Stakeholder involvement in product development in the biotech industry

Author: Guido Peters
University of Twente
P.O. Box 217, 7500AE Enschede
The Netherlands

ABSTRACT: This paper uses new product development theory, business model theory, ecosystem theory, and stakeholder theory to investigate business model change in university spin-off companies. Using a case study method, two companies were investigated. Although the interview subjects mentioned speaking to many different stakeholders at different points in the development process, they could not point out any particular effect of their involvement. Some recommendations for future research are made, and practical relevance, though very limited, is discussed.

Supervisors: Dr. Kasia Zalewska-Kurek, Dr. Rainer Harms

Keywords
University spin-offs, stakeholder involvement, business models, business ecosystems, business development process, business model change.

8th IBA Bachelor Thesis Conference, November 10th, 2016, Enschede, The Netherlands.

1. INTRODUCTION

For some time now, an increasing amount of research has been done concerning the biotechnology industry, as it has been seen as an important driver of economic growth (Powell, Koput & Smith-Doerr, 1996). In the biotech industry, new product development is particularly lengthy, expensive, and risky, due to the fact that it is heavily based on research and development, has to go through clinical trials, and has to obtain regulatory approval, before commercialisation can begin (Gerbin & Drnovšek, 2013). The odds of succesful completion of this process can be improved by valuable resources that are in possession of stakeholders, namely universities, venture capitalists, established firms, governments, and emerging firms (Ebers & Powell, 2007).

Lubik and Garnsey (2015) also found in their study of three advanced materials university spinoff companies that partnering is an important factor to be considered when evaluating business models. They made some discoveries in particular regarding timing of partnership formation, saying that market options should be examined carefully, and that in the analysis of markets should be included an analysis of potential partners, before the spinoff company reaches out to any potential partner. If contact is made too soon, it could lead to the spinoff getting locked in to a market that does not fit its innovation optimally, due to the fact that the partner will most likely be focused on short term results (Lubik & Garnsey, 2015; Gerbin & Drnovšek, 2013).

Further evidence for the benefit of networks to innovation comes from a study by Lehoux, Daudelin, Williams-Jones, Denis and Longo (2014). In their study, they observed a company that benefited greatly from cooperation with academics, speeding up the process of registration by providing clinical proof of their innovation, as well as adoption by practitioners. Additionally, Gerbin and Drnovšek (2013) note that linkages to academic networks have most likely played a significant role in the quick expansion of the US biotech industry and say that biotech companies should be encouraged to form such linkages so that they can benefit from the effects that seem apparent.

Finally, Li, de Zubielqui, and O'Connor (2015) examined how different types of regionally shared resources affect market performance, using entrepreneurship and cluster theory, social network theory (Gordon & McCann, 2000), and the resource-based view. They found that governement support as a shared resource positively affects market performance when a network outside the cluster was present, but had no direct effect. Furthermore, they found that institutional support enhanced market performance when mediated by either a cluster's regional network or an external network, or both. They conclude by saying that more research is needed on the relationship between entrepreneurs, their firms, and the influence of their context, or in other words, how the ecosystem affects entrepreneurs.

It is apparent from the literature that relationships with multiple stakeholders are often utilised in the process of bringing a product to market in the biotech industry: many articles mention relationships with universities or other research institutes to help develop concepts and test prototypes, with large players in the industry or practitioners to gain access to markets and increase adoption rates (Lubik & Garnsey, 2015; Lehoux et al., 2014; Gerbin & Drnovšek, 2013). Furthermore, as has been mentioned before, timing seems to be an important factor in achieving the best fit between university spin-offs and their partners(Lubik & Garnsey, 2015; Gerbin & Drnovšek, 2013). Additionally, according to Andersson, Gleadle, Haslam, and Tsitsianis (2010) speculative stock markets seem to be sensitive to media coverage of the product development cycle. It has been decided to focus on university spin-offs in the biotech sector because they generally lack business knowledge and skills, as well as access to the necessary resources, as opposed to commercial spin-offs, which makes stakeholder involvement essential for them to succeed (Lubik & Garnsey, 2015; Ziaee Bigdeli, Li & Shi, 2015; Vohora, Wright, and Lockett, 2004). However, it seems that the literature has not yet specifically linked stakeholder involvement to product development stages. The research question of this paper, then, is twofold: 1. How do university spin-offs in the biotech sector involve different stakeholders at different stages in the development cycle? and 2. How are business models affected of university spin-offs in the biotech sector affected by involving stakeholders in the development process? The research question will be answered using new product development theory, stakeholder theory and the RCOV framework (Demil & Lecocq, 2010), while taking a business ecosystem perspective.

2. THEORETICAL FRAMEWORK

2.1 New Product Development

It has long been recognised that there are particular activities that have to be performed for development of a new product to be successful. Early models of new product development were portrayed as progressing linearly (Cooper, 1983), were often designed for the project-level only, thus lacking important business processes, be it subsequent or concurrent, as well as often being industry-specific (Fairlie-Clarke & Muller, 2003). Ndonzuau, Pirnay and Surlemont (2002) studied the development process of university spin-offs and developed a model consisting of four stages, however this model lacks detail and does not provide a description of what needs to be done in each stage. Vohora et al. (2004) studied high-tech university spin-offs and found that in the development process there are critical junctures which must be passed before the spin-off can move on to any subsequent stages. These critical junctures are 1) Opportunity recognition, 2) Entrepreneurial commitment, 3) Venture credibility, and 4) Venture sustainability.

This study will use a combination of the model designed by Fairlie-Clarke & Muller (2003) and the critical junctures presented by Vohora et al. (2004). The product development cycle model (Fairlie-Clarke & Muller, 2003) consists of 9 stages: identifying a product opportunity, generating product ideas, evaluating and approving product ideas, identifying requirements, developing a business plan, generating project proposals, evaluating project proposals and business plans, funding and scheduling, and monitoring of projects, as can be seen in Figure 1. In between some of these stages will be the critical junctures. The first critical juncture, that of opportunity recognition, must be passed before the product development process starts, or there would be no spin-off company to investigate. The critical juncture of entrepreneurial commitment is concerned with academics' choice to become an entrepreneur, and is essential to gaining credibility later on in the process (Vohora et al., 2004). It is expected that this juncture needs to be overcome before the stage of developing project proposals or even before the stage of evaluating product proposals, as these stages will require a significant time investment. For the stage of developing project proposals time will have to be invested in generating requirements and business plans and potentially in attracting human resources, while in the stage of evaluating product proposals time may mainly need to be invested in finding people to help evaluate proposals. The third critical juncture is important for attracting not only financial capital,

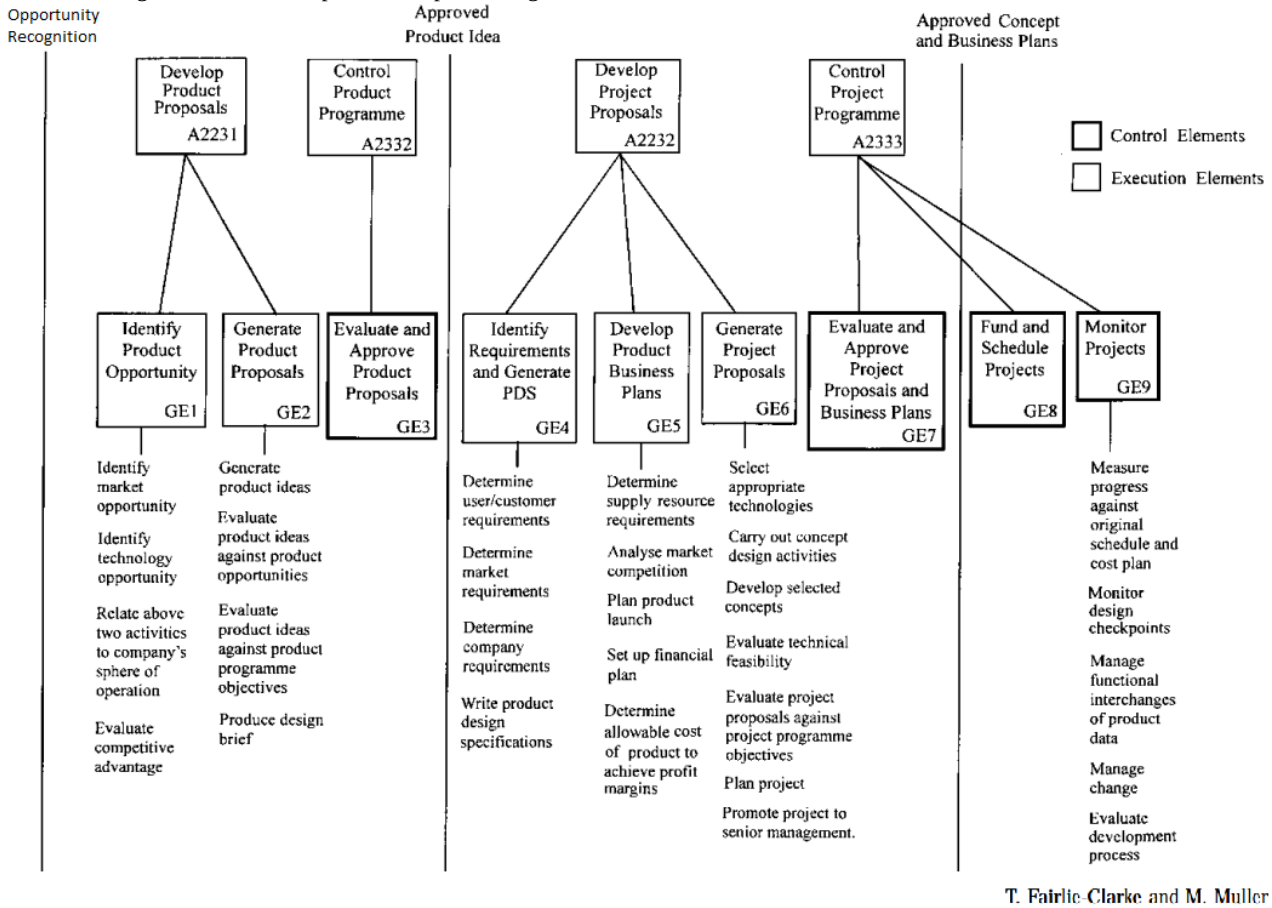
but also human capital, usually in the form of management. Since this juncture serves to attract funding, it must be passed before the funding and scheduling stage. According to Vohora et al. (2004), entrepreneurs can overcome this juncture by getting market data as evidence that their venture is valuable, as well as by having professional management, or at least management that is perceived to be professional. The final critical juncture is not so much a juncture as much as it is an ongoing process wherein the entrepreneur and their team need to develop the skills to reconfigure their resources to adapt to a changing environment, so that they can achieve a phase of sustainability. This final "juncture", then, takes place during the monitoring of projects stage. As has briefly been mentioned before, however, in the biotech industry, new products also have to go through a lengthy process of clinical trials and getting regulatory approval, which is not explicitly mentioned in the model of Fairlie-Clarke and Muller (2003). It can be argued, though, that this, too, is covered by the final stage, that of monitoring, so for the purpose of this study it will be seen that way. In the following section, expectations regarding stakeholder involvement in each stage will be detailed.

2.1.1 Expected Stakeholder Involvement

In the product opportunity identification stage, it is expected that the main stakeholders involved will be businesses operating in the relevant market, practitioners, hospitals, and potentially patients. For the product proposal generation stage, it is expected that key stakeholders to be involved are universities or other research institutes. In the evaluation of product proposals stage it is anticipated that the most important stakeholders involved will be customers, in this case most likely businesses, practitioners, or hospitals. The same goes for the requirements identification stage. In the business plan development stage it is expected that marketing support departments of universities or marketing departments of incumbent biotech firms will be key. For generating project proposals it is predicted that universities or other research institutes will be most important. Following that, in the stage that project proposals and business plans are evaluated, it is likely that university marketing support departments and incumbents' marketing departments will once again be key. Then, for funding and scheduling of projects, incumbents, hospitals, and practitioners are expected to be most important. Finally, for monitoring projects, it is expected that the main stakeholders involved will be universities, other research institutes, hospitals, and practitioners.

2.2 Business Model Analysis

Gomes & Salerno (2010) note that in university spin-offs there is a direct interaction between different stages in the product development cycle and the business model which the university spin-off employs, and that development is recursive and nonlinear. It is consistent with other literature(e.g. Casadesus-Masanell & Ricart, 2010; Moyon & Lecocq 2014; Schilke, 2014; Ziaee Bigdeli et al., 2015), then, to take a dynamic approach to business model analysis in this case. This will be done using the approach used by Ziaee Bigdeli et al. (2015), which was built upon the RCOV Framework originally designed by Demil & Lecocq (2010), which was in turn inspired by Penrose's (1960) view of firms. The main assumption of the RCOV framework is that firms use their resources and competencies (RC) to bring a value proposition (V) in the form of products or services to the market, while designing their organisational structure (O) to best enable them to deliver that value. According to this model, changes in a business model occur due to changes in cost or revenue

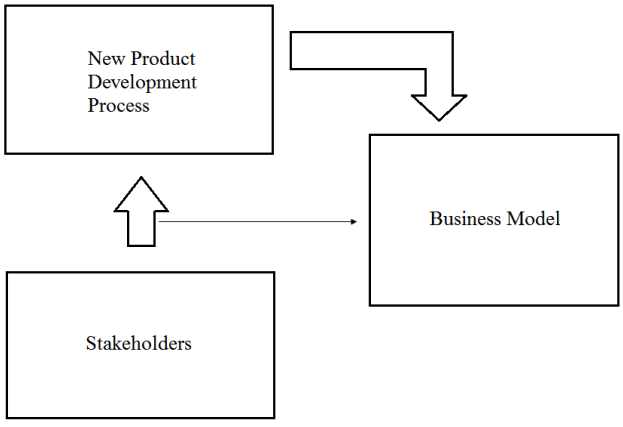


Figuur 1: Product Development Process (Faerlie-Clarke & Muller, 2003)

structure, in competences and resources, and in the value proposition. This is consistent with the idea of critical junctures in that entrepreneurs have to develop new skills or acquire new resources to be able to move on in the development process, as well as with the recursive nature of the product development process.

2.3 Business Ecosystem Theory

Moore (1993) was the one to introduce ecosystem theory, where he suggested that businesses should strive to become central to a complex value network by making other businesses in the ecosystem dependent upon them, rather than vertically integrating into the value chain. While Moore focused mainly on large businesses, the concept of the ecosystem is applicable to university spin-offs as well, although it is somewhat more complex for them than it is for most large businesses due to necessary interactions with parent institutions, government agencies, and academic networks, in addition to the usual stakeholders, which are financiers, customers, complementors, and suppliers (Lubik, Garnsey, Minshall & Platts, 2013). Boh, De-Haan, and Strom (2015) found that universities often act as incubators, allowing faculty staff and students to meet and experiment with the idea of bringing technology invented in the lab to market, although they can also be a source of conflicts of interest (Vohora et al., 2004). Lehoux et al. (2014) found that access to academic networks could greatly reduce the time required to get regulatory approval and adoption by practitioners, while Gerbin and Drnovšek (2013) noted that academic networks played a significant role in the expansion of the US biotech industry. Ayoub, Gottschalk, and Müller (2016) researched how different sources of financing affected university spin-off performance and found that businesses who received funding through a government grant generated 1.7 times higher losses, had fewer employees, and provide a return on equity that is nearly three times lower than university spin-offs which were privately funded. Finally, it is recognised that customers can be a source of ideas, as well as, more recently, a source of financing, through crowdfunding (Golán, 2015).



Figuur 2: Theoretical Framework

2.4 Stakeholder Theory

Mielke, Vermaßen, Ellenbeck, Milan, and Jaeger (2016) came up with a typology of stakeholder involvement in science, based on a literature review, interviews and practical experience. In this typology they defined four unique types of stakeholder involvement, namely: technocratic, neoliberal-rational, functionalist, and democratic. These types are differentiated on the basis of five criteria: role of the scientist (Welp, De La Vega-Leinert, Stoll-Klugeemann & Jaeger, 2006), objectives (Renn & Schweizer, 2009), kind of knowledge (Schneidewind & Singer-Brodowski, 2013; Glicken, 1999), understanding of science, and science-policy interface. Since the article by Mielke et al. (2016) is about stakeholder involvement in science, there is a great deal of consideration for things such as the autonomy of science, which is of no relevance for this paper. It is because of this that this research will mainly take into account the objectives of stakeholder involvement and the kind of knowledge contributed by stakeholders for the different types of stakeholder involvement. Next, the four types of stakeholder will be described.

1. In technocratic stakeholder involvement, the main objective is to collect issue-specific information or data, which is objective and can be falsified. The kind of knowledge that stakeholders contribute in this type of stakeholder involvement is mostly restricted to technological areas rather than cultural or institutional ones (Schneidewind, 2013).

2. In the neoliberal-rational approach to stakeholder involvement, main objectives are efficiently gathering necessary information and data, as well as gaining legitimacy (Schneidewind, 2013). The kind of knowledge that is desired from stakeholders in this approach is not restricted to solely data and information, but can also include subjective assessments and knowledge about systems (Mielke et al., 2016).

3. In the democratic approach, similar to the neoliberal-rational approach, the kind of knowledge provided by stakeholders is not limited to objective information and data, but rather also includes opinions and ideas.

4. The objective of functionalist stakeholder involvement is to initiate learning processes, to increase sensitivity to problems of society and stimulate creativity. In a functionalist approach, stakeholders contribute knowledge from economic, ethical, social, and political perspectives. Democratic type stakeholder involvement can also be seen as collaborative research, which is defined by Wiek (2007, p. 55) as a process wherein "scientists and local experts not only exchange relevant information but jointly generate (new) knowledge on the basis of their scientific as well as local expertise (joint research)". The objective here is to integrate societal actors into the research process in order to gain legitimacy.

3. METHODOLOGY

Due to the fact that not much research has been done on this topic, there is little data on biotech startups available for studying, so inductive methods are appropriate. This paper will utilise a case study methodology to analyse three spin-off companies of the University of Twente. The University of Twente has generated 27 spin-off companies in the biotech sector since 1985. Of these 27 companies, only those of which the website still works and has reported news since at least the year preceding this study will be considered. This leaves 14 companies, of which two are service companies, which are not relevant to the topic of this paper. It is expected that the remaining 12 companies have been succesful in developing and marketing their innovation, so it is likely that these will contribute most to a better understanding of how biotech startups, specifically university spin-offs, can be successful.

Success of a company will be measured differently depending on where a company is in the product development cycle. If a company is not yet selling any products, success will be measured by the extent to which they have been able to achieve their investment goals. If a company has already launched their product, success will be measured by whether or not they are a profitable business. Out of the 12 companies that are left, three will be chosen for interviewing. These interviews will then be analysed using the theories discussed earlier, and will be

compared for any similarities in their approach of innovation development. Next, the interview questions will be discussed, an overview of which can be found in Appendix A.

3.1 Interview Questions

To learn about the opportunity identification stage and the critical juncture, the entrepreneurs will be asked "How did the idea to start your own business come about?".

To find out more about the difference between the opportunity identification stage and the product proposal generation stage, the entrepreneurs may be asked "When did you start seriously thinking about solutions for the product opportunity?".

Because the next critical juncture, that of entrepreneurial commitment, is expected to be somewhere around this point in the product development process, the entrepreneurs may be asked "When did you decide to focus your efforts on becoming an entrepreneur, and why?".

To explore the product proposal evaluation stage, the entrepreneurs may be asked "How did you evaluate your product ideas?"

To learn more about the project proposal stage, the entrepreneurs may be asked "When did you start thinking about product requirements and design specifications?", and "How did you go about creating a business plan?".

For the next stage, that of controlling project programmes, the entrepreneurs may be asked "How did you evaluate your project proposals and business plans?", "How did you go about attracting financing?", and, if necessary, "How were you able to achieve credibility with investors?".

Finally they will be asked to describe the process of gaining regulatory approval, if relevant. If at any stage no mention was made of other parties being involved, the entrepreneurs will be asked if they worked together with some other party on that particular item. Ideally, more general questions will be asked, for example after the question on entrepreneurial commitment, the interview subject might be asked something along the lines of "Once you had decided to become an entrepreneur, what steps did you take next?". This approach can be used for every stage, and is ideal as it does not imply much about the research direction. The more specific questions will only be asked if information on a particular subject is lacking or if time is short.

4. RESULTS

4.1 Case A: Injectable Hydrogel

In 2007, a hydrogel was developed by the Developmental Bioengineering Group of the University of Twente. The hydrogel works by mixing a patient's stem cells with a chemical compound, after which the resulting amalgamation is injected into the area which needs repair. Over the course of a couple of years, it was discovered that this hydrogel could be very useful for repairing cartilage defects, as well as many other applications, such as treatment of burns, and potentially replacement of pancreatic islets. It is at this point that the first critical juncture, that of opportunity recognition, was overcome, and the inventor applied for patents. Next, the stage of opportunity identification could be entered. In this stage, the opportunity was clarified and narrowed down to cartilage repair with the help of others who were also involved in the development of the hydrogel. It is unknown what type of stakeholder involvement was used here, as there was not enough information on that. Subsequently, a company would be expected to enter the stages of product proposal generation and product proposal evaluation, however, it does not seem to have been so in this case. This is likely due to the fact that the invented technology is synonymous with the product that they will be delivering, and that the other potential applications are based on the same product. Once the cartilage repair market had been chosen as the main opportunity to pursue, clinical trials of the technology for use in animals were initiated. In 2014, after a great deal of research had been done, it seemed likely that the hydrogel would be safe to use in both animals and humans. Consequently, the inventor recruited a manager with 35 years of experience in senior executive management, as well as management in small medical and biotech start-ups, and a colleague at the Developmental Bioengineering Group with 15 years of experience in evaluation and production of medical devices, to help develop the business. At this point, the critical juncture of entrepreneurial commitment was overcome, and the company moved on to the stages of identifying requirements and specifications, and developing business plans. For identifying requirements, a consultancy company was involved which provided a roadmap for getting all the necessary certifications required to be allowed to produce a pharmaceutical product, thus the stakeholder involvement used here is of the neoliberal-rational type. Additionally, throughout the research process, hospitals, clinicians, and veterinarians have been involved to provide feedback, as well as evidence of the effectiveness of the invention, thus helping the company gain legitimacy. This type of stakeholder involvement suggests the use of a democratic approach. Business plans were developed by the experienced senior executive manager. The stage of generating project proposals does not seem to have been applicable. For evaluating business plans, input was gathered from colleagues within the University of Twente, a business boot camp, as well as from connections built through work at university. This type of stakeholder involvement can be characterised as being of the neoliberal-rational type, as the knowledge contributed consists of opinions and ideas to a large extent, but is not used to generate new knowledge in the form of articles or other such things. Funding of research was acquired through subsidies from local governments, European level government, and charity. To help secure a subsidy from the European Fund for Regional Development, the injectable hydrogel company involved a company specialised in assisting in applying for subsidies to provide cultural and systems knowledge, thus employing neoliberal-rational type stakeholder involvement.

4.2 Case B: Pain Measurement

Chronic pain has for a long time been a poorly understood topic, both in the academic and the medical world. It is often the case that, after a radical procedure, such as a complete knee replacement, the patient will keep experiencing pain for a long time after it should have been gone. Before, it was thought that this was due to an accident during surgery or due to some other problem in the knee. However, it has turned out that it is often the person's pain system that is afflicted by something, causing them to experience pain even when there is nothing physically wrong with the body. Due to his research in the area, the founder recognised this problem, and came up with a way to measure whether or not someone is prone to developing chronic pain, enabling doctors to treat the patient differently, so that the pain may be prevented. Once the founder had made the invention, he discussed its business potential with the University of Twente's Business Development Team, as well as with hospitals, doctors, and investors. Thus, in the stage of evaluating product proposals, hospitals, doctors, investors, and the university's marketing support department contributed knowledge of systems, market data, and subjective assessments of the product opportunity, meaning a neoliberal-rational

approach to stakeholder involvement was used. Based on the comments he received, and because he saw becoming an entrepreneur as the best way to contribute to society, he decided to start a business. Having overcome the critical juncture of entrepreneurial commitment, the company could move on to identifying requirements and developing business plans. For identifying requirements, a consultancy company was involved which provided advice on the legal and certification requirements for their product, thus the stakeholder involvement used here is of the neoliberal-rational type. Additionally, throughout the research process, hospitals and clinicians have been involved to provide feedback, as well as evidence of demand for the invention, thus helping the company gain legitimacy. This type of stakeholder involvement seems to have been of a democratic nature. For developing business plans, the founder involved the university's business development team, investors, business accelerators, other entrepreneurs, and an external CEO. These stakeholders were involved for efficient gathering of information on different approaches to the market, as well as gaining legitimacy, meaning the type of stakeholder involvement employed here is of a neoliberal-rational nature. The founder later recruited a former student entrepreneur, who developed the Launching Customer Programme. This programme allows them to get their device into the hands of clinicians while bypassing some regulations, helping them obtain feedback from use in practice, as well as providing them with an installed customer base, which they expect to be useful when negotiating with potential investors. The project proposal stage was completed before the critical juncture of entrepreneurial commitment was overcome, and no stakeholders were involved. In the stage of evaluating business plans, the university's marketing support department and a local foundation for innovation were involved in a neoliberal-rational way. For the funding stage, there have been opportunities to secure venture capital, however, through speaking to other entrepreneurs, the founder learned that venture capitalists are generally focused on short-term returns, often to the detriment

of the company, and so decided against accepting venture capital funding. Instead, the company has been relying on subsidies for its funding. The involvement of entrepreneurs in the funding stage seems to be of the neoliberal-rational type. The company intends to create a schedule to help monitor progress. So far, there are no stakeholders involved in this stage.

Table 1. Type of stakeholder involvement per development stage.

Development stage / Stakeholder Involvement Type	Opportunity Identification	Product Proposal Generation	Product Proposal Evaluation	Identifying CR and generating PDS	Develop Business Plans	Evaluating Business Plans	Fund and Schedule Projects	Monitor Projects
Technocratic								
Neoliberal-rational			X	XX	X	XX	XX	
Democratic				XX				
Functionalist								

Table 2. Stakeholders involved per development stage.

Development stage / Stakeholders	Opportunity Identification	Product Proposal Generation	Product Proposal Evaluation	Identifying CR and generating PDS	Develop Business Plans	Evaluating Business Plans	Fund and Schedule Projects	Monitor Projects
University								
Hospitals			X	XX				
Clinicians / Doctors			X	XX				
Consultancy companies				XX			X	
Investors			X		X	X		
Academics	X							
Business boot camps					X	X		
Fellow entrepreneurs					X		X	
University marketing support department			X		X	X		

5. DISCUSSION

5.1 Product Development Process

The model used to analyse the product development process of university spin-offs used in this paper was not optimal, as many stages proposed by the model were not explicitly gone through. The model being as detailed as it was, ended up leading to less detailed results than desirable, due to looking for things that have not seemed to be there. In hindsight, the model developed by Vohora et al. (2004) would likely have been more suitable. Though it is not as detailed as Faerlie-Clarke and Muller's (2003) model, it seems to better represent the way university spin-off companies develop. In their model, the university spin-off starts in the research phase, which continues throughout the development of the company, and from there moves on to rather general stages. This is consistent with the findings of this paper, as, for example, the stages of product proposal generation and project proposal generation seemed to have been inseparable, and thus so their respective evaluations. Research is an area that was particularly hard to inspect using Faerlie-Clarke and Muller's (2003) model of the product development process, as it was not represented by any of the stages in that model. It was expected that a more detailed model would be of great assistance, however, it turned out not to be so.

5.2 Stakeholder involvement

It was initially theorised that stakeholders would be involved in each stage. As can be seen in tables 1 and 2 on the previous page, however, stakeholders did not seem to be involved as much as had been expected. It was expected that hospitals, practitioners, and companies operating in the biotech sector would be a source of opportunity identification, which does not seem to have been the case. Instead, the only stakeholders found contributing to opportunity identification were academics, in the injectable hydrogel case. For product proposal generation, it was expected that universities and possibly other research institutes would be involved, however, no stakeholder involvement was found. For product proposal evaluation, it was expected that customers would be most important. It was found that customers, i.e. hospitals and practitioners, were indeed important, and in addition to that, investors and the university's marketing support department also seemed to be involved. In the stage of identifying requirements and determining product design specifications, it was again expected that the main stakeholders involved would be customers. This seemed to be true in both cases, though both also used a consultancy company to determine legal and certification requirements. To develop business plans, it was expected that the university's marketing support department and incumbents' marketing departments would be key. However, external stakeholders were only found to be involved in business plan development in the pain measurement case, and in addition to the university's marketing support department, it seemed that investors, fellow entrepreneurs, and business boot camps were also an influence. For the evaluation of business plans and project proposals, expectations for involved stakeholders were the same as for business plan development, namely the university's marketing department, and incumbents' marketing departments. The university's marketing support department was indeed found to be involved, as well as business boot camps and investors. For the funding and scheduling stage, it was expected that incumbents, hospitals, and practitioners would be most important, though none of these were found to be involved in this stage. Instead, consultancy companies and fellow entrepreneurs seemed to be involved. In the monitoring stage, there did not seem to be stakeholder involvement, though only one out of the two cases had gotten to that stage.

5.3 Business model analysis

In case A, the interview subject did not mention any changes to the business model. It is possible that this is due to the fact that neither the founder nor the person who was responsible for the business model were available for interview, or it could be that there really have not been any changes. In case B, however, some changes have been found. The first change is a small change in the revenue model and cost structure. Initially, the idea was to make their device available to practitioners for a low price, and charge them on a per-use basis, using software installed on the device. It has been changed to charging a price conforming to the market for the device, and getting per-use revenues from a disposable electrode. The second change concerns the target market, which has changed from originally being only The Netherlands, to also including Belgium, Denmark, and Germany. These changes were made mostly as a result of reflection. The final change is one in approach to the market, which was the result of a change in human resources, namely the hiring of a former student entrepreneur, who developed the Launching Customer Programme. This programme is intended to provide feedback from real use case scenarios, as well as an installed user base before full certification has been acquired.

5.4 Business ecosystem analysis

According to business ecosystem theory, firms should strive to become central to a complex value web consisting of many different stakeholders by making other companies dependent upon them. The injectable hydrogel company of case A has leveraged its position as a university spin-off company to use university facilities to produce prototypes of their technology, while finding partners who could manufacture their product on a larger scale. They also intend to have a medical design company design the tool that will be used to apply their hydrogel, and have another manufacturer produce the tool. In this way, these companies become complementors and they and the spin-off company's customers will be dependent on them for returns in this particular market. The pain measurement company also uses university facilities, though in this case for office space. Additionally, they intend to have three specialised suppliers for the different components necessary and a manufacturer for assembling the product. It seems, then, that both companies are indeed attempting to become central to a value web of stakeholders, as suggested by business ecosystem theory.

6. CONCLUSIONS

This paper has tried to find a link between stakeholder involvement in different stages of the development process of university spin-offs, and effects thereof on their business models, using new product development theory, business model theory, business ecosytem theory, and stakeholder theory. Although stakeholder involvement has been found, no evidence of direct influences of stakeholders on business models seems to be present. It has seemed, though, that stakeholder involvement is centered around the critical junctures proposed in the development model of Vohora et al. (2004), though more research on this is necessary. Nonetheless, there is some relevance to literature and practice.

6.1 Scientific relevance

It seems that the model developed by Vohora et al. (2004) is more suitable for framing analysis of the development process of university spin-off companies than a model of the product development process, though the more detailed model could be of help in coming up with interview questions. Additionally, it does seem to be the case that university spin-off companies in

the biotech sector try to use their ecosystem to their advantage to the best of their ability. In future research, larger sample sizes are necessary, as well as more research on stakeholder involvement in overcoming critical junctures.

6.2 Practical relevance

It was only possible to determine success of the companies so far to a limited extent, as they were still in an early stage of development, and were not in a position to generate revenue or get private investments yet. However, both companies studied have been able to fund research for numerous years by getting subsidies awarded to them. Because of this, they may be useful examples in how to obtain enough funding for executing research.

6.3 Limitations

First of all, the sample size of this paper is very small and cannot be seen as significant. Second, the author was inexperienced in using interviews to gather data, and due to limited time on both the author's end and the companies', follow-up interviews were not an option to collect missing information. Finally, the theoretical framework used was not entirely optimal for analysing the development process of university spin-off companies.

7. ACKNOWLEDGMENTS

My sincerest thanks to my supervisors for their guidance on writing this thesis, as well as to the companies who took some time out of their day to let me interview them.

8. REFERENCES

1. Andersson, T., Gleadle, P., Haslam, C., Tsitsianis, N. (2010) Bio-Pharma: A Financialized Business Model. *Critical Perspectives on Accounting* 21(7): 631-641, doi: 10.1016/j.cpa.2010.06.006
2. Ayoub, M.R., Gottschalk, S., Müller, B. (2016). Impact of public seed-funding on academic spin-offs. *Journal of Technology Transfer*, pp. 1-25. Article in Press. doi: 10.1007/s10961-016-9476-5
3. Boh, W. F., De-Haan, U., and Strom, R. (2015). University technology transfer through entrepreneurship: faculty and students in spinoffs. *Journal of Technology Transfer*, 9 p. Article in Press. doi: 10.1007/s10961-015-9399-6
4. Casadesus-Masanell, R. and Ricart, J.E. (2010) From strategy to business models and onto tactics. *Long Range Planning*, 43 (2), 195–215.
5. Cooper, R.G. (1983). The new product process: an empirically-based classification scheme. *R&D Management*, 13, pp. 1–13
6. Demil, B. and Lecocq, X. (2010) Business model evolution: in search of dynamic consistency. *Long Range Planning*, 43, (2), pp. 227–246.
7. Ebers, M., Powell W. W. (2007) Biotechnology: Its Origins, Organization, and Outputs. *Research Policy* 36 (4), pp. 433-437
8. Fairlie-Clarke, T., Muller, M. (2003) An activity model of the product development process. *Journal of Engineering Design*, 14 (3), pp. 247-272, doi: 10.1080/0954482031000091040
9. Gerbin, A., Drnovšek, M., (2013) How do university IPRs and R&D funding mechanisms affect innovation performance in the healthcare biotechnology industry? Evidence from Europe and the USA. *Periodicum biologorum*, 115 (1), 79-95
10. Glicken, J. (1999). Effective public involvement in public decisions. *Science Communication*, 20 (3), pp. 298–327
11. Golán, M. L. (2015). Crowdfunding: A funding model that succeeds in times of revolt of the masses. *10th Iberian Conference on Information Systems and Technologies (CISTI)*, Aveiro, pp. 1-6. doi: 10.1109/CISTI.2015.7170586
12. Gomes, L. A. de V., and Salerno, M., S., (2010). An integrated model for product development process and initial strategic planning of academic spin-offs. *Gestão & Produção*, 17(2), pp. 245-255. doi: 10.1590/S0104-530X2010000200003
13. Gordon, I., & McCann, P. (2000). Industrial clusters: Complexes, agglomeration and/or social networks? *Urban Studies*, 37(3), pp. 513–532
14. Lehoux, P., Daudelin, G., Williams-Jones, B., Denis, J.-L., Longo, C., (2014) How do business model and health technology design influence each other? Insights from a longitudinal case study of three academic spin-offs. *Research Policy*, 43 (6), 1025-1038, doi: 10.1016/j.respol.2014.02.001
15. Li, H., de Zubielqui, G.C., O'Connor, A., (2015) Entrepreneurial networking capacity of cluster firms: a social network perspective on how shared resources enhance firm performance. *Small Business Economics*, 45 (3), 523-541
16. Lubik, S., Garnsey, E., Minshall, T., Platts, K. (2013). Value creation from the innovation environment: partnership strategies of university spin-outs. *R&D Management* 43 (2), pp. 136-150.
17. Lubik, S., Garnsey, E., (2015) Early Business Model Evolution in Science-based Ventures: The Case of Advanced Materials, *Long Range Planning*, doi: 10.1016/j.lrp.2015.03.001
18. Mielke, J., Vermaßen, H., Ellenbeck, S., Milan, B. F., Jaeger, C. (2016). Stakeholder involvement in sustainability science—A critical view. Energy Research & Social Science, 17, pp. 71-81. doi: 10.1016/j.erss.2016.04.001.
19. Moore, J. F. (1993). Predators and prey: A new ecology of competition. *Harvard Business Review*, 71(3), pp. 75-83.
20. Moyon, E. and Lecocq, X. (2014) Rethinking business models in creative industries: the case of the French record industry. *International Studies of Management & Organization*, 44, (2), pp. 83–101.
21. Ndonzuau, F. N., Pirnay, F., Surlemont, B. (2002). A stage model of academic spin-off creation. *Technovation*, 22 (5), pp. 281-289, doi: 10.1016/S0166-4972(01)00019-0
22. Pisano, G. (2006) Science Business: The Promise, the Reality and the Future of Biotech. *Harvard Business School Press*, Boston

23. Penrose, E.T. (1960) The growth of the firm – a case study: the Hercules Powder Company. *Business History Review*, 34 (01), pp. 1–23.
24. Powell, W. W., Koput, K. W., Smith-Doerr, L. (1996) Interorganizational Collaboration and the Locus of Innovation: Networks of Learning in Biotechnology. *Administrative Science Quarterly*, Vol. 41, No. 1 (Mar., 1996), pp. 116-145, doi: 10.2307/2393988
25. Renn, O., Schweizer, P.-J. (2009). Inclusive risk governance: concepts and application to environmental policy making. *Environmental Policy Governance*, 19 (3), pp. 174–185
26. Schilke, O. (2014) On the contingent value of dynamic capabilities for competitive advantage: the nonlinear moderating effect of environmental dynamism. *Strategic Management Journal*, 35 (2), pp. 179–203.
27. Schneidewind, U., Singer-Brodowski, M. (2013). Transformative Wissenschaft. Klimawandel im deutschen Wissenschafts—und Hochschulsystem. Metropolis-Verlag, Marburg
28. Schneidewind, U. (2013). Transformative literacy. Understanding and shaping societal transformations. *GAIA*, 22 (2), pp. 82–86
29. Vohora, A., Wright, M., and Lockett, A. (2004) Critical junctures in the development of university high-tech spinout companies. *Research Policy*, 33 (1), pp. 147–175
30. Welp, M., De La Vega-Leinert, A., Stoll-Klugeemann, S., Jaeger, C.C. (2006). Science-based stakeholder dialogues. Theory and tools. *Global Environmental Change*, 16 (2), pp. 170–181
31. Wiek, A. (2007). Challenges of transdisciplinary research as interactive knowledge generation—experiences from transdisciplinary case study research. GAIA, 16, pp. 52–57
32. Ziaee Bigdeli, A., Li, F. and Shi, X. (2016), Sustainability and scalability of university spinouts: a business model perspective. *R&D Management*, 46, pp. 504–518. doi: 10.1111/radm.12167

APPENDIX

Appendix A: Interview questions

1. Could you tell me something about how the idea to start your own company came to be?

2. When did you start seriously thinking about solutions for the product opportunity?

3. When did you decide to focus your efforts on becoming an entrepreneur, and why?

General questions

4. - What steps did you take next?

   - What did you do next?

   - Where did you go from here?

   - Was anyone else involved?

Focused questions

5. How did you evaluate your product ideas?

6. When did you start thinking about product requirements and design specifications?

7. How did you go about creating a business plan?

8. How did you evaluate your project proposals and business plans?

9. How did you go about attracting financing?

10. Have you been able to achieve your investment goals?

11. How were you able to achieve credibility with investors?

12. Is your company profitable?