The importance of financial resources and ownership of intellectual property rights for university spin-offs
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The importance of financial resources and ownership of intellectual property rights for university spin-offs: The cases of Finland and Sweden

Abstract
Purpose: This paper focuses on medical device university spin-offs, taking into account the peculiarities of financial and non-financial support and intellectual property rights. We declare that these parameters play a significant role in business development at the early stages.

Design/methodology/approach: Our empirical data consist of individual and group interviews in Finland and Sweden, which are later inductively analyzed.

Findings: Our results show that public financial support contributes to the formation and start of sales stages in small countries and local markets. However, at the validation stage, approaches to supporting entrepreneurship in the field of medical devices may differ. The ownership of intellectual property rights assists in the development of entrepreneurship in the region due to the transfer of research results and researchers to the industry and increases the number of spin-offs and the cooperation of universities with business.

Originality/value: Our contribution is in the identification of the key parameters for the formation, support, and development of the university spin-offs from the point of view of the availability of financial resources and the ownership of intellectual property rights.

Keywords: university spin-off, financial resources, intellectual property rights, medical device, Finland, Sweden
1 Introduction

The life science industry is highlighted as a leader in the knowledge economy in Europe (Okamoto, 2010). Although the pharmaceutical and medical technologies business literature has grown in recent years, the medical device business has received little attention. The majority of articles and reports add medical devices to the general section of life science (DiMasi et al., 2003; Rubin et al., 2015; Angeli and Jaiswal, 2016; Holtzman and Kramer, 2018). Nevertheless, there are medical device companies that are successful in the international market, with impressive experience in creating and capturing value that could be useful for medical device start-ups and other market participants.

The spin-offs resulting from university research to private companies indicates an essential and often applied opportunity to generate value (Urban and Chantson, 2019). University spin-off (USO) has become a widespread approach to commercialize scientific discoveries due to more value production for society, which could also return to the university (Wright et al., 2006); policymakers consider USOs to be the structural development to stimulate the economic development of the region (Perez and Sánchez, 2003) and university prestige growth for students and academics (Jung and Kim, 2018). For this study, we consider the USO as a company that was founded based on the results of the university research, and founders were earlier employed by the university (Pirnay and Surlemont, 2003). We selected intellectual property rights (IPRs) and funding sources as the main parameters for two reasons. First, there are the limitations posed in a classic article on university spin-offs (Stankiewicz, 1994). The author states that the most important areas for further research are the problems with IPRs and financing of commercialization. The protection of IPRs is the fundamental basis for commercialization. Stankiewicz (1994) suggests that IPRs, dynamics, and the importance of the knowledge economy are interconnected, but he invites other researchers to continue his research. Moreover, the issue of financing academic spin-offs is recommended for study and analysis. Various authors pay attention to different types of financing (Stankiewicz, 1994; Pirnay and Surlemont, 2003; Hagedoorn et al., 2018) and insist that, in most cases, companies achieve good results with a diversity of economic resources. However, venture capital “no longer seems to be the answer to all questions” (Stankiewicz, 1994). Previous studies do mention the role of public funding but do not pay enough
attention to the role of financing from public sources. Moreover, researchers do not make comparisons among different practices to identify successful patterns for countries interested in commercializing research from universities. The second reason for this study is our previous research, in which we compared medical business ecosystems in the Nordic countries. During the interviews, we found that medical start-ups perceive opportunities and threats offered in these countries rather differently. Some companies focus on product development, testing and promotion, while others have to overcome additional limitations and seek individual ways of doing business.

The aim of the paper is to shed light on the parameters of the USOs’ business development. The majority of researchers argue that the main parameter for the success of the USO is the team (Grandi and Grimaldi, 2003; Felix et al., 2019). However, we consider that access to various sources of funding and ownership of intellectual property rights (IPR) to the invention have crucial roles in the business development of medical device USOs. We study USOs at the early stages of development, including formation, validation, and the start of growth (Neill et al., 2015; Santisteban and Mauricio, 2017). Therefore, the research question of this paper is: How does the availability of financial, non-financial support and ownership of IPR contribute to the business development of the medical device USOs? This paper starts with the financial resources for start-ups and an IPR literature review. Further, we discuss state-of-the-art medical device innovation ecosystems in Finland and Sweden. Based on the literature review, we detail the rationale for the chosen research design and method. After this chapter, we use cross-case analysis (Eisenhardt, 1989) to identify the role of financial resources and IPR ownership on the business development of medical device USOs in Finland and Sweden and demonstrate the role of the focal parameters in this context. In the discussion section, we conclude by elaborating on the paper’s contributions to existing research on the USOs.

2 Literature review
Researchers have studied USOs for many decades (Cooper, 1971; Adams, 1993). The main characteristics of the USOs are the presence of the university as a parent organization and one or more individuals with a position in the organization but leave it for the development of their own project (Rasmussen et al., 2011). However, researchers interpret the term USO differently; for example, Mustar (1997) emphasizes the heterogeneity of USOs and the
difficulty in defining boundaries and a clear framework for these companies.

2.1. Financial resources

New ventures based on university research results face challenges in attracting investments. One of the most important factors limiting the collaboration between USOs and investment companies is the lack of such experience (Wright et al., 2006; Rasmussen and Sørheim, 2012). Universities use different practices for transferring research results to new companies; however, they differ from the conditions of the private sector.

Researchers pay great attention to bridging the gap between the financing needs of new companies and the desire of investors to offer financial resources. Different approaches are used in the US (Shane, 2004), the UK (Rothwell, 1985), the European Union (Audretsch et al., 2016; Corsi and Prencipe, 2017), and others (Fini et al., 2017). Providing finance by venture capital firms is seen as a key opportunity to overcome the lack of funding for start-ups (Baum and Silverman, 2004). Venture capital companies manage investors’ money through the purchase of shares in small and medium companies with high growth potential (Gompers, 1996; Mayer et al., 2005). However, research in the field of venture capital investment demonstrates that investors view early-stage investments in high-tech companies as highly risky (Vohora et al., 2004). In turn, the emergence of new opportunities on the part of USOs and universities that have not traditionally worked in commercial conditions contributes to the development of new conditions for cooperation. A lack of public and private funding to support university entrepreneurship is one of the most critical barriers for the commercialization of university research (Audretsch et al., 2012; Munari et al., 2018). Public universities and research centers offer various mechanisms to reduce the financial gap. The most popular schemes are proof-of-concept (PoC) programs (Bradley et al., 2013; Hayter et al., 2018) and university seed funds (USFs) (Bradley et al., 2013; Croce et al., 2014; Good et al., 2019). PoC is a fairly new mechanism that is actively gaining popularity in the framework of public policy in support of entrepreneurship. PoC programs combine several advantages for entrepreneurs: money, experience, network, and training to test the potential of the invention and assess the possibilities for entering the markets. These programs are aimed at preparing teams and products to meet with private investors and demonstrate
performances (Munari et al., 2016). In addition to forming a USO, such programs can also target licenses to other interested partners (Maia and Claro, 2013).

USFs, in turn, are focused on investing exclusively in USOs in the early stages (Munari et al., 2015). Most often, such funds are directly related to the university. For example, it could be initiated and managed by university representatives funded with the support of the university, or the university may have a partnership agreement with the foundation (Munari et al., 2018). Such funds tend to finance most university projects until the stage of meeting with potential investors by providing a direct investment or various types of loans.

There is a significant lack of knowledge to compare the effectiveness of PoC and USF programs between countries. The majority of studies focus on comparing programs within the same country (Bozeman et al., 2015; Schaeffer and Matt, 2016). Additional studies are required to evaluate such programs under the influence of local characteristics of regional business ecosystems, as well as to identify parameters for evaluating the effectiveness of the focal programs.

Researchers emphasize internal financing that is independently created by founders as the most promising for USOs (Hall and Lerner, 2010). Studies show that entrepreneurs most often cover up to 70% of the required capital with their own resources (Huang et al., 2012; Muñoz-Bullon et al., 2015). However, universities and founders of USOs can offer limited financial opportunities in life science and medical devices in particular due to the long research and development (R&D) stage. Therefore, universities offer small amounts or partially cover the costs of market analysis or patenting mainly using Technology Transfer Office (TTO) services.

Researchers point out the small role of banks in financing USOs and emphasize the need to attract investment from business angels and venture capital firms (Leitch and Harrison, 2005; Pierrakis and Saridakis, 2019; Martinez et al., 2019). In turn, venture capital firms had little interest in investing in new technology-based companies in the 1990s (Munari and Toschi, 2010), but they eventually had to change their approach and consider new technology companies (Lockett et al., 2002). One possible obstacle to the use of venture capital investments is the minimum amount of investment. The majority of USOs consider initial investments less than 500,000 euros and have minimum funds and experience in preparing
the company for due diligence (Lockett et al., 2002). In addition, the probability of venture capital investments is decreased based on the difficulty of assessing the profitability of technology and lack of knowledge and experience in applying new technologies in the market (Wright et al., 2006; Pierrakis and Saridakis, 2019). These investment companies are interested in obtaining independent recommendations to determine the business prospects of the university research results. In turn, USOs may not be fully aware of the required amount of investment. The business models of USOs may differ significantly in the market, and they may depend on the university. Moreover, USOs’ low valuation at the early stages of development reduces the mutual interest of companies and investors. Lack of property and business experience reduces the proposed investment and increases the required share in the company by the investor (Pattnaik and Pandey, 2017).

On the one hand, researchers argue that USOs receive more venture capital than other tech start-ups (Teece, 1986; Colombo and Grilli, 2010). On the other hand, many studies state the exact opposite (MacMillan et al., 1987; Drover et al., 2017). From the point of view of many qualitative studies, one of the basic requirements of venture capitalists for USOs is the presence of managerial experience in the focal industry (MacMillan et al., 1985; Drover et al., 2015; Caselli and Negri, 2018). Moreover, venture capital includes all sorts of advisory and mentoring services that contribute to the growth of managerial skills for the founders of USOs or provides access to such services (Colombo and Grilli, 2010). Researchers argue that venture capitalists tend to finance promising technologies that contain a higher risk in the short term, some due to a lack of managerial experience (Baum and Silverman, 2004; De Vries et al., 2017). Moreover, venture investors tend to replace managerial staff with more experienced employees, which favorably affects the prospects for USO. This opinion is also supported by Clarysse and colleagues (2007), who argue that founders without managerial experience often attract venture financing and, together with new project participants, adapt the company’s development strategy. However, we agree with Westhead and Storey (1997), who argue that increased demand for venture capital is created by start-ups that require a long R&D period, for example, related to medicine. Along with a lack of practical experience in business, such companies create more uncertainty for investors.

A significant number of researchers consider universities as points of formation and
development of new technology companies (Shane, 2004; Spigel, 2017), as public and private centers or entrepreneurship support programs (Maresch et al., 2016), or as the connection of the industry with new knowledge, technologies and employees (Ankrah and Omar, 2015). However, universities will typically not receive any significant revenues from this activity (Brown, 2016). Universities and regional entrepreneurship support centers will have higher costs than revenues but will be creating more benefits for the business ecosystem and society. The success of such centers depends on their integration into the regional economy and the level of regional technological development (Leitch and Harrison, 2005). However, universities and research centers contribute to the formation of not only technology but also of human capital that is absorbed by other market participants through consulting, licensing, the formation of subsidiaries and joint projects with industry (Siegel et al., 2007).

Policymakers consider entrepreneurial centers and business alliances as sources for sustainable development and economic growth (Bekkers et al., 2006). This is mainly because USOs tend to form close to their parent organizations. Therefore, workplaces and taxes are formed locally, unlike corporations where new knowledge is more likely to be transferred to another region or country.

Regional centers and associations are also aimed at entrepreneurs who have not fully decided on the transition from university to industry. Despite the definition of USO, some nascent entrepreneurs may not prioritize company growth (Roberts, 1991). Such entrepreneurs may feel discomfort in the current academic development. In turn, regional entrepreneurship support centers set the goal of forming new motivated teams for the successful development of the companies. Regional entrepreneurial centers are focused on providing training and support services for marketing and sales activities that are often not available to entrepreneurs from the academic environment (Perez and Sánchez, 2003). However, the quality of the proposed infrastructure of public and private universities and other centers may vary significantly. Both types of universities offer the development of new technologies; however, public universities offer fewer business incubation programs, access to capital and other opportunities (Powers and McDougall, 2005). In turn, other
public programs take on the role of providing such infrastructure to offer an integrated approach to the development of the business ecosystem.

2.2. Intellectual property rights

The relationships between patenting, research, and spin-off is studied as the response to opportunities in state-of-the-art changes for academics, policymakers, and society. The majority of researchers focus on the US (Thursby et al., 2001) and EU experience (Breschi et al., 2007), but researchers are contradictory and make mutually opposite conclusions, from the negative impact of patenting on research to the complementarity of these processes (Crespi et al., 2011; Ferretti et al., 2019).

The success and failures of the USOs depend on many factors. Scholars highlight university programs that support the commercialization of projects (Bray and Lee, 2000) and that study government-supported entrepreneurship policies (Liu and Jiang, 2001; Eniola and Entebang, 2015; Wonglimpiyarat, 2016) and the complexity of commercializing ideas (Gao and Haworth, 2016; Hsu et al., 2015; Dabić et al., 2018). Nevertheless, not all researchers support the formation and development of USOs (Veld and Veld-Merkoulova, 2004; Alexander et al., 2015). Critics of patenting and the formation of USOs argue that the desire for patenting leads to a shift in research programs to more applied ones, a reorientation to programs that could give more patents to the financing party, and a decrease in the speed of publication and the possibility of exchanging ideas between researchers (Gerken et al., 2015; Heikkilä and Lorenz, 2018). The possibility of the free dissemination of ideas, which, in turn, contributes to new research and knowledge, is being questioned. There is a practice of postponing publication from the industry prior to the filing.

Collaborative research, attending conferences, co-supervision of doctoral students by universities, and the industry facilitate the patenting and formation of USOs (Cohen et al., 2002; Bekkers and Freitas, 2008). Kenney and Patton (2009) underline the need for the existence of government programs aimed at patenting research, as well as the creation of a strong link between universities and the industry. For example, Jensen and Thursby (2001) emphasize the close relationship between researchers and the promotion of the invention to
the market. Moreover, further collaboration between the industry and researchers or the commercialization of research results by scientists contribute to the active promotion of research in the scientific community and increases the likelihood of patenting (Perkmann and Walsh, 2010).

The majority of researchers consider the innovation ecosystem of a single country or the global market. There is a gap in understanding the development of companies, taking into account country-level specificities of financial support for the spin-offs and IPR. Moreover, there is little understanding as to why some countries have an advantage if they use a similar approach to the support of entrepreneurship. The above-mentioned research about USOs, financial resources, and the importance of IPR demonstrate that this area is important for academics and the business community. Our example in the medical device industry complements existing research and demonstrates the role of the availability of financial resources and the ownership of IPR on the business development of USOs.

3 Medical device ecosystems in Finland and Sweden

Many countries invest considerable resources in the development of the life science ecosystems of their countries. However, the probability of raising venture capital investments by projects in Sweden is 2–3 times and the amount of investments is 1.5–3 times higher than in Finland (Huggett, 2013; van Wilgenburg et al., 2019). Studying the phenomenon of success in Sweden based on local USO cases and comparing it with a developing market as Finland gives us the opportunity to create a theoretical assumption that could be used in further research. This research could teach us more about the successful formation and business development of USOs at the early stages.

3.1. Finland

Finland can be considered a typical representative that makes efforts in the development of a certain industry for a long time but achieves little success (Park, 2016). It has been advised that the life science business might grow into one of the sources for Finland’s export-oriented economy (Tulkki et al., 2001). Medical devices and biomaterials are one of the areas in which Finland is a precursor. However, despite the substantial scientific background (Vainionpää et al., 1989) and public investment (COMBIO, 2007), the country shows little success in the life...
science industry. The majority of support programs do not reach commercial tasks or are not significantly changed during the execution of the program. As a result, there is a lack of new Finnish products in life science despite investments.

Finnish scientific research in the field of biomaterials started in the 1980s (Vainionpää et al., 1989), and professional skills remained at the international level. A few companies had already been established to commercialize the progress. However, as pinpointed by Varnai and colleagues (2016), one of the main reasons for the limited business growth was the lack of business experience of the novel companies. As a result, the well-known program for the commercialization of the existing studies, COMBIO (Commercialization of Biomaterials), was carried out in 2003–2007. In addition, there was a mission to create local and international networks for collaboration in the bio industry (COMBIO, 2007).

In parallel with COMBIO, other programs have supported the life science industry in Finland as well. For example, BioIT (Solution for Biological Information) and Trial (Environment for Cognitive Radio and Network) boosted the commercialization of scientific developments, updated existing innovation ecosystems, and helped to promote products to the international market. However, these grandiose financial and ecosystemic goals have not been achieved (Varnai et al., 2016). There are local efforts to renovate activities in the life science ecosystem, such as the launch of the first life science accelerator in Turku, but they show little results.

3.2. Sweden

Sweden, in turn, is one of the European leaders in the field of life science and medical devices in particular (Enzing and Reiss, 2008). It has a long tradition of successfully acquainting life science innovations (Hyde and Paterson, 2001; Nadowska, 2013) with medical devices (Aaboen et al., 2014). Companies offer innovations not only locally but also for the international market. These companies, for example Pharmacia (later merged with Pfizer), AstraZeneca and Nobel Biocare, offer excellent conditions for the development of new products and services, an innovation-friendly infrastructure, a low level of hierarchy in the organizational structure, and an interdisciplinary approach to the R&D process (Smith et al., 2003).

The life science industry is one of the priorities in the structure of Sweden’s economy. First, it
consists of a group of companies that were founded to commercialize the academic innovations of 1940–1960. These big-world companies have a significant share of the international market. Second, a group of 30–50 companies is focused on R&D and production in Sweden. The number of employees in these companies is 100–150 people, and they actively interact within the ecosystem. Third, the majority of medical device start-ups are somehow related to the academic environment (Sandström, 2014).

The Swedish life science centers are concentrated near Stockholm. In addition to this, the Skåne region and the Danish capital form a cluster that is known as Medical Valley, along with several regional clusters in the north of the country (Waluszewski, 2004; Ernst & Young, 2014). Since the establishment of the biggest Swedish life science companies AstraZeneca and Pharmacia, the life science ecosystem was formed around them. As a result, in 2013, pharmaceutical exports in Sweden reached 5.2% of the total export (Statistics Sweden, 2013).

4 Method
Increased interest in the life science industry by many countries, a large number of business development programs in the regions, lack of knowledge on the development of a new industry, and our research question highlight the need for research. The main research approach is based on multiple case studies (Woodside and Wilson, 2003; Eisenhardt and Graebner, 2007). We used qualitative methods to collect and analyze information, which allows us to describe and test the theory (Van Maanen, 1979) or extend the emerging theory (Shah and Corley, 2006). Moreover, the proposed methods provide resources to identify and understand complex phenomena from the point of view of the participants in the process (Miles and Huberman, 1994).

The most important information for the research was gathered based on individual and group interviews with the founders and managers of eight medical device USOs. The agenda for the interviews is presented in Appendix 1. We chose semi-structured interviews in order to explore permanent and variable relationships, to identify constant and emerging processes between participants, and to research the impact of social context (Shah and Corley, 2006). The research examines four Finnish and four Swedish medical device USOs. Each country is represented by companies from the human and veterinary markets. All start-up companies
are selected by geographic location. We proposed this sample in order to direct our efforts in gathering information as the best way to support the development and testing of the focal framework (Locke, 2000). On the one hand, the Turku, Uppsala, and Lund life science clusters were selected as the regions that pay the most attention to medical devices. On the other hand, the majority of start-ups did not respond to contact phones and emails, and corporate sites were unavailable or not updated in the last few years. The selected cases are not polar but have various parameters, such as countries (Finland and Sweden), applications (human and veterinary markets), and purposes (implants, devices for the treatment of chronic diseases, post-operative care, etc.). Table 1 presents a list of parameters that characterize the companies selected for the study. In our case, the sample is not random, which has a positive effect on the results of the study (Eisenhardt, 1989). Seven interviews in Finland and eight interviews in Sweden were held with founders and managers of the USOs. All interviews were conducted in English. Questions for the interviews were prepared by a doctoral student, edited, and approved by senior researchers. Each interview was attended by one doctoral student and one senior researcher. During in-depth individual interviews, representatives of the USOs described personal stories about the formation, validation, and start of growth in terms of financial resources and IPR. From the part of researchers, we sought to ask similar questions to all participants in individual interviews and clarify the new information by phone or during group interviews. The received information was analyzed by all participants of the research group after each interview. Data collection was fairly open and flexible; therefore, the modification of questions for the subsequent interviews was implemented based on the information received (Shah and Corley, 2006). Clarification of information was carried out through correspondence by email and telephone. The project was realized during 2017–2018.

We have identified that the USOs of these countries have different kinds of relationships with universities. The founders and managers of the companies shared their own experiences in the development of companies with the support or non-participation of the university or contrary to it. This was one of the main issues in understanding the role of IPRs and financial resources as parameters of success or failure for USOs. However, universities are not the only partners for the USOs. Interviewees highlighted public organizations that support entrepreneurship, conferences and workshops, consultants and others. Thereby,
we emphasize universities but do not isolate them. Despite the existing agenda, interviewees often paid more attention to one of the parameters that seemed more important to them. The researchers did not limit the statements of the interviewees and allowed the supplementation of different points of view if several interviewees were interviewed at the same time. The absence of disagreement on the IPRs issue contributes to open collaboration with the university, which also helps to raise private and public investments through the open dissemination of information about the company.

The interviewees were co-founders who have C-level positions in a company. In the majority of USOs, this includes the chief executive officer (CEO), chief financial officer (CFO) and the chief technical or scientific officer (CTO/CSO). In some companies, the roles of CEO and CFO were combined. As with most start-ups, USOs do not have a clear division of responsibilities between partners. CEOs were mostly responsible for financial resources and working with partners outside the technical field, and CTOs focused on creating and developing the product. However, key tasks such as preparing and filing a patent application and communication with key public and private investors require efforts from the whole team.

In addition to collecting rich data directly from people participating in the study, we used additional techniques to increase knowledge (Marshall and Rossman, 2014). Extra data were used for the detailed analysis of medical device innovation ecosystems, including information from the websites, integrated development programs for the countries and their regions, and many other resources. To increase reliability and encourage value creation for all participants of the medical device ecosystem, discussions were held individually and in groups. During the collection and subsequent analysis of the received information, we constantly compared the data obtained in order to identify the uniqueness that could form patterns for closer study. Therefore, the collected information and further analysis were conducted in parallel. Some companies were against publishing their names, so they are identified by case number (i.e., cases 1–8) and are divided according to geographic location: cases 1–4 are from Finland and cases 5–8 are from Sweden.
5 Empirical findings

5.1. Finnish cases
All focal Finnish USOs are based on research results in Finnish universities and were founded in 2014–2015. Cases 1 and 3 operate in the veterinary market, cases 2 and 4 in the human market. At the time of the founding of companies, the number of founders in each case was individual and constitutes from one (as in case 1) to five (as in case 3).

To develop an innovative business, all cases received two to four public grants, or a total of 25,000 to 185,000 euros. However, the part necessary for obtaining public investments was generated in different ways: case 1 used the savings of the founder, cases 2 and 3 attracted private investors, and case 4 offered service and consulting services to third companies. Case 4 also received several grants from private foundations, totaling 20,000 euros. At an early stage of development, case 1 was able to start generating revenue due to the fast start of sales and case 4 due to additional services, which had a positive effect on the development of companies. The founders’ own savings played an important role in all cases, but the share of these savings in USOs that generate revenue is smaller. The development of case 2 is challenging due to the negative results of animal tests.

Finnish USOs and other start-ups are actively taking the opportunity to receive a grant for a patent search, which fully covers the services of a patent agency. All Finnish cases have taken advantage of this opportunity. As a result, cases 1–4 received full patents for their inventions; case 4 also received a design patent for several complementary products. Patents cover countries with the most promising markets, which mainly include developed countries. Companies emphasize the time and financial costs associated with obtaining patents. The cost of obtaining a patent starts from 25,000 euros, which includes the filing of a patent, the services of a patent company, and others. The terms of obtaining a patent depend on the chosen strategy, and it takes more than 3 years.

5.2. Swedish cases
Swedish cases 5, 6, and 8 were founded in 2013, and case 7 in 2016 as a result of university research. Cases 5, 7 and 8 operate in the human market; case 6 operates in the veterinary market. One of the founders of case 5 came from a pharmaceutical company, and all other
founders from cases 5–8 are from Swedish universities. The total number of founders at the time of the USOs’ formation was from two to three people.

At the initial stage of development, companies received private and public grants for the formation of companies, marketing analysis, participation in profile conferences, and the patenting of inventions. The amounts received varied from 15,000 to 75,000 euros for each grant. Cases 7 and 8 received 5,000 and 6,000 euros from the University Entrepreneurship Support Fund. Cases 5 and 8 were able to attract venture capital investments. At the time of the interview, cases 5 and 8 generated revenues from the main product, case 6 had a prototype, and case 7 tested a minimum valuable product. Personal savings in Swedish cases played a smaller role than in Finnish cases. The amount of one’s own savings at the initial stage of the USO’s development was noted as insignificant; however, companies found it difficult to identify the size or share in total investments.

The presence of public support for patenting university research also played a role for the Swedish USOs under consideration. Cases 5, 6, and 8 have full patents on their inventions. Case 7 does not provide patent information. Case 6 does not generate revenue and is having trouble attracting investors and extending the patent. The patent of case 5 covers a large number of developed and developing countries. The patent of case 8 covers Sweden, Germany, Japan, and the USA. The conditions, costs, and terms of obtaining a patent are generally similar to Finnish ones.

6 Cross-case analysis
There are two key factors that are equally important for the business development of the USO at the early stages: access to financial resources and ownership of the IPR. However, the studied approaches in the focal countries contribute to the development of the medical device markets may be the same or different, see Table 2.

6.1. Access to financial resources

6.1.1. Public financial resources at the formation stage of development

Direct public financing is highly important at the initial stage of the USO’s development. This is critical for the probability of participant survival and not for the transformation of the
ecosystem into an unviable dependence on access to capital, especially in a country as small as Finland. Access to financial resources at the formation stage of the USO’s development is generally similar in Finland and Sweden. The presence of various public forms of support for start-ups helps to create USOs. Business Finland and Vinnova public organizations play a crucial role in business development at the formation stage of the USOs. Companies could receive grants for market analysis, testing ideas, and participation in the conferences.

6.1.2. Direct financial resources at the validation stage

Representatives of the Finnish USOs highlight the support of the validation process from public funds. Several programs are available for USOs, but all of them cover a part of your costs after the R&D stage or several work packages. Companies cannot use different public programs to cover 100% of the costs. As a result, companies face an acute need for liquidity. Simultaneously, medical device USOs rarely offer additional services that could influence cash flow. One reason for the reluctance to form a medical device USO by university research groups is the long process of development, prototyping, and obtaining the necessary certificates (more applies to the human market).

In turn, representatives of the Swedish USOs insist that the search for money for validation is not the main obstacle. Founders of Swedish USOs agree that it is possible to find money from various sources for this stage, as the idea and the team are more important. The time required for prototyping, developing, conducting long-term and expensive animal tests, and certification are not deterrent parameters for funders.

The number of venture capital funds that invest in the life science industry in both countries is quite large. There are life science funds and funds that do not consider life science a priority. However, it is an issue to highlight funds that have a leading role in Finland and Sweden.

6.1.3. Lock-in in the local market

Local access to financial resources at the formation and validation stages stimulates a lock-in for the company, reducing the necessity to transfer business to other countries, which will
contribute to the development of the region and the innovation ecosystem. The majority of Finnish medical device USOs are interested in entering the US market and seeking investors from the US.

However, Swedish USOs tend to be relocated less often. Companies are considering a global sales market but are confident in local opportunities and emphasize various sources of financing, local network, market openness, and staff qualifications.

In both countries, entrepreneurial recycling is common in this industry (Mason and Harrison, 2006). Successful entrepreneurs consider the local market as basic for the new companies, invest in other life science start-ups, and consult investors. Moreover, they consider USOs to be the natural type of the companies. Existing local experience can be adapted to the needs of new USOs. Additional financial opportunities are also available for groups of companies from one industry, for example, for marketing purposes.

6.2. Public support

6.2.1. Entrepreneurship support programs as indirect funding sources

The goal of the public programs for entrepreneurship is not to offer investment for the projects but to offer non-financial opportunities for the development of USOs. These opportunities include, for example, networking and training of personnel based on business incubators and accelerators.

The outcomes of three Finnish programs supporting biomedical, biotechnological, and pharma ecosystems, as well as the results of short-term and medium-term programs in Sweden, show that detached long-term programs without the support of short-term programs reduce efficiency in the focal ecosystems. They are needed to form a critical amount of scientific research, workforce, and a sufficient number of small and medium companies to start a long-term program.

Furthermore, participants of the program should be ready to collaborate within the focal ecosystem, as well as with other business ecosystems. National insularity, unwillingness to work overtime to achieve the goal, and the growth of unnecessary costs (including salaries)
lead to the failure of key parameters of the start-up or the supporting program. Short-term programs with clear objectives contribute to the emergence of start-ups, research groups, and product development. These short-term programs could become the first step toward the creation of a long-term national program to support specific sectors of the economy.

In turn, the Swedish medical device ecosystem demonstrates a systematic approach in contribution to the economy of knowledge. This innovation ecosystem not only distributes public funding but also complements science by effective methods of business administration. Two- to six-month programs of business incubators and accelerators offer to improve the business skills of participants and contribute to the transition from the academic environment in the industry.

The participants of the business incubators in both countries expressed the opinion that these programs contribute to taking the first step toward establishing USOs for those who doubt. The absence of participation costs, the modularity of the program, access to mentors with experience in start-ups and large companies, and meetings with investors are important parameters for nascent entrepreneurs.

6.2.2. Direct financial support of the start of the growth stage

The capabilities of companies at this stage of development are generally similar in both countries. At this stage, USOs already have a certain background and reputation in supporting organizations and may rely on various financing options. A number of new hired employees and the priority of export factors start playing an important role. Many public financial tools contribute to the marketing activities in both countries. Moreover, both states offer loans with deferred payment and the need to return in case of sales success.

A USO that has achieved the start of the growth stage becomes attractive to various investors. Investors evaluate a formed team with experience in academia and industry, a product that has been developed, prototyped and certified, and export potential, as most of the medical device USOs do not consider the local market a priority. All these factors allow USOs to compete with other start-ups and industries.

Participants of the research that have experience dealing with investors at this stage of
development highlight the new opportunities. Members of the investment business make offers to companies and managers are able to choose the most attractive options for growth.

6.3. IPR ownership

The approaches to IPR ownership of inventions significantly differ in the focal countries. Therefore, the collaboration with TTO is considered by the Finnish USOs in the medical device industry to be an obstacle for business development. The founders of USOs seek to avoid the presence of universities in the company. Entrepreneurs consider universities and TTOs to be an obstacle in negotiations with potential investors, they highlight little value for the company, and they consider the university as a slow and bureaucratic potential partner.

Finnish USOs suffer because of the non-proliferation of information. The speed of development of the USOs and networking decrease, and the link between academia and industry is not used. Moreover, companies are disappointed with the approach of universities in participating in the business development of companies. Universities seek to sell the shares of the company to any buyer and are not concerned about the continued existence and development of the USO.

In turn, the representatives of Swedish USOs with incomprehension commented on the practice of transferring a part of the IPR to the university. Swedish universities receive part of the grant for research, publications, and defending doctoral students; however, all IPRs to the research results belong to researchers who may continue to engage in commercialization. Moreover, universities stimulate entrepreneurship by allocating grants and prizes to both research groups and students.

Moreover, the founders of the company continue to work closely with their laboratories. For example, companies benefit from extended research, including more applied ones, and universities invite founders to demonstrate real business cases for students. Furthermore, the tradition of Swedish research groups to use the USO as an employment opportunity for defending doctoral students in the industry is popular. The research skills of such candidates prevail over business skills; however, the advanced Swedish system of supplementary business education provides the necessary initial knowledge.
7 Discussion

This study offers a contribution to knowledge in the areas of university spin-offs, business formation, and the commercialization of inventions. We have studied the availability of financial resources and IPR ownership in the medical device industry and their roles in the business development of USOs in their early stages. We demonstrate the similarities and differences between Finnish and Swedish public support systems for the formation of USOs, particularly medical device USOs. The public grant system at the initial stage of development of the companies under consideration plays one of the key roles. The state stimulates entrepreneurship based on scientific research and provides opportunities for innovations. Moreover, Swedish companies have a better potential to receive grants from private entrepreneurship funds at the validation stage of business development, for example, to cover the costs associated with R&D. As a result, we validate that financial constraints are not primary for Swedish USOs, unlike Finnish ones. We declare that public support is becoming a factor for students and academic personnel to become entrepreneurs. Such cooperation between the state and universities broadens options for the employment of graduates and the transfer of highly qualified specialists from universities to business.

The role of universities in the development of USOs at the early stages is significantly different. Collaboration of the USOs and Swedish universities is considered an advantage, whereas, according to the founders, Finnish researchers seek to avoid the participation of universities in the project. Finnish USOs in the medical device industry receive little support for a substantial share of the company. Moreover, the ownership of IPR in research results stimulates the formation of new USOs, retains qualified personnel in the local market and contributes to the development of the industry. Swedish medical device USOs do not terminate relations with the university and prefer to continue collaboration and use the network and expertise (Walter et al., 2006; Rasmussen et al., 2011). Finnish founders consider such cooperation undesirable, although they suffer from reduced cooperation with the universities. Moreover, Finnish USOs are forced to collaborate, while Swedish USOs create additional value.

We contribute to the growing interest in transferring research to the industry. However, we
approach the issue of cooperation with the TTO from the perspective of the USO and assess the advantages and disadvantages of such cooperation for entrepreneurs. We argue with Goel and Göktepe-Hultén (2018) and demonstrate that USOs may not bypass such kinds of cooperation; this depends on the structure of the business ecosystem. Moreover, we supplement numerous studies on the lack of effectiveness of the TTO (Shapin, 2003; Sapir and Kameo, 2019). The need to cooperate with TTOs can constrain nascent entrepreneurs and prevent the transfer of potential products to the market.

We are contributing to the rapidly developing trend of entrepreneurial recycling (DeTienne and Robb, 2016; Er et al., 2019). We confirm that entrepreneurial recycling contributes to the sustainable development of local business ecosystems, and we demonstrate how it stimulates the formation of new USOs through increased supply from venture capital, consolidation and retention of promising projects in the local market (Corsi and Prencipe, 2017; Fini et al., 2017). The presence of such entrepreneurs also stimulates the formation of public investment in supporting and developing the region (Spigel and Harrison, 2018).

We further the research by discussing the reasons for medical start-ups’ failures, identifying the parameters that are important for the development of the medical device industry in different countries, and demonstrating that different ways of supporting new industries achieve different results (Segers, 2016; Nyadu-Addo and Mensah, 2017; Hashe and Linton, 2018). Our research contributes to the important topic of institutional and business barriers for the small business (Senarante and Wang, 2018; Bianchi et al., 2018). We show ways of overcoming institutional barriers in the development of new industries and their need to be paid considerable attention.

As a practical contribution, we emphasize the need for a systematic approach to the development of entrepreneurship in countries that consider the life science business a priority. There is a need to combine short-term and long-term programs for the development of fundamental and applied knowledge of universities and training specialists for the transition from academia to industry.

We show policymakers how to distribute IPRs for the successful development of the business ecosystem. The study shows that more advanced countries give the USO all rights
to the results of the study. On the one hand, this stimulates the transition of qualified personnel from academia to business and increases employment and economic stability (McAdam et al., 2017). On the other hand, former academics are in demand in the market, which reduces migration to more attractive countries (Stephan et al., 2015). Despite the fact that developed medical and life science markets like the US also adhere to the practice of sharing IPRs between the university and the USO (Dutfield, 2017), we demonstrate that such a practice can have a negative effect on countries that plan to develop the focal market.

The results of our research could stimulate qualified academic personnel to apply knowledge into practice and move on to the practical development and commercialization of university research. As support for the first steps, nascent entrepreneurs could rely on public entrepreneurship support funds, as well as on business incubators and accelerators and other forms of entrepreneurship support. We emphasize the importance of such programs for the distribution and testing of ideas, as well as practical knowledge for aspiring entrepreneurs (Frimodig and Torkkeli, 2017). The transition from the academy to the industry requires new skills that are rarely available to academic staff; however, the availability of such programs and their promotion allows for the creation of new USOs.

Participants of the study frequently emphasized the role of the university in the commercialization of research. However, representatives of countries differently. We insist that the role of the TTO should be redefined to support entrepreneurship, not control over researchers who are attempting to commercialize knowledge (Huyghe et al., 2016). University representatives have access to networks, facilities and money that should promote or, at least, not oppose the entry of new products into the market. We demonstrate that public funding is critical at the team building stage and during the transition from academy to industry. In the later stages, angel and venture capital investments may be attracted, while public funding and openness to the exchange of information is especially important at the beginning.

8 Limitations and future research

One of the main limitations of this article is the number of USOs that participate in the research. The number of medical device start-ups that can overcome the difficulties of initial
development are few. Moreover, the majority of medical device start-ups prioritize the US market. A logical continuation of medical device research would be the analysis and comparison of the international market, detection of trends, and development of recommendations for new participants of the innovation ecosystems.

Trends and technologies from the human market have an impact on the veterinary market. The sizes of these markets do not allow for an equal comparison. However, veterinarians, no less than their colleagues from the human market, want to use novelties in their work. In turn, the main limitations are related to the life expectancy of start-ups and their changes. The need for fast-moving changes and adaptation under the market makes start-ups difficult to forecast.

Beyond the scope of this research are medical device companies that have existed for more than five years. After the initial development period, the number of failures is reduced and the number of acquisitions is growing. Moreover, changes in the management of the companies require more business competencies than academic ones.

9 Conclusion

We study the role of the availability of financial resources and IPRs on the business development of medical device USOs. We explain that these parameters significantly contribute to the formation of USOs, the commercialization of university inventions, and the business development of the companies at the early stages. However, different public approaches for support and IPR allow some countries to make considerable progress in this area. The availability of public financial support contributes to the development of USOs in small countries and in the local markets. The success of entrepreneurs in the focal industry facilitates the attraction of investments as well as the transformation of entrepreneurs into venture investors or business consultants. In turn, there is little difference between the support of the companies that have reached the start of the sales stage and other industries. The ownership of IPRs assists the development of entrepreneurship in the region due to the transfer of research results and researchers to the industry and increases the number of spin-offs and the amount of cooperation of universities with business.
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