary changes (e.g., avoiding certain foods or alcohol, having to quit smoking).	0.582			
SCCB1	I will not buy a product if I know that the company that sells it is socially irresponsible.		0.826		
SCCB2	I do not buy products from companies that I know use sweatshop labor, child labor, or have other poor working conditions.		0.710		
SCCB3	I have paid more for socially responsible products when there is a cheaper alternative.		0.546		
AOT1	I usually find out about new products and solutions before other people.			0.769	
AOT2	I have benefited significantly from the early adoption and use of new products.			0.701	
AOT4	In my community I am regarded as being on the “cutting edge” regarding technical products.			0.687	
ITI1	I will create a solution, a technical aid product, or a medical device.				0.869
ITI2	I am likely to develop a solution, a technical aid product, or a medical device.				0.944
ITI3	I am contemplating creating a solution, a technical aid product, or a medical device.				0.899
Cronbach’s alpha		0.890	0.735	0.761	0.930

Table 8. Validity Analysis

	CR	AVE	MSV	MaxR(H)	AOT	ITI	SCCB	BOT
AOT	0.763	0.518	0.178	0.768	0.720			
ITI	0.931	0.818	0.178	0.939	0.422***	0.904		
SCCB	0.741	0.494	0.056	0.782	0.138†	0.236**	0.703	
BOT	0.836	0.638	0.059	0.923	-0.087	0.148*	0.137†	0.799

4.5.2. Structural Model

Table 9. Hypotheses results

Hypotheses	Unstandardized Estimate	Standard error	p-value	Results
Direct Effects				
H1 SCCB → ITI	0.421	0.218	0.053	<i>Supported</i>
Moderating Effects				
H2 AOT x SCCB → ITI	0.168	0.079	0.034	<i>Supported</i>
H3 BOT x SCCB → ITI	-0.042	0.043	0.332	<i>Not supported</i>

To test the above hypotheses, a structural equation model (Bagozzi, 1994) was developed to assess the statistical significance of the proposed relationships between SCCB, BOT, AOT and ITI (see Table 9).

All the fit measures indicated that the structural model was acceptable ($\chi^2/df = 1.484$, RMSEA = 0.042, 90% CI for RMSEA = (0.032; 0.051), CFI = 0.963, and SRMR = 0.0509).

The unstandardized regression weights show that two out of three hypotheses that were proposed in the model were supported.

The estimated values of the path coefficients provided empirical support for the direct effect postulated in our model (see Table 9). Thus, results showed that SCCB has a positive and direct effect on ITI ($b_1 = 0.421$; $p = 0.053$), thereby providing empirical support for H1.

In this study, the moderating effect of the patient characteristics (being) Ahead of Trend and the patient's burden of treatment was evaluated, as they may interfere with the intensity of the relationships, which alters the influence of socially conscious consumer behavior on chronic disease patients' intention to innovate.

Based on this premise, we evaluated the hypothesis that the variables (being) Ahead of Trend (H2) and burden of treatment (H3) would have a positive moderating effect on the relationship between patients' social consciousness and their innovative intention were evaluated.

We found out that AOT positively moderates the impact of SCCB on ITI ($b_2 = 0.168$; $p = 0.034$), but we did not find empirical support for the moderating effect of BOT on the relationship between SCCB and ITI ($b_3 = -0.042$; $p = 0.332$). Therefore, the results seem to support H2, whereas H3 is not proven to be statistically significant. This means that the characteristic Being Ahead of Trend strengthens the relationship between Socially Conscious Consumer Behavior and Intention to Innovate.

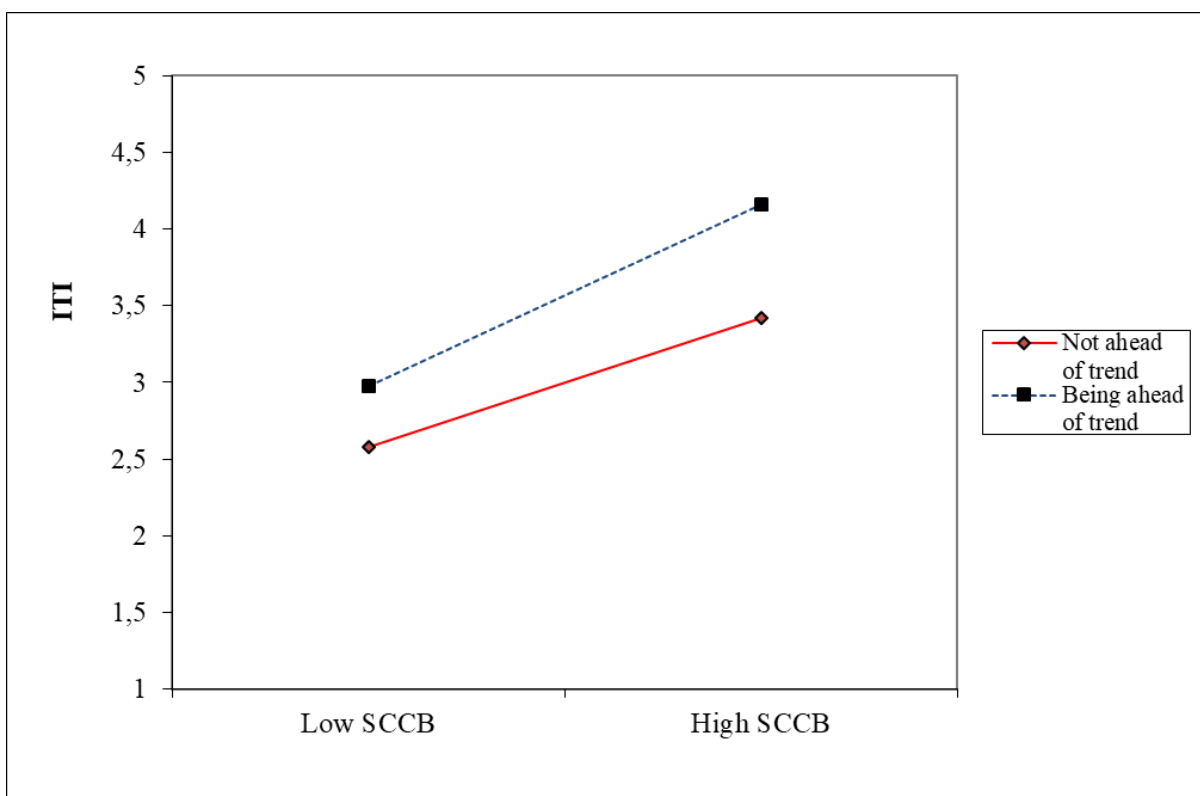


Figure 1. The moderating effect of (being) Ahead of Trend

Being Ahead of Trend strengthens the relationship between Socially Conscious Consumer Behavior and Intention to Innovate.

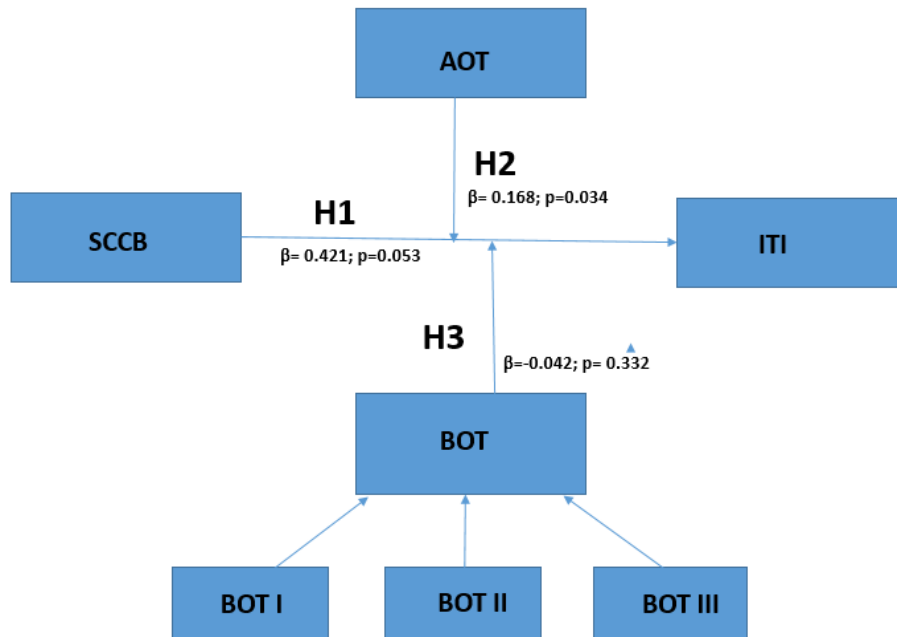


Figure 2. Model Testing Results

Independent variable: socially consciousness consumer behavior (SCCB). Dependent variable: intention to innovate (ITI). Moderators: (being) ahead of a trend (AOT) and burden of treatment (BOT) with three sub-dimensions (pharmacological treatment (BOT I), comprehensive healthcare (BOT II), psycho-social-economic context (BOT III)

4.6. Theoretical Contributions

This study makes a number of valuable contributions to the emerging phenomenon of patient innovation. Firstly, by surveying over 300 chronic disease patients via patients' organizations, we found that patients' socially conscious behavior is positively related to their intention to innovate. This finding resonates with previous empirical studies on user innovativeness in communities that have revealed that altruism prompts users to engage in innovation (Harhoff et al., 2003; Hars & Ou, 2002; Lakhani & von Hippel, 2003; Franke & Lüthje, 2020). When users innovate, they aim to generate user value predominantly for themselves rather than for a broader market. They try to solve problems for their immediate environment: either for themselves or their relatives, friends, or community. Their innovation activities are often not motivated by monetary profit but by self-reward such as: feelings of altruism, fun, signaling competence to and helping their community of peers. In fact, one of the strongest motivations for innovating is the idea that innovations benefit the community — which is reflective of social processes, not of personal benefits (Franke & Shah, 2003; Raasch & von Hippel, 2013).

Secondly, our findings show that (being) Ahead of the Trend positively moderates the relationship between socially conscious behavior and intention to innovate. This means that the more patients are ahead of market trends, the stronger it will influence their socially conscious behavior on their intention to innovate. This finding is in line with von Hippel's lead usersness theory, which states that users who are ahead of an important market trend will be most likely to innovate and develop attractive innovations (von Hippel, 1986). The direct positive effect of the users' (being) Ahead of the Trend has already been proven in many fields (e.g., in the fields of CAD systems, kite surfing, library information systems, surgery, canyoning, boardercross, handicapped cycling, and sailplaning) (Urban & von Hippel, 1988; Franke et al., 2006; Morrison et al., 2000; Franke & von Hippel, 2003; Franke & Shah, 2003; Lüthje, 2004; Lüthje & Herstatt, 2004), although it has not been investigated in the context of patient innovation. In addition, to the best of our knowledge, this is the first study that linked patients' (being) Ahead of the Trend characteristics as a moderating factor which enhances the positive impact of patients' socially conscious behavior on their intention to innovate.

Thirdly, our research contributes to the literature by showing that the burden of treatment does not moderate the relationship between SCCB and ITI. This finding was somewhat surprising as we expected that a greater treatment burden would strengthen the relationship between socially conscious consumer behavior and intention to innovate and ultimately lead to greater innovative activity. To the best of our knowledge, this research is the first in the user (patient) innovation field to consider the burden of treatment as a potential factor influencing innovation, even though recently there has been more focus on the concept of burden of treatment in the literature. We included the construct of burden of treatment (BOT) as a measure of serious disruption or unmet treatment needs patients face in managing their disease. Research so far has shown a positive association between the expected benefits from innovations in satisfying users' previously unmet needs and users' intention to innovate (von Hippel, 1986; 2006). Users' unmet needs as a factor that triggers the innovation of new, commercially attractive, "leading edge" products and services has previously been demonstrated in the fields of computer-aided systems for the design of printed circuit boards (PC-CAD) (Urban & von Hippel, 1988), kite surfing (Franke et al., 2006), library OPAC search systems (Morrison et al., 2000), open source software design (Franke & von Hippel, 2003), sailplaning, canyoning, boardercross snowboarding, handicapped cycling (Franke & Shah, 2003) and outdoor-related consumer products (Lüthje, 2004). Therefore, we postulated that the higher burden of treatment (especially considering comprehensive healthcare aspects implicit in such a burden) would significantly and positively moderate the influence of socially conscious behavior on patients' intention to innovate. However, our data did not prove the hypothesis that the burden of treatment compounds the effect that SCCB has on ITI. The reasoning behind this could be that the survey participants were mainly based in Denmark and in other developed European countries. In many ways, Denmark's healthcare system is well equipped to deal with external stressors such as a global pandemic. Healthcare is available to everyone and is either free or heavily subsidized by the state. Death rates during the COVID-19 pandemic in developed countries (e.g. Denmark) were significantly lower than in the other parts of the world, so this might mean that in this context, patients did not experience the healthcare burden as much as they did in other countries during the pandemic.

Another reason might be that a high treatment burden prevailed over patients' social consciousness (for instance, if the patients' situation was so serious as to make them desperate to find a solution), this could add further complexity to the interpretation of the results.

4.7. Managerial Implications

As von Hippel (2006) states in his work, companies in various industries could benefit significantly from users' creative capabilities by involving them in the innovation process. Integrating lead users into corporate new product or service development has been shown to be a promising means of developing breakthrough ideas (e.g., Lilien et al., 2002; Urban & von Hippel, 1988). However, there is a major challenge in applying the lead-user method, namely identifying leading-edge users. In the context of patient innovation, the successful identification of lead patient innovators is vital, as they can contribute to improve other patients' quality of life by developing new products or services within the patients' communities, or within the commercial or research entities.

Our findings confirm that patient characteristics such as socially conscious behavior moderated by their ahead of trend characteristics would improve their intention to innovate.

Therefore, the healthcare industry and government regulators should support patients' innovative communities and help them develop in medically and socially valuable directions. Innovating in such communities would nurture patients' socially conscious and ahead of trend behavior and lead to more and better innovation. Managing and supporting patient innovative communities is an efficient way to empower patient innovators and facilitate their intention to innovate by enabling them to find innovation-related resources, information, knowledge and experience. The main challenge is to organize and manage patients' communities so as to effectively channel patients' innovation activities and make their innovations available to others.

4.8. Limitations and Future Research

This study has several limitations. One of the limitations, similar to that from other studies that involve online surveys, is that our sample is not representative of the general population of patients. Despite its limitations, however, the use of online surveys and platforms for data collection has its advantages (e.g., researchers are able to involve a large number of patients in a very short time).

The generalizability of the study's findings is limited to the specificity of the studied research context as the focus of the study is solely on user innovation among patients, which is different from user innovation in other sectors concerning regulations, stakeholders etc. This implies that not all the findings can be easily generalized into other contexts. To acquire a different perspective

in other sectors, future researchers may perform this study in a different context or do a comparative study between different sectors.

Even though this study has surveyed more than 300 chronic disease patients, research on user innovation would benefit further from empirical testing on a larger scale.

Thirdly, as the study has been conducted solely through a survey method, this could lead to mono-method bias. To deal with this concern, future research could triangulate the survey and validate the data qualitatively (e.g., with the use of semi-structured interviews with patient innovators or through observations of patient communities).

Another limitation is that both literature and data clearly show that the burden related to comprehensive healthcare depends on the country where the respondents reside. More research is needed to understand the specific aspects of treatment burden, and how and why patients might experience these different aspects in different countries (e.g., in Denmark, the public health insurance program guarantees free healthcare for patients with chronic conditions). We suggest that future research could study the effect of burden of treatment on intention to innovate among patients in other contexts, i.e. in less developed countries.

Additionally, it will be interesting to explore the association of burden of treatment with innovation likelihood among rare disease patients.

Finally, the intention to innovate and to develop a solution will depend on the users' skills, their contacts and networks. Therefore, other user innovators' characteristics such as technical expertise, community-based resources and personality could also be explored in relation to intention to innovate.

Despite the limitations, we believe that this study will enrich user innovation theory with a better understanding of the user innovation process and further enhance patient innovation.

4.9. References

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5. THE IMPACT OF INNOVATION-RELATED RESOURCES AND LEGAL BARRIERS ON USER INNOVATORS' WILLINGNESS TO SHARE: A STUDY OF PATIENT INNOVATION

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5.1. Abstract

Research reveals that users develop innovations to serve their own and their community's unmet needs. However, social welfare benefits of user innovations will be considerable only if user-developed innovations of general value are shared with others who can benefit from them. Therefore, user innovators' willingness to share innovations is a key concept that needs investigation. By utilizing a sample of chronic disease patients (end-users of healthcare products and services), the present study explores the impact of innovation-related resources (technical expertise and community-based resources) on users' willingness to share their innovations. Furthermore, this study investigates the moderating effect of legal barriers on the relationship between innovation-related resources and users' willingness to share innovations. The empirical findings supported the two hypotheses that technical expertise and community-based resources both positively affect users' willingness to share innovations. However, the findings also suggested that legal barriers weaken the positive effect of community-based resources on willingness to share. Consequently, the study paves the way for further research on the effect of legal barriers on user innovation diffusion. This paper provides a first empirical analysis of the independent effects of two key variables (technical expertise and community-based resources) on users' willingness to share. The findings could be valuable for advancing the field of user innovation and to manufacturers and policymakers interested in benefiting from user-developed innovations.

Keywords: user innovation, patient innovation, willingness to share, innovation diffusion, community-based resources, technical expertise, legal barriers

5.2. Introduction

Since von Hippel's seminal work (1976) showed that users can be major sources of innovation, user innovation literature has grown tremendously. Further research confirms that both the scope and scale of user innovation is substantial (von Hippel et al., 2011). Moreover, users are particularly good at developing breakthrough innovations (Lettl et al., 2006; Lilien et al., 2002).

User innovators are driven by the aim to generate value for themselves rather than the broad market. By innovating, they try to solve unfulfilled needs for themselves or their immediate environment. Therefore, users' incentives to innovate differ from producer innovators' as innovation market potential is not as important for user innovators (Pieper and Herstatt, 2018). Instead, they are more likely to innovate if their expected benefits from innovation are higher (Riggs and von Hippel, 1994). However, while users often have an advantage over producers with respect to "need knowledge" (unique expertise and experience in product use), they generally lack knowledge of efficient technical solutions to manufacture their innovation, i.e. "solution knowledge" (Franke and Shah, 2003; Henkel and von Hippel, 2004; Lakhani and von Hippel, 2003; Slaughter, 1993).

Patients, end-users of healthcare products and services, have a strong incentive to innovate, since they expect to benefit from the use of these self-developed solutions (Habicht et al., 2013). Their unique "need" knowledge is acquired through their own experience of use, translated as everyday lives with their conditions (von Hippel, 1986). Some patients have specific and hardly transferable perceptions of their needs and are well positioned to develop solutions to their unmet medical needs. The "stickiness" of this information (cost or difficulty of transferring information) reduces the ability of users (patients) to advise producers of their needs. This often shifts the locus of innovation to users (patients) themselves (von Hippel, 1994; Göldner, 2021).

However, social welfare benefits from user innovations will be considerably enhanced only if user-developed innovations are diffused to others who can benefit from them (de Jong et al., 2015). Although research shows that millions of users innovate, few of these innovations are shared (Canhão et al., 2017). For instance, in a Finnish study on clinician-developed innovations, only 19% of them were shared (von Hippel et al., 2017). Another study on rare and chronic disease patient innovation shows that 32% of those who developed solutions, shared information with others (Oliveira et al., 2015). In both studies, user innovators believed that most innovations that were not shared could be valuable to others. Some of the reasons why patient innovators are reluctant to share innovations are lack of financial incentives and skills, or a time-consuming process of approval and commercialisation (Canhão et al., 2017). According to von Hippel et al. (2014, 2017), the lack of sharing innovation is a type of market failure, as the value gained from user innovation could be an externality to users themselves. If user innovators invest more in innovation diffusion, social welfare will accordingly increase.

Therefore, an important question is: how can more user innovators be helped to bring their innovative solutions to a wider audience? (Canhão et al., 2017). User innovation diffusion within user communities and to the broad market is, to our knowledge, underexplored by both user

innovation theory in general (Baldwin et al., 2006; Franke and Shah, 2003) and patient innovation literature in particular. Given the importance and increased research interest in the user innovation phenomenon, this study aims to fill a gap in the literature, exploring factors that influence users' willingness to share innovations by addressing the following research questions:

RQ1: What is the impact of users' technical expertise (TE) on their willingness to share (WTS) their innovations?

RQ2: What is the impact of community-related resources (CBR) on users' willingness to share (WTS) innovations?

RQ3: Do legal barriers (LB) moderate the technical expertise (TE) impact on users' willingness to share (WTS) innovations?

RQ4: Do legal barriers (LB) moderate the community related resources (CBR) impact on users' willingness to share (WTS) innovations?

To answer these questions, the author developed a model to explore the relationship between innovation-related resources (users' TE and access to CBR) and users' WTS. Moreover, the moderating effect of LB was also investigated. To test the model, the author collected data by surveying 318 chronic disease patients. The findings showed that TE and CBR have a positive impact on the user innovators' WTS. Furthermore, the results indicated that LB negatively moderate the effect of CBR on users' WTS innovations.

The study contributes to the under-researched phenomenon of patient innovation, and its novelty comes from different aspects. It is the first empirical study that explores the impact of innovation-related resources (TE and CBR) on users' WTS innovations, and, and it is the first to investigate the moderating effect of LB on WTS. Moreover, the study suggests a negative moderating effect of LB on users' WTS. This finding, to some extent, contradicts current literature, which does not consider LB an issue when user innovations are diffused non-commercially (de Jong and von Hippel, 2009; Demonaco et al., 2020). The findings are important both with respect to advancing the field of user innovation and to practical matters for manufacturers and policymakers interested in benefiting from user innovations.

5.3. Theoretical Background

5.3.1. User Innovation

User innovation is an innovation mode that increasingly competes with and may displace producers' innovations in many parts of the economy (Baldwin and von Hippel, 2011). This shift is facilitated by the availability of low-cost, web-based communication and transition to digitized design and production practices (ibid). Von Hippel et al. (2011) show that millions of people innovate according to their needs and that user innovations represent a significant share of the overall R&D spending of many countries. Several empirical studies found out that users'

contributions to total innovation output are much higher than previously considered (von Hippel et al., 2011; von Hippel, 2017). There are many user innovation studies in various fields, such as printed circuit CAD software (Franke and von Hippel, 2003a; Lakhani and von Hippel, 2003), construction industry (Herstatt and von Hippel, 1992), scientific instruments (Riggs and von Hippel, 1994), sporting equipment (Baldwin et al., 2006; Franke et al., 2006; Lüthje et al., 2005; Tietze et al., 2015), banking services (Oliveira and von Hippel, 2011), process equipment (de Jong and von Hippel, 2009; von Hippel and Tyre, 1995) and procedures' innovation (Habicht et al., 2013). Furthermore, in a study conducted with cystic fibrosis patients, 50% of the medical devices were developed by patients (Hinsch et al., 2014).

Early user innovation studies justified user innovators as a significant source of new products in different industries (e.g., Shaw, 1985; Slaughter, 1993). Later research focused mainly on the lead user-innovator identification and use of innovation toolkits (e.g., Franke and von Hippel 2003a, 2003 b, Franke and Piller, 2004; Franke and Schreier, 2002; Jeppesen, 2005; Morrison et al., 2000; von Hippel, 2001). Recently, intellectual property and ownership-related topics have been researched in relation to user innovation processes (e.g., Bauer et al., 2016; Bosch-Sijtsema and Bosch, 2015; Hyysalo et al., 2016; Pieper and Herstatt, 2018; Tietze et al., 2015). User innovation contrasts with producer innovation, which is dominated by patent policy. As user innovators often benefit from “freely revealing” their innovations to others, patenting and trade secrecy are not central motives for their inventive activity (Strandburg, 2008).

5.3.2. Patient Innovation

User innovation in health care follows the general patterns of other product and services industries (Habicht et al., 2012; Oliveira et al., 2015). To highlight the health care context, Zejnilović et al. (2016) refer to user innovation by patients and their caregivers as “patient innovation”. The patients and caregivers acquire distinct “need knowledge” (different from healthcare professionals' knowledge) as they deal with unfulfilled medical needs (von Hippel, 1994). The knowledge about their own conditions and their unmet needs (“need knowledge”) is the starting point for innovation. Yet they have to acquire “solution knowledge” (Schweisfurth, 2017), i.e., legal, technical and regulatory knowledge, during the innovation process (Göldner, 2021). Patients want to heal, and they are willing to invest in what they need to do so (Halabi and Richard, 2020). They invest significant time and effort searching for information about the state of information about the state of their health, a specific health condition and its management, or about disease prevention (Brashers et al., 2002; Zejnilović et al., 2016). They act proactively and become experts in their health issues (Hartzband and Groopman, 2010).

Furthermore, other reasons also facilitate patient innovation. The world's population is getting older and chronic diseases have taken over as the main cause of death (Suzman et al., 2015; World Health Organization, 2022). As chronic diseases are associated with a significant decrease in health-related quality of life, patients have a strong incentive to increase their knowledge about their disease (Göldner, 2021; Rothrock et al., 2010). On the other side, health spending has

increased faster than economic growth in all OECD countries within the last 20 years (www.oecd.org, 2015). Therefore, all stakeholders in the healthcare value chain welcome solutions that contribute to improving individual well-being and reducing costs. A logical step is to empower those with the strongest needs to contribute — patients (Zejniliović et al., 2016).

There is evidence that healthcare professionals, as “intermediate users”, develop solutions or devices for their work-related needs and their patients’ unmet needs (Chatterji, 2009; Lettl et al., 2006; Lüthje and Herstatt, 2004). More recently, there is a growing body of examples of patients (“end users” of healthcare products and services) who developed solutions that made a significant impact on medical practice and improved quality of life (Jacinto et al., 2021; Oliveira et al., 2015). However, the literature on patients as innovators is still scarce (Habicht et al., 2013; Oliveira et al., 2015), particularly in the case of chronic diseases (Göldner, 2021).

5.3.3. Willingness to Share

Social welfare benefits of user innovations will be considerable only if the user-developed innovations of general value are diffused to others who can benefit from them (de Jong et al., 2015). Innovation diffusion is defined as “the process by which an innovation is communicated through certain channels over time among members of a social system” (Rogers, 2003). Users share their innovations either within a peer-to-peer network or through producers that place the innovations on the market (Baldwin et al., 2006; de Jong et al., 2015; Harhoff et al. 2003). However, empirical data show that user innovation diffusion is inefficiently low from a social welfare perspective: the fraction varied from 5% to 17%, with the most common diffusion pathway being peer-to-peer (de Jong et al., 2015; von Hippel et al., 2012). Certainly, users invest less than might be socially desirable to inform or assist others to adopt their innovations, even when such innovations would be highly valuable to others (de Jong et al., 2015; von Hippel et al., 2014; Zejniliović et al., 2016).

User innovators may choose to protect their inventions by trade secrecy or patenting, but in most cases, legal protections are not the central motivation for users to engage in innovation (Goldner, 2021). Instead, they often “freely reveal” their innovations, i.e., they are open to others at no cost, and all parties are given equal access to them (de Jong and von Hippel, 2009; Harhoff et al., 2003). Accordingly, it is important to understand *why* user innovators would invest time and money in sharing their innovations without any expectation of being paid for either their labour or product designs.

There are few incentives for users to share their innovations freely (de Jong et al., 2018; von Hippel, 2017). Researchers argue that user innovators’ willingness to share stems from altruism (Sahlins, 1972) or collective norms (Ekeh, 1974; Franke and Shah, 2003). One of the main reasons is the individual benefits from using the innovations rather than from selling them (Harhoff et al., 2003; Strandburg, 2008). Positive peer feedback is another reason for users to share innovations within their community (Göldner, 2021). Innovators often get valuable feedback and improvement suggestions from adopters (de Jong and von Hippel, 2009). Moreover, free access

to user innovations usually increases diffusion, which then increases the innovations' value through network effects (de Jong et al., 2015). Free revealing of innovations could also lead to a rise in innovators' reputation (de Jong and von Hippel, 2009; Demonaco et al., 2020). Additionally, by participating in the user innovation projects, participants derive valuable private gains such as fun and learning (de Jong and von Hippel, 2009).

The free diffusion of user innovations has been reported in various industries and sectors, such as library information systems (Morrison et al., 2000), sporting equipment (Franke and Shah, 2003), semiconductor production (Harhoff et al., 2003), household sector (de Jong et al., 2018; von Hippel, 2017) and web server software (Balka et al., 2015; Füller et al., 2013; von Krogh and von Hippel, 2006).

In the patient innovation context, innovation diffusion is inefficiently low and is mainly to other patients the innovators already know (Oliveira et al., 2015). Patients make their own non-commercial copies from free designs (Demonaco et al., 2020). It is important to emphasise that when patient innovations are diffused non-commercially, they are exempt from the Food and Drug Administration (FDA), the European Medicines Agency (EMA) or other medical authority regulations; similarly, legal barriers are not considered an issue. Zejnilović et al. (2016) discuss that patient innovators are willing to share their innovations with others, when there is a convenient way to do so. However, without infrastructure that enables easy sharing, adequate support to explain the innovations and make them easily replicable, any attempt to enhance innovation diffusion is likely to fail (*ibid*). From this perspective, online communities are one of the ways for user innovators to disseminate and further improve their innovations with their peers (Franke et al., 2008; Göldner, 2021; Hienert and Lettl, 2011). Patient communities offer both CBR and technical knowledge-sharing among the members. Therefore, the present study aimed to investigate the impact of CBR and TE on user innovators' WTS.

5.4. Hypotheses Development

The study's conception is based on the proposed model (Figure 3), which applies user innovation theory in the healthcare context. We analysed TE and CBR as independent variables in connection with the dependent variable WTS. Furthermore, we employed LB as a moderating variable because previous studies have demonstrated that LB are not a concern for non-commercial user innovation diffusion (de Jong and von Hippel, 2009; Demonaco et al., 2020). Furthermore, to the best of our knowledge, the construct of LB has not yet been investigated in the context of WTS.

5.4.1. Technical Expertise

The user innovation process requires certain preconditions like users' technical knowledge or experience. Patients have extensive knowledge about their own conditions and unfulfilled medical needs ("need knowledge"), which could be used when developing medical devices or solutions. They acquire "solution" knowledge (i.e., technical, legal, and regulatory knowledge) if needed,

mostly through education (Goeldner and Herstatt, 2016). They use their pre-existing technical knowledge and skills to develop solutions to problems they experience (Lüthje et al., 2005). Users with higher technical knowledge on how devices and equipment function are shown to be more likely to innovate. They are able to relate technologies to new areas as they have technical expertise to know how the varied technical issues may be solved (Boh et al., 2014). Franke et al. (2006) define technical expertise (TE) as users' ability to actually make modifications or changes to existing equipment.

Lüthje et al. (2005) has divided innovators' TE in two components: "use" experience and technical knowledge (theoretical knowledge, knowledge from other fields and practical skills). These authors introduce the term "innovation-related resources" (which includes TE and CBR) and confirm the positive relationship between the innovation-related resources and innovation likelihood in the mountain biking community (ibid).

However, to our knowledge, neither TE nor CBR have been studied in connection with user innovators' WTS innovation.

In the patient innovation context, as in other user innovation contexts, TE is considered crucial for innovation. Could TE lead to innovators' higher WTS their innovations? Would user innovators' expected benefits (i.e., recognition of their technical expertise, increase in respect and reputation gains within their community) lead to their increased WTS innovations within the community?

Therefore, the present study examined whether innovators' technical capabilities would lead to higher WTS innovations across the community.

H1 Technical expertise has a positive effect on users' willingness to share.

5.4.2. Community-Based Resources

Recently, an increasing number of non-profit initiatives such as patient communities have emerged aiming to support patients' innovation potential. Patient communities have become an integral part of the everyday lives of chronic disease patients. It is through these communities (online or in person) that they give each other support, and share knowledge and experiences on how to better manage their diseases. They are not only potential venues for information exchange but also for collaboration in the innovation process.

The website PatientsLikeMe (<https://www.patientslikeme.com/>) is a health data-sharing platform which facilitates the collection of patients' vital health indicators related to their medical conditions in order to disseminate this information to patients with similar illnesses. By using big data, one patient could use information shared by others to further advance their own medical knowledge. Another online non-for-profit platform is Patient Innovation (<https://patient-innovation.com/>) where patients, as part of a community, freely share various solutions that could improve their conditions.

The community-based system provides user innovators with access to resources (information, assistance, and links to other innovators). Within these communities, individuals often assist other innovators even if they will not benefit from the innovation themselves or receive anything in return. Franke and Shah (2003) explore why community members provide innovation-related assistance and why they freely reveal their innovations. If the activities are self-rewarding, individuals exchange information and assistance without financial reward (Czikszenmihalyi, 1996). From this perspective, they do not perceive their contributions as costs that need to be compensated, but rather as activities that are enjoyable in and of themselves (Franke and Shah, 2003). In fact, the motivation for assisting is the enjoyment they gain from working with others while innovating and the idea that innovations benefit the community — are reflective of social processes, not of personal benefits (Raasch and von Hippel, 2013).

In the healthcare context, the most significant benefits from the community-based system are the knowledge and experience-sharing among patients with similar health conditions (Zejnilović et al., 2016). In that sense, community matters not only in directly providing resources for innovation development, but also in influencing the process by which these resources are shared and exchanged (Franke and Shah, 2003).

However, the influence of CBR on users' WTS innovations is something yet to be investigated. Therefore, we hypothesized that:

H2 Community-based resources have a positive effect on users' willingness to share.

5.4.3. Legal Barriers

Despite the existence of a large body of data on user innovation, the literature provides only a few insights into the effects of barriers on this phenomenon (Braun and Herstatt, 2007; Pieper and Herstatt, 2018). Innovation barriers are factors impeding user innovation-related activities during a certain period of time (Pieper & Herstatt, 2018; Raasch et al., 2008). Furthermore, barriers to user innovation diffusion hinder user innovators' ability to generate social welfare (Svensson and Hartmann, 2018).

Initial work on user innovation barriers was done by Braun and Herstatt (2007; 2008; 2009), who classified the barriers into financial, technological, social, and legal. According to the authors, legal barriers (LB) have a significant impact and directly affect user innovators in legally "gray" areas (ibid). To proceed with the innovation, users often face barriers such as warranties or guarantee rights on products and components or problems derived from patents, copyrights or secure codes (Braun and Herstatt, 2007, 2008; Morrison et al., 2004; Pieper and Herstatt, 2018). For instance, some manufacturers in the medical device sector hamper user innovation by implementing measures that prevent users from modifying their products (Braun and Herstatt, 2008). This may partially be explained by restrictive medical device regulations that hinder medical device modification (Göldner, 2021). Policymakers and administrations build up legal requirements, liability laws or laws limiting tinkering (Braun and Herstatt, 2007).

Directly linked to the legal barriers' issue is the impact of ownership on user innovation as only users with private ownership possess the right to modify products (Pieper and Herstatt, 2018; Tietze et al., 2015). Recently, intellectual property and ownership-related topics have started to attract researchers' interest (Bauer et al., 2016; Bosch-Sijtsema and Bosch, 2015; Hyysalo et al., 2016; Tietze et al., 2015). Moreover, some authors argue that intellectual property law is one of the most significant areas of legislation that needs to be changed to allow patient innovation (Halabi and Richard, 2020).

Nevertheless, studies show that it is quite rare for user innovators to attempt to protect or restrict access to their innovations (Raasch et al., 2008). One of the reasons could be the high costs of obtaining IPR protection as patents usually cost thousands of dollars to apply for and take years to obtain. Rather than seeking to protect their designs, as commercial innovators do, more than 90% of user innovators make their designs available to everyone for free (Demonaco et al., 2020).

In healthcare innovation, certain aspects are unique, e.g.g., the complex and time-consuming process of regulatory approval of new drugs and medical devices. Whereas new drug approval takes an average of 12 years, moving a new medical device from concept to market takes an average of 3 to 7 years (Fargen et al., 2013). It is relevant here to acknowledge that safety in patient innovations is not guaranteed and various safety concerns could hinder the innovation process (Demonaco et al., 2020). Patient innovators cannot simply adopt FDA gold-standard clinical trial designs to prove how safe their innovations are, as these trials are too expensive and time consuming for them to conduct on their own (*ibid*). Moreover, it is not legal for patient innovators to sell copies of their innovations without receiving regulatory (e.g., FDA or EMA) approval (Torrance and von Hippel, 2015; Demonaco et al., 2020). However, free sharing of patient innovations is a non-commercial activity and does not require regulatory approval. The innovation can be diffused non-commercially allowing users to make their own copies (Demonaco et al., 2020), implying that there are no legal constraints in free diffusion of patient innovations.

Although barriers negatively influence user innovation-related activities (Raasch et al., 2008), there is scant evidence of their impact on users' WTS innovations. To explore this phenomenon, we employed the construct of LB as a moderator, hypothesizing that it negatively moderates the positive impact TE and CBR may have on users' WTS.

H3 The relationship between technical expertise and users' willingness to share is negatively moderated by legal barriers.

H4 The relationship between community-based resources and users' willingness to share is negatively moderated by legal barriers.

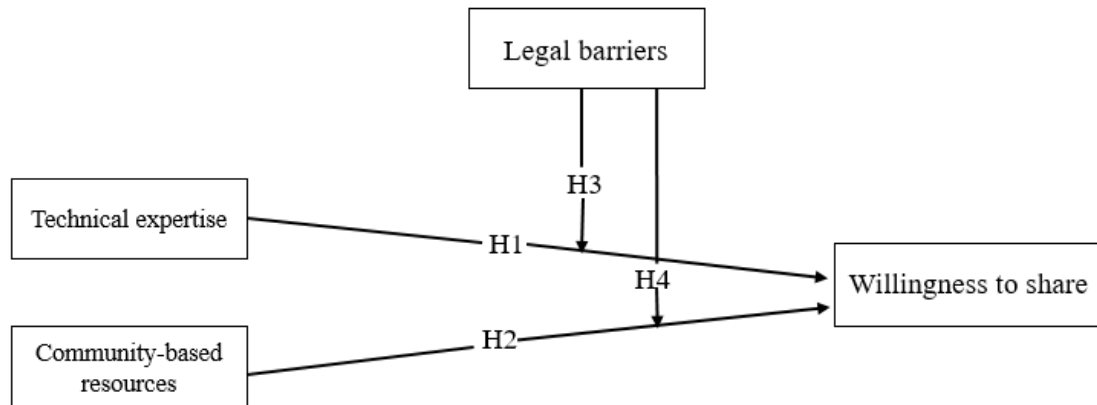


Figure 3. Conceptual framework and research hypotheses

Independent variables: Technical expertise (TE), Community based resources (CBR). Dependent variable: Willingness to share (WTS). Moderator: Legal barriers (LB)

5.5. Methodology

5.5.1. Data Collection and Sample

Data collection was conducted in autumn 2021 and early 2022. An online survey was sent to several European chronic disease organizations. As the author is based in Denmark, mostly Danish patient organizations were contacted. The survey was also distributed through the European Patient Forum’s newsletter to reach a wider audience. The survey was either posted directly on the organizations’ websites or sent to their members by newsletter or via email by patient organization leaders. The patient organization leaders were chosen as they have already established trusting relationships with the members. Where necessary, at least one reminder was sent out.

The purpose of the study was outlined, the participants were informed that they were under no obligation to participate and that their aggregated results may be published. Furthermore, they were presented with the right to withdraw from the project and to issue complaints to relevant data protection authorities (e.g., Datatilsynet, www.datatilsynet.dk). The respondents were also given the chance to participate in a lottery. An ethical approval was obtained from the local Ethics Council. According to local Ethics Council guidelines, participants were not asked about any

sensitive data (e.g., type of chronic disease they had). The data were analysed as part of a group with no individual disclosure of information according to the Helsinki Declaration for human studies.

The survey was pre-tested using the following steps. Firstly, three experts in user and open innovation evaluated the formulation and adequacy of the questionnaire. Then, feedback on the survey was provided by the patient organization leaders. Lastly, a few target respondents pre-tested the survey and provided feedback about the wording, clarity, and relevance of the items. Throughout the survey, we provided definitions and examples in order to familiarize respondents with some of the more technical terms. Attention checks were included through the survey as a way of finding out if the respondents had paid attention to the questions (Abbey and Meloy, 2017).

The data collection process resulted in 318 responses, out of which 43 did not pass the attention check test or had missing data. The responses with missing data were deleted from the list and excluded from further analysis according to the most common approach for dealing with missing data (Graham et al., 2003). This resulted in 275 responses that were used for further analysis.

5.5.2. Survey and Measures

The survey consists of four constructs that were measured by adapting existing scale items from innovation literature (see Table 10). There were 22 questions divided into four constructs: i) technical expertise (TE); ii) community-based resources (CBR); iii) legal barriers (LB); and iv) willingness to share (WTS).

Innovation-related resources were divided into two conceptually independent, resource-based constructs: TE and CBR. Technical expertise (TE), defined as the ability of users to actually make modifications or changes to existing equipment (Lüthje et al., 2005), was measured by seven items, while community-based resources (CBR), the potential contacts which users can use at low or no cost when facing a problem with existing equipment (Franke et al., 2006), was measured by six items. They were measured using a 5-point Likert scale anchored from “strongly disagree” to “strongly agree”.

Legal barriers (LB) were measured using a 7-point Likert scale ranging from “strongly disagree” to “strongly agree”. The scale was adopted from Pieper and Herstatt (2018) and describes how user innovators felt influenced by: legal requirements, liability laws or laws limiting tinkering, warranties or guarantee rights and patents, copyrights or secure codes.

The willingness to share (WTS), a 5-point Likert scale, adopted from de Jong and von Hippel (2009) examined whether users would be willing to give access to their innovation to all interested parties without direct payment or other compensation.

Table 10. Constructs and items used in the survey

Construct	Items	Reference(s)	Note
Technical Expertise (TE)	I can repair my own medical devices.	Franke, von Hippel and Schreier (2006)	5–point Likert scale (1 = strongly disagree... 5 strongly agree).
	I try to keep up to date with regard to innovations, and possibilities with regard to my disease.		
	I can help other patients solve problems with their disease.		
	I am handy and enjoy mending and improving things.		
	I can make technical changes to my medical devices on my own.		
	I am a huge fan of the technical aspects within the area of medical devices.		
	I come from a technical background in my profession or education (e.g., engineering, chemistry, physics).		
Community-Based Resources (CBR)	If I wanted to make changes to my medical device, I would know enough people who could help me do so.	Franke, von Hippel and Schreier (2006)	5–point Likert scale (1 = strongly disagree... 5 strongly agree).
	When I encounter technical problems, I know exactly who to ask for advice.	Schweisfurth and Raasch (2015)	
	I know patients who are capable of repairing their own medical devices.		
	I know many patients who have a thorough knowledge of medical devices.		
	In my surrounding, I can find people who know how to help me make improvements to medical devices.		
	If I were to make changes to my medical devices, I could count on getting positive feedback about the changes from my patient peers.		

Legal barriers (LB)	<p>The fear of theft or plagiarism prevents me from innovating.</p> <p>Problems covering legal requirements, liability laws or laws limiting tinkering prevent me from innovating.</p> <p>Problems covering warranties or guarantee rights for the product or components I modify prevent me from innovating.</p> <p>Problems covering patents, copyrights or secure codes influence my innovation.</p>	Pieper and Herstatt (2018)	<p>7-point Likert scale</p> <p>(1 = strongly disagree... 7 = strongly agree).</p>
Willingness to share (WTS)	<p>Other parties interested in my innovation are welcome to inspect it.</p> <p>Other parties interested in my innovation are welcome to imitate it.</p> <p>I would be willing to share the design of my innovation with others.</p> <p>I would be willing to help others to adopt my innovation.</p> <p>I am prepared to share my innovation for free.</p>	de Jong and von Hippel (2009)	<p>5-point Likert scale</p> <p>(1 = definitely not... 7 = definitely yes).</p>

5.6. Results

5.6.1. Construct Validation

The variables in the research's hypotheses: technical expertise (TE), community-based resources (CBR), legal barriers (LB) and willingness to share (WTS) were measured by reflective complex construct measurement (Churchill, 1979).

The direct effects of the independent variables (TE and CBR) on the dependent variable (WTS) were hypothesized as being moderated by the construct of LB.

We employed confirmatory factor analysis with AMOS 26 using maximum likelihood estimation to fit the model to assess overall measurement quality (Anderson and Gerbing, 1988). The analysis of the model fit led to the dismissal of four items from the TE construct (TE7, TE2, TE3 and TE4) and three items from CBR construct (CBR2, CBR3 and CBR4) due to a low factor loading (lower than 0.5) (Bagozzi, 1994). After the removal of these items, all the values were within their acceptable ranges (Bollen, 1989). Global fit measures supported the study's measurement model ($\chi^2/df = 1.859$; RMSEA = 0.056, 90% CI for RMSEA = (0.044; 0.068), CFI = 0.950; and SRMR = 0.0458).

The Fornell-Larcker criterion (1981) was used to assess the degree of shared variance between the latent variables of the model. To establish convergent validity (CV), we considered the factor loadings of the indicators, composite reliability (CR) and the average variance extracted (AVE) (Hair et al., 2017). The AVE criteria (AVE > 0.5) were met for three constructs CBR (AVE = 0.520), LB (AVE = 0.645) and WTS (AVE = 0.546). Even though TE had a borderline AVE (0.482), the author decided to retain the last three items as research suggests the items per factor should range from three to five for factor representation (MacCallum et al., 1999; Raubenheimer, 2004). Moreover, the AVE value of less than 0.5 is considered acceptable when CR is higher than 0.6 (Fornell and Larcker, 1981). As the CR of TE was 0.729, the CV of this construct was accepted (Table 11).

Table 11. Validity & reliability analysis.

	CR	AVE	MSV	MaxR(H)	LB	CBR	TE	WTS
LB	0.878	0.645	0.161	0.895	0.803			
CBR	0.763	0.520	0.318	0.791	-0.401***	0.721		
TE	0.729	0.482	0.318	0.772	-0.302***	0.564***	0.694	
WTS	0.855	0.546	0.159	0.893	-0.253***	0.398***	0.387***	0.739

LB – Legal Barriers; CBR – Community-based resources; TE – Technical expertise; WTS – Willingness to share

* $p < .050$ ** $p < .010$ *** $p < .001$.

Outer loadings value could be considered for deletion if removing indicators with outer loadings between 0.40 and 0.70 contributes to an increase in CR and AVE (Ab Hamid et al., 2017). On the other hand, indicators with outer loading below 0.40 should always be removed (Hulland, 1999). In the proposed model, all factor loadings varied from 0.50 to 0.90, satisfying the CV criterion (see Table 11).

To test the reliability of the construct, CR and maximum reliability (MaxR) were used (Bacon et al., 1995; Raykov et al., 2016). The reliability of each construct was satisfactory with a CR value of at least 0.70 and a MaxR of at least 0.70. Individual item's reliability was checked using Cronbach's alpha and ranged from 0.704 to 0.877 (Tavakol and Dennick, 2011). Cronbach's alpha values were for LB (0.877, good); for CBR (0.752, acceptable); for WTS (0.850, good) and for TE (0.704, acceptable). These results provide evidence for the CV of the constructs used in this study (see Table 11).

The researchers assessed discriminant validity using Fornell-Larcker criterion (1981). This method compares the square root of the AVE with correlation of latent constructs as latent constructs should explain better the variance of its own indicator rather than the variance of other latent constructs. In the present model, the square root of each construct's AVE has a greater value than the correlations with other latent constructs suggesting sufficient discriminant validity (Hair et al., 2017; Ab Hamid et al., 2017).

Table 12. Standardized factor loadings

Items		TE	CBR	LB	WTS
TE1	I can repair my own medical devices.	0.74			
TE5	I can make technical changes to my medical devices on my own.	0.80			
TE6	I am a huge fan of the technical aspects within the area of medical devices	0.50			
CBR1	If I wanted to make changes to my medical device, I would know enough people who could help me do so.		0.64		
CBR5	In my surrounding, I can find people who know how to help me make improvements to medical devices.		0.83		
CBR6	If I were to make changes to my medical devices, I could count on getting positive feedback about the changes from my patient peers.		0.68		
LB1	The fear of theft or plagiarism prevents me from innovating.			0.66	
LB2	Problems covering legal requirements, liability laws or laws limiting tinkering prevent me from innovating.			0.83	
LB3	Problems covering warranties or guarantee rights for the product or components I modify prevent me from innovating.			0.88	
LB4	Problems covering patents, copyrights or secure codes influence my innovation.			0.82	
WTS1	Other parties interested in my innovation are welcome to inspect it.				0.71
WTS2	Other parties interested in my innovation are welcome to imitate it.				0.66
WTS3	I would be willing to share the design of my innovation with others.				0.90
WTS4	I would be willing to help others to adopt my innovation.				0.78
WTS5	I am prepared to share my innovation for free.				0.61
Cronbach's alpha		0.704	0.752	0.877	0.850

TE – Technical expertise; CBR – Community-based resources; LB – Legal Barriers; WTS – Willingness to share

An empirical model was analysed by applying multivariate regression methods. To test the above hypotheses, a structural equation model was developed to assess the statistical significance of the proposed relationships between TE, CBR, LB and WTS (see Table 13). All the fit measures indicated that the structural model is acceptable ($\chi^2/df = 1.859$, RMSEA = 0.056, 90% CI for RMSEA = (0.044; 0.068), CFI = 0.950, and SRMR = 0.0458).

After the general model fit of the data was tested, the author tested the parameters to decide whether to accept the proposed relationships between the constructs. The unstandardized regression weights (see Table 13) present that three out of four hypotheses proposed in the model were supported.

The estimated values of the path coefficients provided empirical support for the direct effects postulated in the present model (see Table 13). Accordingly, results showed that TE has a positive and direct effect on WTS at a significance level of 0.05 ($\beta_1 = 0.188$; $p = 0.021$). Furthermore, CBR had a positive and direct effect on WTS at a significance level of 0.01 ($\beta_1 = 0.256$; $p = 0.01$), thereby providing empirical support for H1 and H2 respectively.

We found that LB negatively moderates the impact of CBR on WTS on a significance level of 0.10 ($\beta_3 = -0.068$; $p = 0.085$), but we did not find empirical support for the moderating effect of LB on the relationship between TE and WTS ($\beta_5 = 0.040$; $p = 0.309$). Therefore, according to the results, H4 was supported, whereas H3 was not proven statistically significant. This suggests that LB weakens the impact of CBR on WTS (Figure 4).

Table 13. Hypotheses results

Hypotheses	Unstandardized Estimate	Standard error	p-value	Results
Direct Effects				
H1 TE → WTS	0.188	0.082	0.021	<i>Supported</i>
H2 CBR → WTS	0.256	0.099	0.010	<i>Supported</i>
Moderating Effects				
H3 LB x TE → WTS	0.040	0.039	0.309	<i>Not supported</i>
H4 LB x CBR → WTS	-0.068	0.040	0.085	<i>Supported</i>

TE – Technical expertise; CBR – Community-based resources; LB – Legal Barriers; WTS – Willingness to share

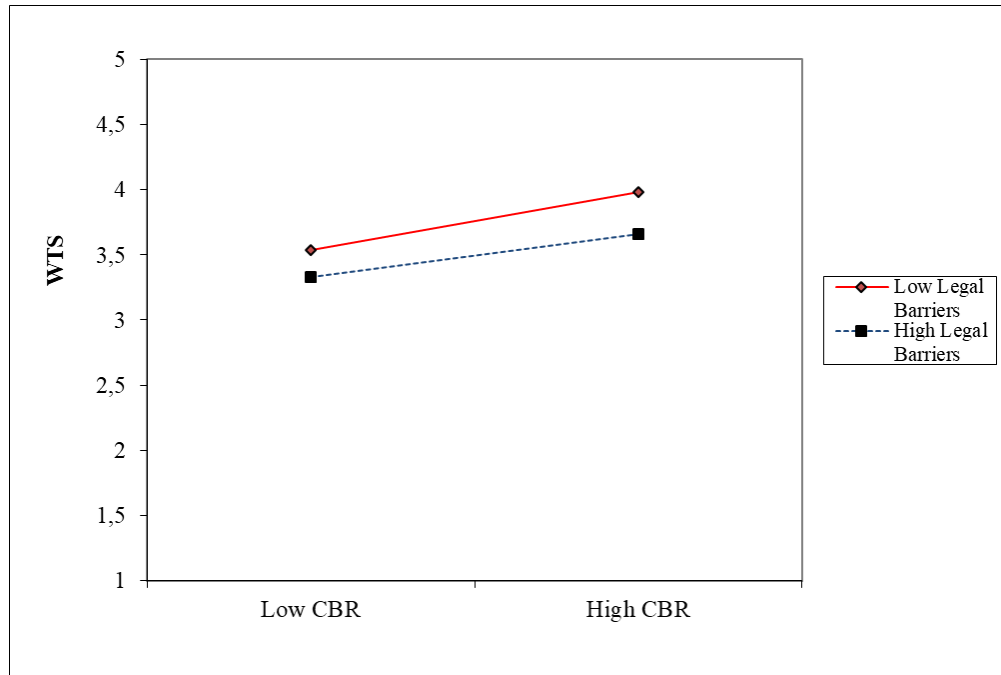


Figure 4. The moderation effect of legal barriers

Legal barriers weaken the relationship between community based resources and willingness to share.

LB – Legal Barriers; CBR – Community–based resources; WTS – Willingness to share

5.7. Discussion

5.7.1. Theoretical Contributions

The economic reality is that the healthcare industry will never be able to deliver everything patients need. Patient innovators, if properly supported, could be used to fill some of these gaps. Patients are driven by the objective to generate user value, predominantly for themselves rather than the broader market and only a small fraction of them commercialize their innovations (Shah and Tripsas, 2007; von Hippel, 2017). Although users are generally willing to share their innovations (Harhoff et al., 2003), they have neither incentives nor capacity to diffuse them commercially (de Jong et al., 2015; von Hippel, 2017). User innovators maximize their utility through non-pecuniary benefits, a common indicator for social innovation (Pol and Ville, 2009). This is in line with the emerging field of social innovation research and its connection to user innovation.

However, the social welfare benefits of user innovations are achieved only in cases where innovations are diffused to others who can benefit from them (de Jong and von Hippel, 2009).

Therefore, as important as user innovativeness is, sharing those innovations is equally important. Successful user innovations could lead to a few different outcomes: users could become entrepreneurs, sell or license their ideas to manufacturers or freely share their innovations within communities. Over time, the generally valued innovations would spread among the user community, and manufacturers would eventually produce some of them commercially. In the worst-case scenario, user innovators do nothing to diffuse their innovations and potentially valuable contributions get lost. Hence, users' willingness to share innovations is a key concept that needs further investigation. What are the factors that lead user innovators to share their own solutions within their community?

Although there is some literature on the topic, user innovation diffusion is, to our knowledge, largely unexplored by user innovation theory in general, and patient innovation literature in particular (e.g. Baldwin et al., 2006; de Jong and von Hippel, 2009; Franke and Shah, 2003).

Therefore, there are two main aspects about this study that make it novel: it is the first empirical study to explore the impact of innovation-related resources (TE and CBR) on users' WTS, and it investigates the moderating effect of LB on the relationship between innovation-related resources and WTS.

The study data shows that innovation-related resources (TE and CBR) have a positive impact on the users' WTS.

The likelihood of finding a positive relationship between TE and innovation was already proven in the mountain biking community: users with higher technical knowledge are more likely to innovate (Lüthje et al., 2005). However, to our knowledge, users' TE has not yet been studied in connection with their WTS.

Our survey, which was conducted among chronic disease patients, showed that patients' TE increases their WTS innovations. The positive impact of users' technical knowledge and expertise on their WTS could be explained by an expected increase in respect and reputational benefits they would receive within their community. This is in line with previous studies, which show that successful participation in the innovation community might leverage some job opportunities by building reputation among one's peers (Bogers et al., 2010; Lakhani and von Hippel, 2003).

Furthermore, this study is the first to report the significant positive association between CBR and users' WTS innovations. This finding could be explained by drawing on previous studies on user innovativeness in communities that have revealed that altruism, the idea of helping others, prompts users to engage in innovation (Franke and Lüthje, 2020; Franke and Shah, 2003; Harhoff et al., 2003; Lakhani and von Hippel, 2003). Additionally, users benefit from the process of innovation itself, as they simply enjoy problem-solving (Lüthje, 2004; von Hippel, 2005). From this viewpoint, user innovators consider themselves as a part of an interrelated community with others, peers with similar needs and complementary skills. Accordingly, the sense of belonging to a community and access to CBR could facilitate not only their innovative activities, but also their WTS. Communities of patients with similar needs are venues where they can not only exchange their experiences, but also connect with people who have complementary skills

(Zejnilić et al., 2016). Therefore, communities where patients and caregivers share their innovations are key and should be supported by both policymakers and entrepreneurs.

Thirdly, this is the first study to explore the moderating effect of LB on the impact of CBR and users' TE on their WTS. Institutions (e.g. state authorities, legal firms, or companies) have the legislative power to force user innovators to follow their demurs and to penalize them for their tinkering (Pieper and Herstatt, 2018). Discussions about patent law and policy have for the most part remained rooted in the paradigm of commercial sale as motivation for innovation (Strandburg, 2008). However, new functionalities produced by the Internet have generated considerable discussion on copyright law and policy and its impact on non-sales mechanisms for user innovation. Therefore, it is important to include LB in the research on user innovation and innovation diffusion.

Our results suggested that LB constitute an impediment to sharing, which reduces the positive effects of CBR on users' WTS. This finding, to some extent, contradicts the current literature, which does not consider LB an issue when user innovations are shared non-commercially. Indeed, free sharing of patient innovations is not a commercial activity and does not require regulatory approval. The innovations can be diffused non-commercially, allowing users to make their own copies (Demonaco et al., 2020), which implies that there are no legal constraints in free diffusion of patient innovations. However, the negative impact of LB found in our study could be explained by the fact that it is costly to obtain intellectual property, patents, and copyrights. This might prevent some innovators not only from innovating but also from sharing user innovations with the community. Nevertheless, the impact of legal barriers (e.g., intellectual property, patents, and copyrights) on innovation likelihood and innovation diffusion needs to be investigated further.

Taking all these factors together, this study will enrich user innovation theory with a better understanding of the user innovation and diffusion process and enhance patient innovation further.

5.7.2. Managerial Implications

The study contributes to the identification of factors that would facilitate users' WTS innovations. The findings could be important to manufacturers interested in benefiting from innovations developed by users. By exploring user innovations, manufacturers gain information about emerging market needs ("need knowledge") that would be difficult to obtain otherwise. They can then advance the generally valued user-developed solutions by turning them into robust products (Henkel and von Hippel, 2004).

Patient innovators contribute to improving other patients' quality of life by innovating and sharing innovations. However, without infrastructure that provides credible information exchange and support for ensuring safety, the efforts of many (innovative) patients may fall short (Zejnilić et al., 2016). Therefore, the healthcare industry and government regulators should support the free patient innovation system and help it develop in medically and socially valuable directions (Tiwari & Buse, 2019). Policymakers can support the development of health care innovations by engaging

open-source patient communities and exploring ways to integrate these into the health care practice (Zejnilović et al., 2016). Policymakers need to find venues for establishing networks that would facilitate experience sharing between patients and individuals with skills and knowledge that may help patients realise their innovation ideas. Online platforms constitute such venues as they facilitate participation and easy interaction amongst patients and healthcare professionals. While we referred mainly to the policymakers' role, most of the considerations also represent opportunities from a managerial perspective. Consequently, it needs to be explored further to what extent and in what way managers should adapt to incorporate patient innovation into the complex healthcare system.

Furthermore, LB could be ameliorated by helping get permission to change the properties of products and use restricted components (Pieper and Herstatt, 2018). Policies related to intellectual property (such as patent and copyright law and tax breaks and subsidies) strongly influence users' ability to innovate and share innovations. Additionally, the tendency towards stronger intellectual property protections has a negative impact on user innovation (Gallini, 2002). In particular, policies that restrict product modification by users must be considered very carefully (Benkler, 2002; Bogers et al., 2010) as they hinder patient innovation and innovators' WTS.

5.8. Limitations and Future Research Directions

The generalizability of the findings could be limited to the specific empirical field being researched. This study focuses on the healthcare sector, which differs from other sectors regarding regulations, motives, stakeholders, products etc. Correspondingly, not all of the findings could be transferable to other sectors. To gain a more thorough perspective, future researchers could perform a comparative study between different sectors.

Even though more than 300 chronic disease patients were included in the analysis, user innovation research will further benefit from empirical testing on a larger scale.

Another interesting aspect to look into might be how other user innovation-related variables would be affected by LB and by CBR and TE. It could be beneficial to explore the impact of reputation effects as a factor in users' intentions to innovate and WTS. Additionally, it could be interesting to study openness to experience, as a personal trait that innovators may or may not possess, in relation to intention to innovate and WTS.

The concept of ownership is also a broad field that is closely related to user innovation barriers. The fact that ownership is not included in this research could be perceived as a limitation of the research and a recommendation for future studies.

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6. CONCLUSION

6.1. Theoretical Contributions

Both phenomena of user innovation and co-creation discussed in this PhD thesis involve active user contributions to the development of new products, services, or solutions.

Co-creation refers to a collaborative process where users actively participate in the development of new or improved products, services, or solutions led by the firms. This co-creation allows firms to better understand users' needs and preferences, ultimately leading to the creation of more user-centric solutions.

User innovation occurs when users identify gaps in the existing market and independently develop alternative solutions to address those needs. User innovators use their unique knowledge and experiences to create solutions that would not have been created by traditional producers.

While there are similarities between the two, co-creation involves collaboration which is led by firms, whereas user innovation is driven by users' independent efforts. User co-creation focuses on creating shared value through collaboration between users and firms, while user innovation focuses on users independently creating value.

6.1.1. Theoretical Contributions to the Co-creation Field

Prior research discusses a number of potential challenges when co-creating with users as external stakeholders during the innovation process (e.g. internal bureaucratic processes, a lack of understanding of the benefits and challenges of collaborating with other stakeholders, unwillingness to share information, a lack of transparency or openness) (Enkel et al., 2005; Schaarschmidt & Kilian, 2014; Smith et. al, 2015; Ulwick, 2002).

One of the main theoretical contributions from our study on patient co-creation described in Chapter 3 is that we empirically identify the ethical challenges that arise in the patient co-creation process from both the patient co-creators and managers' perspectives. Our findings build upon a framework which links co-creation with the universal moral standards (UMS) (Schwartz, 1998; 2002). We have further extended the framework with the moral standards of inclusivity, diversity, and equality, which emerged as relevant from our empirical data.

This study reveals that the healthcare industry generally does not value patients' knowledge and expertise as highly as they do the knowledge generated by other stakeholders (for instance, healthcare professionals). However, patients possess unique knowledge and experience ("need knowledge") that is crucial for successful innovation (von Hippel, 1986). This hinders the co-creation process as successful co-creation is possible only between equal partners (Prahalad & Ramaswamy, 2004).

Linked to this is the fact that the industry does not fully consider the moral standards of diversity and inclusivity when selecting participants from different races, ethnicities, geographical and socio-economic backgrounds. This lack of diversity and inclusivity limits the generalizability to a broader population and showcases the need for these industries to recruit participants from diverse backgrounds, thereby regaining the trust of these underrepresented populations.

Another important aspect of this study is that we focus on both managerial and patients' perspectives. In this way, we enhance accuracy and mitigate biases (Schwenk, 1985). This dual perspective highlights the complexity of the co-creation process and reveals that ethicality in co-creation is dependent on managing expectations by all involved stakeholders (in this case, patients and managers). For both parties to benefit from co-creation, it is important for them to understand and align their mutual expectations. The industry needs to move towards a more collaborative business model with active involvement of users in all stages of the process. Thus, firms should focus on ensuring shared value for both parties throughout the co-creation process. This is in line with Prahalad and Ramaswamy (2004), who suggest that only high-quality interactions enable users to co-create unique experiences with firms to unlock new sources of competitive advantage.

In our study, we found that the standard of trustworthiness is a crucial factor in co-creation. Transparency is difficult if stakeholders do not have the same access to information (Prahalad & Ramaswamy, 2004). Previous studies show that firms traditionally benefit from exploiting information asymmetry between them and the consumers (e.g., Nayyar, 1990). Therefore, regular follow-up and feedback with patients is a critical challenge that firms need to focus on. This is in line with Ind and Coates (2013), who state that firms need to move beyond a situation where co-creation simply exploits external stakeholders who provide their resources for the firms' benefit to a position where firms engage stakeholders in a reciprocally useful way.

Another valuable finding in our study on which the two sets of respondents broadly agree is that patients are often engaged too late in the innovation process, even though it is crucial to involve them from the beginning. This is in line with previous research which has called for changes to the R&D process so as to allow external stakeholders to be involved much earlier in the innovation process (Bosch-Sijtsema & Bosch, 2015).

An aspect that emerged from the data is the perception that longer-term, earlier engagement accrues more rights to compensation and IPR. This points to an underlying theme of trust, which according to the DART (Dialogue, Access, Risk Assessment, Transparency) principles (Prahalad & Ramaswamy, 2004) is one of the building blocks of successful co-creation.

The managers in the study identified compliance and the many and complex regulatory processes as significant barriers to effectively involving patients in the co-creation process. Therefore, the industry needs to address these legal, institutional and structural barriers and move from the traditional concept of the market as firm-centric towards an emerging concept of the market as focused on interactions.

In the study, we identified the patients' (as end users of healthcare products and services) incentives to be included in the process of co-creation with the pharmaceutical and medical technology industries. Although they maintain a critical stance towards these industries

(perceiving the process, at least partially, as a marketing or publicity stunt), they are still willing to share their unique knowledge, experience and skills to contribute to the common good, which is associated with the moral standard of citizenship. This is in line with previous research that has shown that as most external co-creators are intrinsically motivated, they maintain their interest and commitment throughout the whole co-creation process (Füller, 2010). They are keen to participate in co-creation for various self-development and social reasons (Carù and Cova, 2015; Schau et al., 2009).

6.1.2. Theoretical Contributions for the User Innovation Field

The research presented in Chapters 4 and 5 offers important contributions to the phenomenon of user innovation. The study is, for example, the first to report the significant and positive impact of socially conscious consumer behavior (SCCB) on users' intention to innovate (ITI). Communities where users work together to develop new ideas is a stimulating experience (Nambisan & Baron, 2007). Franke and Shah (2003) demonstrate that one of the strongest motivations for assisting user innovators is the idea of helping others in the community. Users can enhance their creativity by learning to trust their peers while developing products together (Ind et al., 2013). Finally, most users are not concerned with financial rewards for innovation (Füller, 2010).

The research described in Chapter 4 shows that (being) Ahead of Trend strengthens the positive relationship between socially conscious consumer behavior (SCCB) and users' intention to innovate (ITI). This is aligned with lead user theory, which states that lead users are likely to innovate and develop attractive innovations (von Hippel, 1986). Lead user theory is proven in many fields (e.g., Franke et al., 2006; Franke & Shah, 2003; Franke & von Hippel, 2003b; Lüthje, 2004; Lüthje & Herstatt, 2004; Morrison et al., 2000; Urban & von Hippel, 1988). However, this is the first study that links lead userhood and intention to innovate among chronic disease patients.

Chapter 4 also details the first study in the user (patient) innovation field to consider the burden of treatment (BOT) as a potential factor influencing intention to innovate (ITI). The burden of treatment was employed as a moderating factor on the impact of socially conscious consumer behavior (SCCB) and intention to innovate (ITI). Although we postulated that increased BOT (especially comprehensive healthcare and psycho-social-economic context of the burden) could significantly and positively influence patients' intention to innovate, we did not find any empirical support for our hypothesis. However, these inconclusive results could be explained by the fact that survey participants were mainly based in Denmark and other developed European countries. Healthcare in these countries is available to everyone and is either free or heavily subsidized by the state. Therefore, patients might not experience the burden of treatment as much as they did in other countries. We therefore suggest that future research could study the effect of burden of treatment on intention to innovate among chronic disease patients in less developed countries.

The study presented in Chapter 5 contributes to current user innovation literature as it is the first empirical study to explore the impact of innovation-related resources (technical expertise (TE))

and community-based resources (CBR) on users' willingness to share innovations (WTS). Furthermore, it is the first to investigate the moderating effect of legal barriers on the relationship between innovation-related resources and willingness to share (WTS). The data presented in Chapter 5 showed that innovation-related resources (technical expertise (TE) and community-based resources (CBR) positively affect users' willingness to share their innovations (WTS).

User innovation diffusion is still under-unexplored in literature (e.g. Baldwin et al., 2006; de Jong & von Hippel, 2009; de Jong et al., 2015; Franke & Shah, 2003). The positive relationship between users' technical expertise and their intention to innovate was first reported by Lüthje et al. (2005) in the mountain biking community. The positive impact of users' technical expertise on their willingness to share could be related, among other things, to an expectation of increasing their reputation and gaining more respect from peers within their community. Previous research has shown that success in innovating in a community might build reputation among the user innovator's peers and even provide some job opportunities (Bogers et al., 2010; Lakhani & von Hippel, 2003).

Furthermore, the study presented in Chapter 5 is the first to report the significant and positive impact of community-based resources (CBR) on users' willingness to share innovations. Prior studies on user innovation in communities show that altruism and incentives to help others prompts users to engage in innovation (Franke & Lüthje, 2020; Franke & Shah, 2003; Harhoff et al., 2003; Lakhani & von Hippel, 2003). Thus, a sense of belonging to a community and access to community-based resources could facilitate not only users' innovative activities, but also their willingness to share. Therefore, communities where user innovators share their innovations are important and should be supported by both policy-makers and entrepreneurs.

Additionally, in Chapter 5, we explored the moderating effect of legal barriers (LB) on the impact of community-based resources and users' technical expertise on their willingness to share. This is the first study to show that legal barriers may have a negative moderating effect on the influence of community-based resources on users' willingness to share. This finding, to some extent, contradicts the free innovation literature because legal barriers are not considered an issue when user innovations are shared and diffused non-commercially. Freely sharing and the non-commercial diffusion of user innovations do not require regulatory approval (Demonaco et al., 2020). This implies that there are no legal constraints in free diffusion of user innovation. However, the negative moderating effect of legal barriers we found could be explained by the costly and time-consuming process of acquiring patents, copyrights and intellectual property rights. Although most user innovators decide to freely share their innovation, some innovators might still be reluctant to share their innovations with the community. However, the impact of legal barriers (e.g., intellectual property, patents, and copyrights) on the likelihood of user innovations and innovation diffusion needs further investigation.

The findings presented in Chapter 4 and Chapter 5 will enrich the field of user innovation by providing a better understanding of user innovation and diffusion of user innovation and hopefully further enhance innovation among users.

6.2. Managerial Implications

6.2.1. Managerial Implications in the Co-creation Field

Our analysis from Chapter 3 shows that managers in the medical/pharma industry need to overcome their reluctance to and change their negative perceptions about external stakeholders' ability to actively participate in the co-creation process. This could be achieved through firms increasing their education and training on including external stakeholders in the co-creation process from early on. The aim would be to raise employees' awareness about the importance of external stakeholder involvement in the co-creation process.

Co-creation must be built on transparency, and the data shows that improvements are needed in that area – for example, managers need to keep their co-creators informed about the long-term goals. They also need to provide feedback from the co-creation projects and follow-up during and after the process as this has been shown to be key to successful partnerships. All in all, this would guarantee mutuality and trust and result in long-term partnerships, rather than just collaboration on single projects. In addition, more information regarding firms' corporate social responsibility practices is necessary to build long-lasting and committed partnerships with co-creators.

It is crucial for firms and external stakeholders to understand the benefits of collaboration - to generate value and transformative solutions for both, to ensure the best outcome and to aim towards a common goal.

Chapter 3 shows that to achieve a successful co-creation in these highly regulated industries, despite the legal and regulatory obstacles identified in the study, the industry has to address barriers early on in the process through working closely with governmental and regulatory bodies both at national and international level.

6.2.2. Managerial Implications in the User-Innovation Field

The study presented in Chapter 5 contributes to identifying factors that facilitate user innovation. The successful identification of lead users can contribute to improving new product development processes. Prior research shows that integrating lead-users into new product development is a useful means to develop breakthrough ideas (e.g., Lilien et al., 2002; Urban & von Hippel, 1988). Firms can benefit from users' creative capabilities if they involve them (von Hippel, 2006). Our findings confirmed that user characteristics such as displaying socially conscious consumer behavior along with their (being) ahead of trend lead to increased intention to innovate. Therefore, managers and government regulators should support this free user innovation system and help it develop in socially beneficial directions.

They could do so by supporting user innovative communities as an efficient way for users to find resources, information, knowledge and experience that will positively influence their intention to innovate. The main challenge is organizing and managing user communities in order to effectively channel the innovation activities and make innovations available to others.

Without infrastructure that allows innovation-related information exchange and provides support, the efforts of many user innovators may fall short (Zejniliović et al., 2016). Online platforms and communities are such venues which can facilitate participation and interaction amongst user innovators. As these platforms and communities also represent opportunities for managers, it needs to be further explored to what extent and in what way managers can incorporate user innovation in the complex innovation process.

Policies could play a crucial role in supporting user patient innovators, providing them with the necessary guidance, resources, and funding. Policies can be put in place to provide accessible regulatory guidance for patient innovators. This can be facilitated through dedicated advisory services where patient innovators could seek advice on regulatory processes. Furthermore, simplifying the approval process might enable patient innovators to bring their innovations to market more efficiently (e.g. fast-track pathways or regulatory frameworks designated for patient-led innovations).

Government and other regulatory bodies need to support networks, platforms or innovation hubs that connect patient innovators with healthcare professionals, regulatory experts, and industry.

Moreover, policy can promote the recognition of patient innovators as valuable contributors to the healthcare system. This can include initiatives to raise awareness about patient-led innovations, share success stories, and incorporate patient perspectives in policy and decision-making processes. Financial support in the form of grants, funding programs, or tax incentives will encourage patient innovators to pursue their ideas.

Trends moving towards stronger intellectual property protection have a negative impact on user innovation (Gallini, 2002). Instead, policies need to ensure that patient innovators have adequate protection for their intellectual property. This can be done by streamlining patent processes, providing legal assistance, or organizing awareness campaigns to help innovators understand the importance of protecting their innovations.

By implementing these policy measures, governments and regulatory bodies will create an environment that empowers patient innovation, reduces barriers to innovation, and promotes the development of user-generated solutions in healthcare.

6.3. Limitations and Future Research

6.3.1. Limitations and Future Research in the Co-creation Field

In the study on co-creation presented in Chapter 3, we adopted Schwartz's universal moral values for corporate codes of ethics (2002) as a basis to build up a framework of ethical challenges in the co-creation process. In future studies, challenges concerning co-creation can be analyzed using other ethical frameworks. This might lead to reconfirming the challenges we identified or to discovering other challenges.

As the present study sheds light on the importance of moral standards such as diversity, inclusivity and equality that are not included in Schwartz's universal moral values for corporate codes of ethics (2002), it is likely that more ethical issues will arise as co-creation with external stakeholders evolves.

The focus of our research is on healthcare (pharmaceutical and medical technology industries), although the findings could be applied to other industries engaging in co-creation with external stakeholders. However, the ethical challenges or their intensity might differ if different industries and sectors are considered.

Additionally, it would be interesting to study the ethical challenges in the co-creation process cross-culturally, especially if we consider significant differences in the institutional practices, legal frameworks and cultural practices that exist.

Moreover, ethical challenges in co-creation and their causes could be explored in depth in future studies as the focus of the present study was mainly to identify them and to propose ways to overcome them.

6.3.2. Limitations and Future Research in the User Innovation Field

The studies described in Chapters 4 and 5 have several limitations. Because of the COVID-19 pandemic, the data collection was conducted through an online survey, and participants had to be able to access an electronic communication device. Consequently, our sample is not representative of the general population of users. However, online surveys have their advantages (for instance, researchers are able to reach a larger number of users in a shorter period of time).

Some of the findings presented in Chapters 4 and 5 might be related to the specificity of the field investigated. The studies focus on the highly regulated healthcare sector; significantly different results might be obtained in other sectors concerning regulations, stakeholders' motivations etc. This could mean that not all of the findings may be equally transferable to other sectors. To acquire other perspectives, future researchers may perform a comparative study between different sectors.

Additionally, the data we presented in Chapter 4 show that the burden related to comprehensive healthcare clearly depends on the country where the participants reside. More research is needed to understand the specific aspects of burden of treatment and why users might vary in the different countries.

Ownership is also a broad field that is closely related to user innovation legal barriers. The fact that ownership is not included in this research could be perceived as a limitation of the research and a recommendation for future studies.

Other users' characteristics which could be useful in relation to intention to innovate, such as technical expertise, community-based resources and various personality traits, could also be explored.

Another aspect to look into might be how other dependent, user innovation-related variables are affected by legal barriers, by community-based resources and technical expertise. Furthermore, it could be interesting to explore how variables related to user innovators' personal traits, such as reputation and openness to experience, might affect users' intention to innovate and willingness to share.

Lastly, it could be interesting to see how the findings of this study might differ if user innovation by other (non-patient) user innovators were investigated (e.g., health professionals as intermediate users of health products or services).

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7. APPENDICES

Appendix A

Table 14. Interview guide – Patients

Filtering questions	
1.	So, have you engaged in co-creation with a pharma or MedTech company?
2.	Has this co-creation activity been part of a clinical trial?
Warm up	
3.	Can you describe the co-creation activity that you have undertaken with the pharma/MedTech company?
Motivations to participate in co-creation	
4.	What expectations did you have before engaging in co-creation?
5.	Which were your motives to engage in co-creation with the pharma/MedTech company?
6.	Did you have previous experience in co-creation?
Participation in co-creation	
7.	What was your role in the co-creation process, and to what extent have you contributed?
8.	In which phase of the co-creation process have you been involved?
9.	With which department(s) have you been co-creating?
10.	How often have you interacted with the company during the co-creation process on average per year?
11.	How did the interactions take place (e.g., online, offline, workshops, and plenaries)?
12.	Have you expressed your personal inputs/ feedback/ expertise to the company?
13.	Do you feel that they have taken them seriously? Why?
14.	Have you also interacted with people outside the organization during the co-creation process? How and with whom?
15.	Have you faced any obstacles during the co-creation process?
16.	Have you tried to overcome such obstacles?
17.	Was your role in the co-creation process clearly defined from the beginning?
18.	Was the expected level of interaction clearly defined from the start?

19.	Were the goals of the co-creation activity clearly defined at the beginning?
20.	Did you have the possibility to openly share your ideas/ opinions? And have you done it?
21.	Do you feel that your ideas/ opinions have been respected and valued?
	Ethical implications of participation in co-creation
22.	Have you obtained any monetary or non-monetary compensation for participating in co-creation?
23.	Do you think that the compensation is fair?
24.	Have the principles of confidentiality been clarified to a sufficient extent? Could anything have been done better in this regard?
25.	Has training on the principles of confidentiality been provided? Could anything have been done better in this regard?
26.	Have the principles of privacy been clarified to a sufficient extent? Could anything have been done better in this regard?
27.	Has training on the principles of privacy been provided? Could anything have been done better in this regard?
28.	Have you signed an informed consent regarding the co-creation activity? If so, was it clearly formulated and understandable?
29.	Has your information, as a patient, been protected to a sufficient extent?
30.	Has the IPR of the output that you have co-created been addressed well?
31.	Do you perceive the pharmaceutical/MedTech company you have co-created with as socially responsible and why?
32.	Do you believe the pharmaceutical/MedTech company you have co-created with supports good causes, contributes to society and/or is beneficial for the welfare of society? Why and how?
33.	Why do you think that the company has invited you?

Table 15. Interview guide – Managers

Introduction	
1.	Can you describe the co-creation projects that you have undertaken with patients?
2.	What was your role in the co-creation process?
Motivations, success factors and barriers	
3.	What expectations did you have before engaging in co-creation?
4.	Which were your motives to engage in co-creation with patients? How do you think this aligns with the motivations of your collaborators?
5.	What would you define as a successful outcome of this process?
6.	What do you think a successful outcome for your collaborator is?
7.	What are the main barriers that you found during the co-creation project?
8.	How did you overcome these barriers?
Ethics	
9.	Have the principles of confidentiality been clarified to the involved patients to a sufficient extent?
10.	What about managers?
11.	Has training on the principles of confidentiality been provided to the involved patients?
12.	What about managers?
13.	Have the principles of privacy been clarified to the involved patients to a sufficient extent?
14.	Has training on the principles of privacy been provided to the involved patients?
15.	Have you signed an informed consent regarding the co-creation activity with the patients?
16.	How have the Intellectual Property Rights of the output that you have co-created been addressed?
Patients' role and goals of the co-creation activity	
17.	Was the patients' role in the co-creation process clearly defined from the beginning?
18.	Were there any disagreements regarding the process?
19.	At what stages of the process were they involved?

20.	What was the involvement of the patients in collecting, analyzing, and interpreting results?
21.	Was the patients' expected level of involvement clearly defined from the start?
22.	Were the goals of the co-creation activity clearly defined at the beginning?
23.	Who defined the goals?
24.	How were they defined – was there co-creation at the defining stage?
Other stakeholders' participation	
25.	Were other external stakeholders, apart from patients, involved in the co-creation process?
26.	How did you align the different expectations regarding process, outcomes, involvement of participants?
Practicalities about the co-creation process and follow-up	
27.	Which department(s) have been involved in the co-creation?
28.	How often have you interacted with the participants during the co-creation process?
29.	How did the interactions take place?
30.	How did you follow up with participants once you received their input?
31.	What was actually implemented from the ideas generated by participants?

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