

The consequences of entering an OTC market for a prescription-based business model in the hearing aid industry

Author: Roelof van Santen
University of Twente
P.O. Box 217, 7500AE Enschede
The Netherlands

ABSTRACT

The direct sales of hearing aids to consumers will start soon because of the introduction of the ‘Over-the-Counter Hearing Aid Act of 2016’ and has therefore received some attention in the academic literature. The focus is mainly on the perspective of the hearing care professional, however the manufacturer perspective is missing. This research paper aims to determine what the consequences are of entering an OTC market for a prescription-based business model in the hearing aid industry. We conducted a single case study at a large hearing aid manufacturer to collect our primary data. Our research is qualitative by nature, and we use multiple sources of evidence (including interviews), and triangulation, to increase internal validity and get a clear multi-perspective view. The results of our research have provided us with a manufacturer perspective and shown that there are different consequences of entering an OTC market for a prescription-based business model, starting at solving a new value proposition for a new customer segment: consumers with mild to moderate hearing loss.

Graduation Committee members:
Prof. Dr. Ir. L. J. M. Nieuwenhuis
X. Stegehuis MSc
Dr. R.P.A. Loohuis

Keywords

Hearing aid industry, over-the-counter (OTC), business model innovation, ecosystem, hearing aid manufacturer

1. INTRODUCTION

1.1 Situation and complication

In 2016, U.S. senators Elizabeth Warren and Chuck Grassley introduced the 'Over-the-Counter Hearing Aid Act of 2016'. This is a bipartisan bill that would allow certain types of hearing aids to be sold 'Over-the-Counter' (OTC), instead of being sold in the traditional way via a hearing care professional (HCP) (Warren & Grassley, 2017). This law passed congress in 2017 (under the name 'Over-the-Counter Hearing Aid Act of 2017'), and was part of the 'Food and Drug Administration Reauthorization Act of 2017', which was signed by President Trump in that same year (Jilla et al., 2018). Currently, the United States Federal Drug Administration (FDA) is working on regulations for these OTC hearing aids. At first they were expected to release regulations by the end of 2020 (Nanof, 2020). However, due to the Covid-19 virus, the release of these regulations has been postponed. The FDA missed the statutory deadline and has so far failed to deliver any updates on when the regulations will be released. However, it is expected that the FDA will do this by the end of 2021. (Franck & Rath, 2020).

Foreseen impact

Research has shown that allowing hearing aids to be sold OTC can be beneficial to a lot of people who do not have access to hearing healthcare or cannot afford it. One statistic that supports this is that only one in seven Americans who can benefit from using a hearing aid use one. This means that there is a lot of potential in the new OTC market (Blustein & Weinstein, 2016). There are two main reasons why so many people who need a hearing aid do not own one in the United States. The first reason is the lack of health insurance in the U.S., but the second and most important one is cost (Blustein & Weinstein, 2016; Grundfast & Liu, 2017). In a study from 2011, a large number of participants stated that cost was one of the main reasons for not owning a hearing aid (Fischer et al., 2011). The costs of buying a pair of hearing aids vary from \$1,182 to \$2,876 (Kirkwood, 2009), and with additional costs included can rise to certain individuals paying up to \$6,800 for a pair of hearing aids (service and additional costs included) (Donahue et al., 2010). There are two reasons why costs are so high: the first is the hearing aid market being non-competitive and the second is the lack of effective distribution channels for hearing aids (Blustein & Weinstein, 2016).

Why is change necessary?

Let us first take a look at the current hearing aid market. The current hearing aid market is classified non-competitive. The 'big six' hearing aid manufacturing companies make up 98% of the global market (Kirkwood, 2013). After the merger of Sivantos and Widex in 2019, the big six has become the big five. More recent information from Statista, shows that currently the big five even make up 99% of the market (Stewart, 2020). This altogether shows that the market is indeed what you can call non-competitive and very concentrated. Therefore in 2015, the President's Council of Advisors on Science and Technology (PCAST) wrote a letter to President Obama to plead for the OTC sales of hearing aids. In this paper they mention this high market concentration, in combination with the earlier mentioned lack of effective distribution channels. Currently, hearing aids are sold through audiologist and hearing instrument specialists. They are sold by their private offices, and currently get more and more competition from big box stores (like Costco). All sales however must go through an HCP. These HCP's often have close relationships with manufacturers. This causes customers not to be able to see the full range of products, but also make it more difficult for new innovative manufacturers to enter the market

(because of these close relationships) (Blustein & Weinstein, 2016; PCAST, 2015). Therefore, the way the current market is organized is one of the main reasons the OTC of hearing aids is going to come into play.

Literature on the hearing aid market and the OTC

Summarizing, the OTC of hearing aids will be beneficial to patients and shake up the non-competitive hearing aid market. However, there is also a reason why the hearing aid market is organized the way it currently is: hearing aids are complex devices and hearing healthcare requires a lot of service and support from specialists (fitting and adjusting hearing aids requires the expertise of an HCP). Research has been done on the potential of the new OTC market (how big the OTC market will be in terms of potential customers), mainly focussing on the customers' willingness to buy OTC hearing aids, without the intervention of an HCP (Edwards, 2020). This is complemented by research on the effect of service delivery on the purchase of hearing aids and the role the HCP plays in the process of buying hearing aids (Humes et al., 2017; Kochkin et al., 2010). An interesting notion is that one of the main reasons why hearing aids are becoming available for OTC sales is cost (a lot of research and articles suggest that cost is a big factor in the low percentage of people owning a hearing aid compared to how many people should actually own one) (Blustein & Weinstein, 2016; Grundfast & Liu, 2017). The research that is done that focusses on the service aspect in the process of buying hearing aids contradicts this to a certain point (it shows at least that there is more than simply cost when buying a hearing aid). Some researchers even suggest that cost is not such a big factor as people think, and that service is actually more important for people who want to buy a or are buying hearing aids (Valente & Amlani, 2017).

Analysing the entrance of an OTC market

The current hearing aid market is a complex market. Many stakeholders are involved in it, and all sales go through an HCP. Because of the many stakeholders involved, the business ecosystem and business model of a hearing aid manufacturer are very complex. To fully understand what entering the OTC market would mean for the business model of a manufacturer, it is a good thing to look at the current business model and ecosystem first. Adner (2017) pleads for the ecosystem-as-structure view. This implies starting off with the value proposition of the focal firm, after which actors, activities and links can be added to the ecosystem to support this value proposition. In this way the ecosystem is a good representation of how a manufacturer operates in the hearing aid market. This is further operationalized in the Ecosystem Pie Model tool (Talmar et al., 2020). A business model has many different definitions in the academic literature. Osterwalder & Pigneur (2003) define a business model as a conceptual tool consisting of different elements and the relationship between these elements. Teece (2010) also sees a business model as merely being a conceptual tool, which embodies the organisational and financial architecture of a company.

1.2 Research objective

In the current academic literature, there is, as mentioned, research on pricing in the hearing aid market (Amlani, 2019), and literature on the potential of the OTC market in terms of customers (Edwards, 2020), and on the effect of service delivered by HCP's on hearing aid outcomes (Humes et al., 2017). All this research is focussed on the market from a customer and HCP point of view but does not include anything on what entering the OTC market means for the business model and business

ecosystem of a hearing aid manufacturer. This is important, because the big hearing aid manufacturers are an important player in the hearing aid market. Parallels could be drawn between the OTC hearing aid market and the release of OTC medicines, about which a lot of academic literature has been written. There is even some literature of implications of OTC sales for pharmaceutical companies (Roblek, 2015). This research has proven that the consequences of entering an OTC market are different for consumers, medical specialists and manufacturers; this emphasizes the need for taking the manufacturer perspective. However, it is difficult to draw parallels between OTC sales of medicines and OTC sales of medical devices, like hearing aids, because the markets are simply too different. Medicines are subject to a very strict path before entering the market. A randomised, placebo-controlled, clinical trial is obligatory for all medicines, whereas it is not for medical devices. Furthermore, all medicines are subject to very heavy regulation, whereas medical devices are classified in 4 categories, and only those in the heaviest category are subject to such heavy regulation (Parvizi & Woods, 2014). Clearly, there is a gap in the academic literature: there is not much research on OTC hearing aids from a manufacturer perspective, and there is some literature in the OTC pharmaceutical market, however the two of them are too different to compare. Therefore, in this paper, we aim to make a good analysis of the implications of entering the OTC market for a medical devices company, by doing a case study at company X, a large hearing aid manufacturer. This will fill the academic gap mentioned earlier and can be used at the same time by hearing aid manufacturers who aim to enter an OTC market.

1.3 Research question

The goal of this study is to find out what the consequences are for the business model and business ecosystem of a hearing aid manufacturer of entering the OTC market. The research will be conducted in the form of a case study at company X, and their case will be used to draw conclusions for any hearing aid manufacturer that wishes to enter the OTC market. Therefore, the research question that is answered in this paper is the following:

- *What are the consequences of entering the OTC market for a prescription-based business model in the hearing aid market?*

To come up with a good and clear answer to this research question, it is important to formulate clear sub-questions, that each tackle an aspect of the research as described in the research objective. The following sub-questions were formulated:

1. What is a business model?
2. What is a business ecosystem?
3. What does the current prescriptions market look like?
4. What is an OTC market? What will change because of the new OTC market?
5. What does the current business ecosystem of a hearing aid manufacturer look like?
6. What is the business model of the different stakeholders in the ecosystem of the hearing aid manufacturer?
7. What will the ecosystem and business model(s) of the hearing aid manufacturer look like after the OTC?

Hence, we stand by giving a clear definition and theoretical background on business ecosystems and business models. Then, we will elaborate on the current prescription hearing aid market, and what the implications are of the new OTC market and what will change in the field of hearing aids because of the OTC. After this, the research focuses on mapping out the ecosystem of

company X and mapping out business models of all the important actors within this ecosystem. This is done to ultimately come up with changes that should be made to the business model/ecosystem of company X when they enter the OTC hearing aid market. The conclusions drawn from this case study can be used by any hearing aid manufacturer who wishes to enter an over-the-counter hearing aid market.

1.4 Academic relevance

The academic relevance of this paper is that it aims to find out what the consequences are for the business model of a hearing aid manufacturer of entering the OTC market. This is done by doing a case study at hearing aid manufacturer company X, a company that aims to enter the OTC hearing aid market. There is some theory on the OTC sales of hearing aids, however the focus in these papers is on the market segment that will be reached with OTC hearing aids (Edwards, 2020), or the implications for audiologists or the role audiologists will play (Humes et al., 2017). All these papers on the OTC sales of hearing aids look at the OTC from an audiology or a market perspective, but do not look at the implications for hearing aid manufacturing businesses and their business models. There is research that was conducted on the OTC sales of certain medicines (Zamora et al., 2016), and on the impact of the sales of OTC medicines for businesses (Roblek, 2015). There is however a big difference in regulations between the OTC sales of medicines, and the OTC sales of hearing aids, and the manufacturers and markets are so different that they are hardly comparable. This means that there is a gap because there is no clear research on what the implications are for a prescription-based business model when entering an OTC market. The research in this paper tries to fill this gap and come up with a good academic framework for what the implications of entering an OTC market are on a prescription-based business model. We will do this by building on earlier research in the field of business models ((Osterwalder & Pigneur, 2010), (Teece, 2010), (Zott & Amit, 2010)), business model innovation ((Mitchell & Bruckner Coles, 2004), (Bucherer et al., 2012), (Khanagha et al., 2014)) and business ecosystems (Adner, 2017).

1.5 Practical relevance

The research conducted in this paper will be conducted by doing a case study at company X, one of the big five hearing aid manufacturers worldwide. Their business ecosystem and business model will be analysed, to see what the consequences are for their business model and more generally the consequences for the business model of any hearing aid manufacturer once the OTC market is entered. At the end of this research, we aim to have a clear view of what these consequences are for any hearing aid manufacturer that wishes to enter the OTC market.

2. THEORETICAL FRAMEWORK

This section provides a theoretical framework on business models and business ecosystems. In this section, we will answer sub-questions 1 and 2 of our research: “What is a business model?” and “What is a business ecosystem?”.

2.1 Business models

To make a good analysis of the business model of the hearing aid manufacturer, we first provide a good definition of what a business model is and what it does.

2.1.1 Defining business models

Zott & Amit (2010) advocate an activity system perspective on business models. They conceptualize a firm’s business model as

a system of interdependent activities conducted by the firm, that transcends the focal firm and its boundaries. They state that the activity system allows the firm (in cooperation with its partners) to create value and use this value accordingly. Teece's view (2010) on business models is in line with this. He states that with a business model, you formulate the logic behind a business and provide evidence of how it creates value. In his view, the architecture of a business' revenues, costs and profits are outlined. He states that a business model is a conceptual model, that is an embodiment of organisational and financial architecture of a business. According to Osterwalder & Pigneur (2003), a business model can be defined as a conceptual tool which consists of a set of different elements and the relationships between these elements: this allows for the expression of the business logic of a company/manufacturer. Similarly to Zott & Amit and Teece, they emphasize that value creation is very important in a business model. They even go one step further by stating that a business model consists of many different elements, however that the value proposition is at the base of it. The value proposition in their eyes is the first step when generating a business model, and the rest of the model is built around it. For this paper we will use the definition provided by Osterwalder & Pigneur (2003), since it is similar to the view of the other authors, and even goes one step further, making it a more complete definition.

2.1.2 Different elements of a business model

Next, let us look at the different elements a business model comprises of. A business model depicts the different activities and elements that together add up to describing the business logic and ultimately the way a business creates value. The activity system of Zott & Amit (2010) comprises of two design parameters: design elements and design themes, which together characterize the business model of a firm. Design elements describe the architecture of an activity system, and there are three design elements that are mentioned by Zott & Amit: content, structure, and governance. Content relates to the question of what activities should be performed, structure to how they should be linked and sequenced, and governance to who in the organisation should perform them and where. Design themes describe the source of value creation of the various activities, and Zott & Amit mention the following: novelty, complementary, lock-in and efficiency. This activity system clearly describes value creation of a business model for all stakeholders and includes every activity and step involved in the business model of a firm. This is coherent with earlier definitions and conceptualizations of business models, but on top of that moves away from focussing solely on the focal firm's business model, instead moving towards a business ecosystem including all activities and stakeholders involved in the business model of a firm (Zott & Amit, 2010).

Teece (2010) defines a business model as the architecture underlying the mechanisms of a firm for value creation, delivery and adaption. A very important notion Teece makes, is that to create a competitive advantage for a business, a business model itself is not enough. It is a generic model of the company and its activities, but needs to be connected to a business' strategy before it can be used to create competitive advantage (Teece, 2010).

Osterwalder & Pigneur (2010) have developed a business model canvas, containing all the different elements of a business model. The canvas they developed will be used in this paper to create a business model for all the different stakeholders in the ecosystem of company X. In their book *Business Model Generation*, written in 2010, but based on their dissertation written in 2003, they provide a framework for analysing/creating business models.

They provide a 9-step approach, which combined are worked out in a canvas that gives a clear and simplified overview of the business model of an enterprise. The 9 steps can be seen as building blocks of the business model canvas (see image below). Their business model canvas will be used in our research to create a business model of all the stakeholders in the company X ecosystem. The reason is that their framework is a good tool for concisely making complex business models, starting at the value proposition, and because their business model canvas incorporates views of Zott & Amit and Teece.



Figure 1. The business model canvas

2.1.3 Business model innovation (BMI)

The next step is determining what business model innovation (BMI) is. Mitchell & Coles (2004) come up with a very concise and clear definition: they equalize business model innovation to business model replacements. Their definition is that these business model replacements offer new, previously unavailable, products and services to customers; they state that the process in which these replacements are developed can also be referred to as business model innovation (Mitchell & Bruckner Coles, 2004). This definition captures the essence of business model innovations. Ultimately, business model innovations are about changing the business model in such a way that a business can offer new products or services to customers. Bucherer et al. (2012) define business model innovation as a certain process, in which the core elements of a firm and the firm's business logic are deliberately changed. In their paper, they state that products and services that are offered by a firm heavily influence its business model, meaning that product and process innovations also lead to business model innovations (Bucherer et al., 2012). This is very much in line with the view offered by Mitchell & Coles. Both papers conclude that the core of a business model innovation is offering new products or services to customers. We agree with this view and see a business model innovation as the process of adding products or services to the current business model of a firm.

Foss & Saebi have provided a paper reviewing 15 years of research on BMI. They recognize different streams of research on BMI, ranging from conceptualizing BMI to consequences of BMI. They identify that the main gap in BMI research is that it is mostly descriptive instead of explanatory. Therefore, they aim to dimensionalize BMI next to defining it. They start off with Teece's previously mentioned definition of business models, and define BMI as: "Designed, novel, and nontrivial changes to the key elements of a firm's business model and/or the architecture linking these elements." In our opinion, this definition complements the earlier provided definitions, and it will be the definition of BMI we use in our research, because it captures all the dimensions of BMI (Foss & Saebi, 2017).

2.2 Business ecosystems

To answer the question what the consequences of entering the OTC market on the business model of company X, it is important to make a good overview of the ecosystem of company X, as a starting point, before making good business models of the different stakeholders (actors) in the ecosystem. Adner (2017) has added valuable contributions to the literature on ecosystems, and his theories will be used in this paper to make a good analysis of the company Xecosystem.

2.2.1 Ecosystem as structure

Before moving to Adner (2017), it is important to make the connection with Zott & Amit (2010). Their activity system perspective on business models can be used as a sort of gateway to business ecosystems. As mentioned earlier, besides being a good and clear conceptualization of business models that is in line with earlier conceptualizations, their activity system perspective takes it one step further. Instead of solely focussing on the focal firm's business model, they focus on all the activities and stakeholders involved in the business ecosystem of the focal firm. This is not yet a business ecosystem but can be seen as a step towards it.

Ecosystem-as-structure

Adner makes a clear distinction between two general views on ecosystems: the first is ecosystem-as-affiliation, and the second is ecosystem-as-structure. Ecosystem-as-affiliation focusses on the ecosystem as a community of actors, who are defined by their network, whereas the ecosystem-as-structure view sees an ecosystem as a configuration of activities that are defined by a value proposition. The main difference is that the two of them have an opposite way of strategy construction. The ecosystem-as-affiliation view start with different actors, the links, and ends up with a possible value proposition because of that. The ecosystem-as-structure view on the contrary starts off with a value proposition, then considers what activities need to be present to materialize this value proposition, and then looks at different actors that need to be linked to fulfil this value proposition. The second view, ecosystem-as-structure, is in line with most of Adner's own work, and a view that is advocated by him. His own definition of ecosystems is as follows: "The ecosystem is defined by the alignment structure of the multilateral set of partners that need to interact in order for a focal value proposition to materialize" (Adner, 2017, p. 40). An important notion is that he uses the term multilateral. Adner states that an ecosystem construct only matters in case of multilateral relationships among actors in the ecosystem. If the multilateral interdependence between the different actors can be decomposed into multiple bilateral relationships, a new ecosystem construct is not required.

Elements of the ecosystem-as-structure approach

The ecosystem-as-structure approach has four elements of structure that underlie it:

1. Activities
2. Actors
3. Positions
4. Links

These four elements can be seen as a blueprint that underlies the way value is expected to be created in the ecosystem that underlies a value proposition. The ecosystem is latent when an industry is mature and predictable, and not very relevant. Only when innovation requires the configurations of these elements to change, the ecosystem view becomes relevant and interesting. In this way, the ecosystem view can also be linked to business model innovation.

In his paper, Adner also moves from ecosystem structure to ecosystem strategy. Based on his previous definition of ecosystem structure, Adner (2017, p. 47) defines ecosystem strategy as follows: "Ecosystem strategy is defined by the way in which a focal firm approaches the alignment of partners and secures its role in a competitive ecosystem." Here he stresses that ecosystem strategy is different for different actors in the ecosystem, but that for the ecosystem strategy to be successful, the strategy of the focal firm should be as closely as possible in line with the strategy of other actors in the ecosystem.

3. METHODOLOGY

3.1 Choice of research design

The research in this paper is qualitative by nature and will be conducted by means of a case study. A case study design is an appropriate research design for studies that focus on complex contemporary phenomena about which not much prior knowledge is available, and when existing theories hardly address the subject or existing research on the subject does not adequately address the subject. This is exactly the case in our research on the consequences of entering an OTC market for a prescription-based business model. Previous literature does not adequately address this subject, and there is not much prior knowledge on it.

The research in this paper will thus be conducted by doing a case study at company X. The research question answered in this thesis, is what the consequences are of entering an over-the-counter market for a prescription-based business model. Company X is a large hearing aid manufacturer, which are currently operating in the prescription hearing aid market, where hearing aids can only be sold through an HCP. The company plans on entering the over-the-counter hearing aid market once FDA regulations are approved, making it the perfect organisation to do a case study at for conducting our research. Its current business model is purely prescription based, so entering the OTC market is exactly the kind of business model adaption this paper wants to conduct research on.

3.2 Case description

To start analysing the business model of company X and the consequences the OTC will have on the business model of company X, it is important to first look at the current market, and the way hearing aids are currently sold, to get a clear view of what will change once the OTC is implemented compared to the current market. So, after introducing the company and the research design of the study, we now describe the current prescription hearing aid market, and describe the new OTC hearing aid market and what it will look like. Thus, we will answer sub-questions 3 and 4 in this section: "What does the current prescriptions market look like?", "What is an OTC market?" and "What will change because of the new OTC market?"

The company

Company X is a large multinational hearing aid manufacturer, with offices all around the globe.

3.2.1 The current prescription hearing aid market

The role of the hearing care professional (HCP)

In the current prescription hearing aid market, all sales of hearing aids go through an HCP. It is possible to buy other hearables, like Personal Sound Amplification Systems (PSAP's) without

intervention of an HCP. However, PSAP's are not intended to treat hearing loss, and are merely a luxury product to make sound more enjoyable. Buying an actual hearing aid is not something easy, but an entire process, starting the moment you recognize the need for buying a hearing aid. After this you seek the help of a HCP who will guide you in the process. In some cases, you are referred to a HCP by your otolaryngologist (Kochkin et al., 2010).

Market segmentation in the current market

To understand the current prescription hearing aid market (and the new OTC market), it is good to look at market segmentation (price-based segmentation). The hearing aid market can be divided into three segments: a value-based segment, a behavioural segment and a demographic segment (see graph below) (Amlani, 2019).

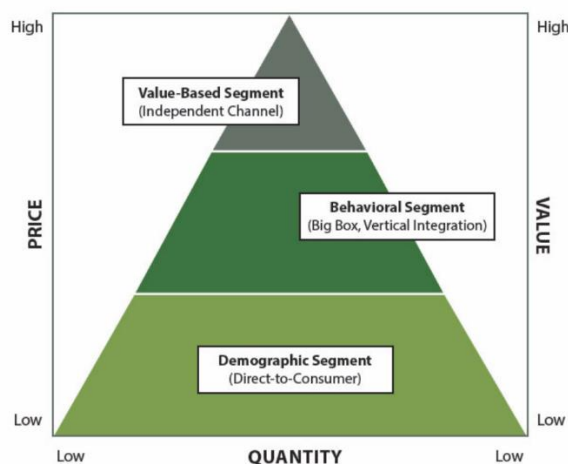


Figure 2. Market segmentation in the current market

The demographic segment consists mostly of direct-to-consumer hearing devices, the behavioural segment consists of traditional hearing aids with regular service, but that are sold mainly through retail outlets. The value-based segment consists of hearing aids that are sold through the HCP and mostly independent channels. Whereas the demographic segment and the behavioural segment (partially) compete on price, the value-based segment solely competes on service level. In this segment value is derived from the level of service that is provided to the customer. The hearing aid industry is becoming a multi-segmented and retail-based market (the introduction of OTC hearing aids being one of the biggest examples). Practices and sales channels that compete on price are participating in the so called 'Race to the Bottom' of the market (moving away from the value-based segment). A risk that is associated with this race to the bottom is market cannibalization (Amlani, 2019).

Market cannibalization means that introduction of a similar product by the same producer or lowering the prices of a product causes sales volume and revenue to decline (creating an adverse effect). This is what is likely to happen in the hearing aid industry during this 'Race to the Bottom'. The reason that market cannibalization is likely to occur is that the hearing aid market has an inelastic demand. This means that lowering prices will not cause the number of units sold to increase (or revenue to increase). This is only the case in an elastic market (Amlani, 2019). Market cannibalization will also play a role in the market once the OTC happens.

3.2.2 The new OTC hearing aid market

For our research it is important to clearly mention what the new OTC hearing market will comprise of, and what will change because of this new market. This is needed to determine how the business model of company X should change once they enter the OTC market. As mentioned in the introduction, the reason why hearing aids will be allowed to be sold over-the-counter is because of the price of hearing aids, the non-competitiveness of the market and availability issues (customers do not have access to the full range of products because of close relationships between HCP's and manufacturers). In the new market, hearing aids will be sold to consumers at a much lower price, and over-the-counter, meaning, as mentioned before, that they can be sold without the interference of a HCP.

Over-the-counter channels

OTC hearing aids will thus be sold without interference of an HCP; however, this raises the question which channels will be used. Logical options seem online, or via big store chains like Walmart. Research, conducted by Nielsen, commissioned by company X, has shown that consumer's top 5 expected channels through which OTC sales will go are (Nielsen, 2021):

1. Amazon
2. Costco
3. Walmart
4. CVS
5. Walgreens

Over-the-counter target group and expected market size

Besides looking at how OTC hearing aids will be sold, to get a good understanding of the implications of entering the OTC market, it is important to determine who the target group of this new market is, and what the expected market size is.

In a study from 2020, Edwards did research on this, on how many people might potentially be willing to buy an OTC hearing aid. He divided the market in 5 segments (A, B, C, D and E), and identified that the people from segment E (people with hearing loss and who acknowledge this hearing loss but do not own a hearing aid) are the segment that might buy OTC hearing aids. According to his estimations, this is a group of 3.4 million Americans. So, according to him, the potential for the OTC hearing aid market is 3.4 million customers. However, he found out that only a small percentage of this group is willing to hearing aids OTC, and value delivered by HCP's is still greatly valued. Estimating that the average price of a pair of OTC hearing aids will be \$1500 dollars, the expected market size in dollars is \$5,000,000,000, so 5 billion dollars (Edwards, 2020).

3.3 Research design

So, we conduct our main research in the form of a case study. We conduct our case study in two phases. In the first phase, we map out the current business ecosystem of company X, and the different business models of the important actors in the company X ecosystem. In the second phase, we will come to the core of our research, namely determining what the consequences are of entering the OTC market for the ecosystem of company X and the business models of the different ecosystem actors.

Phase 1: the current ecosystem of company X and business models of the actors

So, the first phase of our case study consists of mapping the current business ecosystem of company X and the business models of the different ecosystem actors. In this phase, we answer sub-questions 5 and 6 of our research. To map out the ecosystem, the previously mentioned and elaborated theory of

Adner (2017) is used to approach this scientifically, in combination with obtained company information on the current ecosystem. With the ecosystem we focus on mapping out the positions of the most relevant stakeholders within this ecosystem, the activities each stakeholder conducts and the links between the stakeholders. This is in line with Adner's theory. Adner states that these 4 elements lie at the basis of how the focal firm expects to deliver value through its ecosystem. Expert interviews are conducted with a few high ranked employees of company X to gain useful additional information on the company X ecosystem. Questions asked in these interviews will focus on determining the links between the stakeholders, so determining exactly how for example the manufacturer is linked to the end-consumer, and the activities and positions of each stakeholder; this starts off with the value proposition, and with how the actor cooperate to achieve this value proposition, using the Adner's ecosystem-as-structure approach. Since the ecosystem of company X is so complex, expert interviews are needed to precisely determine all these aspects. The approach we are using is making a first draft of the ecosystem, based on Adner (2017), which will be shown to experts, after which we start off with the value proposition and go over all the actors and the links between them, to determine how the company X ecosystem creates value.

Next, we map out the business models of the different actors in the company X ecosystem. The business model canvas generation handbook of Osterwalder & Pigneur (2010) is used to ensure a scientific approach and as a tool for doing it correctly. We use expert interviews here again to complement this and to tackle any unclarities or unknowns that might come up while generating these business models.

Phase 2: ecosystem and business models in the new OTC market
In the second phase we determine what will change in the ecosystem and the business models once they enter the OTC market. In this phase we answer sub-question 7 of our research. This phase of our case study will be conducted by using previous research conducted by the company and doing expert interviews with high-ranked employees who closely deal with the OTC. The interviews conducted at this stage will be semi-structured interviews, and will be used to gain information on how company X plans on entering the OTC market (they plan on launching a new hearing aid brand, in the U.S.), what in their view will be needed to make this a success and, looking at the business model of company X, where in the business model changes will be made and how they will contribute to the overall strategic success of the company. In these interviews, the current business ecosystem will be shown to the interviewees, and they will be asked what they think will change for each actor in the ecosystem after the OTC. This will be complemented by questions on (potential) new actors in the ecosystem and the role of their new consumer brand in the new ecosystem.

3.4 Sample and sampling

So, we conduct our qualitative research in the form of a case study. For qualitative research, two sampling techniques are most used: purposeful sampling and conventional sampling. Purposeful sampling means selecting individuals for your research based on the criterium of them being information rich or not (Omona, 2013). For our research, this is the method of sampling we have chosen. The interviewees were chosen based on their knowledge on the business model and strategy of company X and their role in the OTC sales of hearing aids. For mapping out the company X ecosystem in the first phase of our research, we interview manager 1 of company X, who deals closely with strategic decisions that affect company X and its

business model. Furthermore, manager 2 will be interviewed, who deals closely with all kinds of markets company X operates in. After this, they will be interviewed regarding unclarities/dissimilarities and other issues that might come up while generating the business models of the different company X ecosystem actors. People who we will interview in the second phase of our research are the manager 1 again, who is also partly responsible for the entering of the OTC market. Also, manager 3 will be interviewed, who is responsible for the OTC sales of hearing aids worldwide, and who has lead the OTC sales of hearing aids in other parts of the world. The last person who will be interviewed is manager 4, who is leading the OTC sales in the U.S., and is the Brand Manager of the new consumers brand.

3.5 Data collection

When conducting a case study, it is important to have direct interaction with people involved in the phenomenon in focus (interaction of a qualitative nature), to get a view of the research subject that is as complete as possible (Yin, 2009). Therefore, we choose semi-structured interviews as our main method of data collection. A big advantage of using interviews is that you can create a deeper understanding and knowledge of the subject and looking at it from multiple perspectives. This goes even further than describing, and allows you to understand the reason behind certain arguments (Weiss, 1995). Therefore, since our goal is to get a very deep and multiple perspective understanding of the consequences of entering the OTC market for a prescription-based business model, we firstly rely on semi-structured interviews for our data collection. Secondly, we use company documents on the research subject as source for data collection.

Validity

We use multiple sources of evidence in our research (people involved in the phenomenon in focus and relevant company documents), in combination with conducting a case study. We have used triangulation for these data sources, which has allowed us to get a good, multi-perspective view on the phenomenon, while at the same time increasing the internal validity of our research (Carter et al., 2014). Furthermore, since company X is a large hearing aid manufacturer, a case study conducted at company X is a good representation for another big hearing aid manufacturer that wishes to enter the OTC market. So, our case study findings are (to some extent) generalizable beyond the immediate case study of company X, which means that our case study research has (some) external validity.

3.6 Data analysis

We analyse the data from the interviews firstly by transcribing the interviews. After transcribing the interviews, we further analyse the data using the different theories mentioned earlier in this paper.

Phase 1

We will analyse the data collected in the first phase of our research by mapping out the business ecosystem of company X using Adner's theory (2017) and by mapping out the business models of the different actors in the company X ecosystem. The business model canvas generation handbook of Osterwalder & Pigneur (2010) is used to ensure a scientific approach and as a tool for doing it correctly.

Phase 2

Firstly, we will analyse and structure the data from phase 2 of the research by developing a new business ecosystem using Adner (2017). Besides using Adner, we will also use the Ecosystem Pie Model tool (EPM) (Talmir et al., 2020). The tool they developed

can very effectively be used to make a good analysis of a new innovation ecosystem, which is exactly what we need to do to analyse the ecosystem of company X once they enter the OTC market.

The Ecosystem Pie Model (EPM)

Based on Adner's work and the work of other authors, Talmar et al. (2020) provide a good visual strategy tool for modelling ecosystems: the Ecosystem Pie Model (EPM). This tool is complementary to Adner's work and provides a logical way of visualizing ecosystems. The tool is built on the logic that any ecosystem is dependent on two things: the properties of each individual actor in the ecosystem and the properties of the network of the ecosystem. At the centre of the tool (the pie) is the value proposition of the ecosystem. This is in line with the previously presented view by Adner (2017), that an ecosystem is a configuration of activities that are defined by the value proposition of the ecosystem. Therefore, in the EPM, the value proposition of the ecosystem is in the centre, and the rest of the ecosystem is built around it. In the tool, the constructs and the relationships between those constructs are considered at the ecosystem level (value proposition, user segments and actors) and the actor level (resources, activities, value addition, value capture, dependence, and risk). The EPM can be used in two ways: to analyse the value proposition of a current ecosystem or to map out an innovation ecosystem and its value proposition.

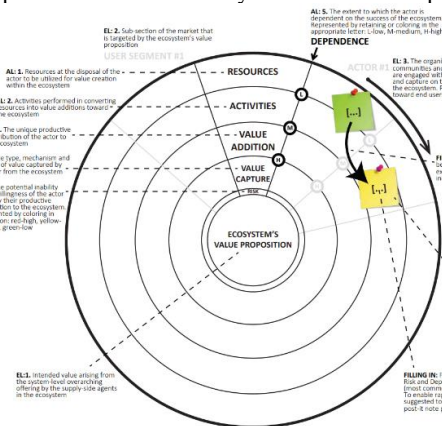


Figure 3. The Ecosystem Pie Model (Talmar et al., 2020)

Lastly, we will develop new business models (Osterwalder & Pigneur, 2010) for all actors based on the interviews and the OTC expectations derived from these interviews. In the end, this will lead to a conclusion on what the consequences of entering the OTC market are on the business model of company X.

4. RESULTS

The results of this research are based on the literature review, conducted expert interviews, internal company reports and other company information that we obtained by conducting the case study. As mentioned in the research design, the case study was conducted in two phases. In section 4.1 we provide the results of the first phase of our research, and in section 4.2 and 4.3 we provide the results of the second phase of our research.

4.1 Analysis of the current company X business ecosystem & models

In this section, we provide the results of the first phase of our research. We are answering sub-questions 5 and 6: "What does the current business ecosystem of a hearing aid manufacturer look like?" and "What is the business model of the different stakeholders in the ecosystem of the hearing aid manufacturer?"

4.1.1 Company X Ecosystem

Firstly, we determine what the current business ecosystem of company X looks like. To do this we will use Adner's (2017) theory on ecosystems.

Ecosystem using Adner

As mentioned earlier, Adner pleads for an ecosystem-as-structure view, which looks at the value proposition first, then looks at the activities needed to be conducted to materialize this value proposition, after which the different actors will be identified that need to be linked to achieve this value proposition. The information on the current ecosystem is derived from the conducted interviews and internal company reports.

For company X, its value proposition is to deliver hearing care solutions to battle hearing loss, hearing care solutions that are provided to consumers through hearing care professionals. These HCP's take hearing tests to diagnose people with hearing loss and provide them with a suitable hearing aid. There are two other actors through which consumers are linked to the HCP. Party 1 and a party 2. Taking all this into account, the current ecosystem of company X looks as follows (enlarged version in appendix A):

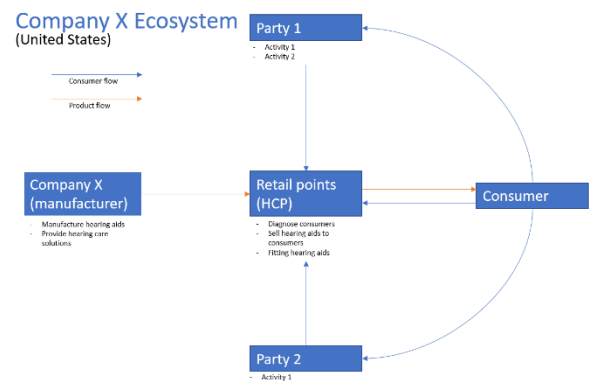


Figure 4. The current company X ecosystem

A few things stand out in the current ecosystem of company X. Even though Company X is the manufacturer of the hearing aids, and the hearing aids manufactured are all intended to battle hearing loss for the end-consumer, all sales of hearing aids go through a retail point where an HCP provides service. As can be seen in the ecosystem, there are alternative methods of generating customers for company X hearing aids, but ultimately, they all refer clients to the HCP first.

4.1.2 Business models of the different actors in the company X ecosystem

So, we now describe the business models of the different actors in the company X ecosystem. To do this, we use the Business Model Generation handbook (Osterwalder & Pigneur, 2010). Again, we obtained information on the current business models of the actors in the company X ecosystem from the conducted interviews and the internal company reports. Using these business models helps us to better understand the role that each actor plays in the ecosystem of company X.

In the business model of company X (the focal firm), customer segments are the HCP's and consumers with severe hearing loss. The value proposition of company X is to provide hearing care solutions to those consumers with hearing loss and offer hearing aids to HCP's who in turn help consumers with hearing loss by setting them up with the right hearing aid. For party 1 and party 2, different activities are conducted. For the HCP's, customers

segments are the consumers with severe hearing loss, and their value proposition is to set-up these consumers with the right kind of hearing aid. In this public version we do not provide the complete business models (only this summary), since they would expose too much confidential information of company X.

4.2 Changes when company X enters the OTC market

In this section and section 4.3, we provide the results of the second phase of our research. We are answering sub-question 7: “What will the ecosystem and business model(s) of the hearing aid manufacturer look like after the OTC?” Based on the expert interviews, complemented with internal company reports, we will now describe what will change for company X and the other actors in the ecosystem, when the company enters the OTC market. We will start with company X itself as a manufacturer, and then discuss the results of the other actors in the ecosystem.

4.2.1 The role of company X (the focal firm) in the new OTC market

A few things will change for company X once they enter the OTC market. Firstly, company X will start serving a different customers segment in the new OTC market: people with mild to moderate hearing loss. This requires a new value proposition and in to correctly deliver this value proposition company X needs to innovate its business model.

4.2.1.1 New customer segment

It has become clear from the interviews that in the OTC market a different customer segment is served. In the regular hearing aid market consumers with severe hearing loss are served, but in the new OTC market consumers with mild to moderate hearing loss will be served. The sales of OTC hearing aids will be a way for company X (and other hearing aid manufacturers) to lure consumers into their ecosystem. The hope is that having an OTC hearing aid gives these consumers a first pleasant experience with hearing aids, and after a period of time they will easily transition to regular hearing aids once their hearing loss progresses.

4.2.1.2 New value proposition

To serve the new customer segment, company X has a new value proposition in the OTC market, namely providing hearing care solutions to consumers with mild to moderate hearing loss. To achieve this new value proposition, company X will use a new hearing aid brand. Using a new hearing aid brand will also prevent company X from cannibalizing its old market, which would be the case if they entered the OTC market with an existing hearing aid brand. A new brand is a little more expensive at the start, but it is worth these costs if this will prevent cannibalization of the regular market from happening.

4.2.1.3 Business model innovation

In the current hearing aid market, as mentioned before, hearing aids are delivered through an HCP, who also delivers complementary service. The hearing aids need to be fitted, adjusted and maintenance work needs to be carried out. For the new category of OTC hearing aids, these services will not be delivered by an audiologist. Therefore, the responsibility to deliver these complementary services comes to lie with the manufacturer of the hearing aids. This means that a hearing aid manufacturer aiming to enter the OTC market needs to come up with a business model innovation to add the delivery of these services to its business model.

The four interviewees all have quite similar views on how service should be delivered with the consumer brand and how it should be incorporated in the business model of company X. The service delivered should be of good quality, but the focus should be on optimizing the process of buying and fitting the hearing aids, by providing clear instructions and making it clear to customers that there is a high chance that the OTC hearing aid will be successful for them. A good customer service system must be in place, and be added to the business model of company X, most likely in the form of customer representatives who handle customer requests from home.

4.2.2 The role of the different actors in the new OTC market

Next, we will look at the role the different actors in the company X ecosystem will play in the new OTC market, or what will change for each individual actor once company X enters the new OTC market.

For party 1 and party 2, from the interviews it has become clear that they can be used to partially sell the new consumer brand to consumers with mild to moderate hearing loss.

For HCP retail points, there are different roles they can play in the new OTC market. They will still sell hearing aids to regular customers with severe hearing loss (because the OTC market targets consumer with mild to moderate hearing loss). Therefore, the current market of HCP's will hardly be cannibalized. The OTC hearing aids will even have an advantage, according to the interviewees. It will lure people into the ecosystem of the HCP, who will in this way possibly even generate more customers than before the OTC sales of hearing aids. In this way, entering the OTC market is actually advantageous for HCP's.

4.2.3 OTC customer channels

In section 3.3.2.1, we discussed expected OTC sales channels for OTC devices, based on the conducted market research. From the interviews, we learned which customer channels company X intends to use for selling the consumer brand and how company X intends to do this. Currently, there are four channels through which company X plans on selling the consumer brand.

The first and main channel through which company X plans on selling the new consumer brand hearing aids is through an own ecommerce website. The intention is to make this the main OTC sales channel. When selling through the website, the advantage is that company X will not need to pay a percentage of each sale to another party, which would be the case if the hearing aids are sold through Amazon for example. The hearing aids are sold directly to the consumer at the highest margin, which makes this the most attractive option for selling the hearing aids. The problem is that company X needs to invest a lot of money to create brand recognition for the new consumer brand first, otherwise people will hardly buy hearing aids through the website, because they will not know about this option. Another problem, that was pointed out during the interviews, is that buying hearing aids online is not something that people will do easily, because it is a product that people would like to see and feel first before buying it. Therefore, the question is how successful online sales channels for OTC hearing aids will be. On the other hand, people who buy the OTC hearing aids are most likely younger, want to spend less money, and are more tech-savvy. Therefore, they might not see buying the hearing aids online as too much of an obstacle, since they want to spend less money anyway and therefore not necessarily require to see and

feel the hearing aids before buying them (they are also more used to buying products online).

The second channel through which company X plans on selling the new consumer brand hearing aids is Amazon. Amazon is a big player in the ecommerce business, and selling through Amazon can be beneficial, because Amazon is a platform with many customers, who can easily find the product through Amazon. A disadvantage, that we mentioned earlier, is that sales that go through Amazon require company X to pay a percentage of each sale to Amazon. Another potential disadvantage, similar to selling the hearing aids through the consumer brand's own website, is that consumers might be less inclined to buy hearing aids online and might prefer to see and feel the product before buying it. However, similarly to the own ecommerce website, this disadvantage might turn out to be less of a problem, because the target group of the new consumer brand is more tech-savvy and willing to spend less money.

The third channel through which company X can potentially sell the new consumer brand hearing aids is through big-box chains, like Costco. This entails the advantage that consumers can see and feel the hearing aid, before actually buying it. Another argument in favour of selling through Costco is that they currently already sell regular hearing aids, for which they have employed their own HCP's. Therefore, it will not be a new channel for consumers to buy hearing aids through, so company X might have easier customer access when selling through Costco. Walmart is another big-box chain through which company X could potentially sell the new consumer brand. However, the problem here is the fierce competition between Costco and Walmart. It can cause friction for a company to have contracts with Costco and conduct business with Walmart.

The fourth and last channel company X can use is pharmaceutical chains, like Walgreens in the U.S. Like Costco, a big advantage of selling the new consumer brand hearing aids through Walgreens is that they are a big and well-known chain. It will be easy for consumers to access the product when they go to Walgreens. A disadvantage of selling through Walgreens, is that it is not a place people go to, to buy expensive products. They go there to buy small pharmaceuticals and other groceries, but they do not go there expecting to buy a hearing aid of more than \$1000. They might look at it and consider it, but they will never buy it in the store. They will most likely memorize it and search for it at home, resulting in them buying the hearing aid online. Nevertheless, having Walgreens as an OTC sales channel is still beneficial, because of its huge reach of potential hearing aid buyers.

4.3 Company X business models & ecosystem after entering the OTC market

We now have a clear view of what will change for company X and the other actors in the ecosystem once they enter the OTC market. The next step is to make a new visualization of the company X ecosystem and business models of the actors when they have entered the OTC market. These visualizations are again based on Adner (2017), Talmar et al. (2020) and Osterwalder & Pigneur (2010).

4.3.1 The new company X ecosystem

For the new ecosystem of company X, once they have entered the OTC market, we use Adner (2017) and Talmar et al. (2020) again.

The new ecosystem using Adner

The value proposition of company X is still to deliver hearing care solutions to battle hearing loss. In the new OTC market however, these solutions are not only delivered to consumers through HCP's, but also directly in the form of OTC hearing aids, and indirectly through retail points that now sell the new consumer brand hearing aids without the HCP. Furthermore, the new consumer brand hearing aids will also be sold to party 1 and party 2, who will also sell these hearing aids directly to consumers. Taking these things and further information from the interviews (4.2) into account, the new ecosystem of company X looks as follows (enlarged version in appendix A):

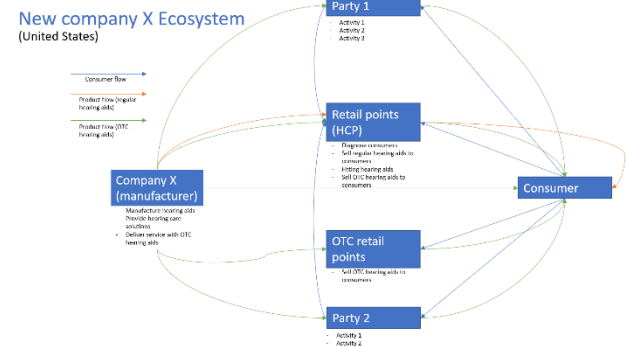


Figure 5. The new company X ecosystem

Further analysis of the new ecosystem using the EPM

Next, we use the EPM to make an analysis of the innovation ecosystem and its value proposition: selling OTC hearing aids directly to consumers with mild to moderate hearing loss. In this way, we can make a good analysis of what the impact of selling OTC hearing aids and being involved in the OTC hearing aid market is for each actor. Below is the EPM (enlarged version in appendix B):

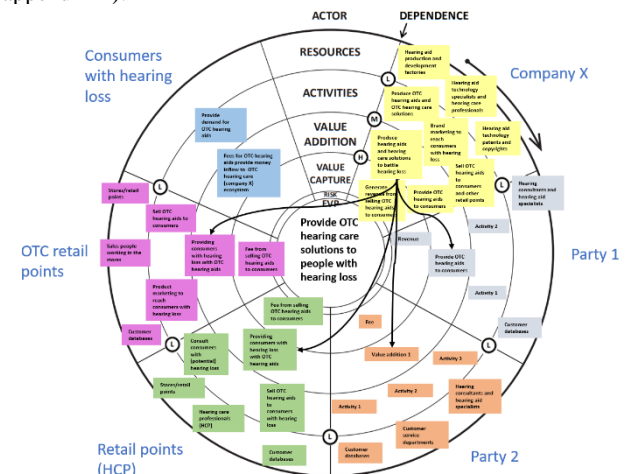


Figure 6. Ecosystem pie model of the OTC sales

In the EPM of the sales of OTC hearing aids, there are a few things that stand out. Firstly, a new actor comes into play, namely OTC retail points. OTC retail points are a generalization of any physical retail point that sells OTC hearing aids where no HCP is involved. An example is Costco or the pharmacies (Walgreens) through which company X plans on selling OTC hearing aids. Again, the relationships are clear, the only arrows that used to indicate relationships are between the production of the OTC hearing aids and the sales of the OTC hearing aids. What stands out is that company X produces the OTC hearing aids, and each actor in the ecosystem will sell them in the OTC market. Whereas, in the regular market, all actors only exist to ultimately allow HCP's to sell regular hearing aids to the consumer.

Furthermore, we now see that (compared to the regular market), all actors have a low dependence on the ecosystem. This means that each actor does not depend very much on the sales of OTC hearing aids. This is logical, since it is a new market, and most actors still depend largely on the sales of regular hearing aids. OTC retail points also do not depend a lot on the sales of OTC hearing aids, since they are big-box chains like Costco, or pharmaceutical chains like Walgreens, for whom the sales of OTC hearing aids is only a very small part of the business model. The last thing that stands out, is the risk. Whereas the risk was low for each actor in the EPM of the sales of regular hearing aids, it is different for the sales of OTC hearing aids. The reason is, which is also elaborated in the results from the interviews, that for the actors who are currently working closely with HCP's to sell regular hearing aids, selling OTC hearing aids might cause trouble with HCP's. For company X as a manufacturer the risk is medium, since they are actively engaging in the OTC market and want to play a role in it, but it should not be at the expense of their business with regular hearing aids. For party 2, the risk is medium as well. For the party 2, the risk is high.

4.3.2 *New business models of the different actors in the company X ecosystem*

Next, we provide an analysis of the business models of each actor in the company X ecosystem once company has entered the OTC hearing aid market. We again use the Business Model Generation handbook from Osterwalder & Pigneur (2010). Note that we present an extra business model in this section, because there is an additional actor in the OTC ecosystem: the OTC retail points. This actor represents the retail points like Costco and Walgreens where OTC hearing devices will be sold in the OTC market. The business model presented here only presents the business that they are conducting when selling OTC hearing aids. The rest of their conducted business (which is much more than selling OTC hearing aids) is left out, because it is not relevant for our research.

There are a few things that have changed in the new business models. For the focal firm, company X, they serve a new customer segment in the OTC market: consumers with mild to moderate hearing loss. Their value proposition also changes, they not only provide hearing care solutions to consumers with severe hearing loss, but also sell OTC hearing aids directly to consumers with mild to moderate hearing loss. For the party 1, they also serve consumers with mild to moderate hearing loss as a new customer segment and will also sell OTC hearing aids directly to this customer segment. This is similar for party 2. For the HCP's, not a lot will change, except that they will also sell OTC hearing aids to a new customer segment: the consumers with mild to moderate hearing loss. Lastly, there is a new actor, the OTC retail points. As mentioned before, their business model only contains the business they conduct with selling OTC hearing aids to consumers with mild to moderate hearing loss. Again, we do not provide the complete business models (only this summary), since they would expose too much confidential information of company X.

5. CONCLUSION

Our research is focussed on answering the main research question: "What are the consequences of entering the OTC market for a prescription-based business model in the hearing aid market?" To answer this question, we have conducted a case study at company X, a large hearing aid manufacturer. The fact that we have chosen a case study design, in combination with using multiple sources of evidence in our data collection, increases the internal validity of our research. Since we

conducted our case study at company X, which is a large hearing aid manufacturer, our results can also be used by other large hearing aid manufacturers, since company X and its business model are very representative. So, our case study findings are (to some extent) generalizable beyond the immediate case study of company X, which means that our research has (some) external validity. We have used theories and literature of Adner (2017), Talmer et al. (2020) and Osterwalder & Pigneur (2010). We fill the literature gap, by describing the OTC hearing aid market and its entrance from a manufacturer perspective, analysing the strategic implications for the business model of a manufacturer, instead of focussing on the perspective of the HCP, which was the case in previous literary work. The only research focussing on the perspective of the manufacturer was on the OTC sales of medicines, however the two markets are very hard to compare. While conducting our case study, we have analysed what the consequences of entering the OTC market are for each actor in the ecosystem of the manufacturer. Entering the OTC market has different consequences for a prescription-based business model. Firstly, the manufacturer needs to target a new customer segment (mild to moderate), which requires the manufacturer to solve a new value proposition. Furthermore, a way of delivering service with the hearing aids should be added to the manufacturer's business model, the manufacturer should determine which channels should be used for OTC sales and how it will use the different actors in its ecosystem in the OTC market. These consequences of entering the OTC market for a prescription-based business model also provide the manufacturer with a framework of how to approach entering the OTC hearing aid market. Below we further elaborate on those consequences.

So, the first consequence is that the manufacturer needs to target a new customer segment: consumers with mild to moderate hearing loss. This requires for the manufacturer to solve a new value proposition: namely delivering hearing care solutions for this new customer segment. Besides, it is important to prevent market cannibalization from happening. Therefore, the manufacturer should decide whether to use a current brand extension or entering the market with a new consumer brand; the latter being the best option to prevent cannibalization from happening, since people do not associate the brand with a regular hearing aid. Secondly, where *service* was previously delivered by an HCP, the manufacturer is responsible for delivering this service when selling OTC hearing aids. Besides delivering good service when consumers first buy and fit the hearing aids, for which many options are possible, this entails setting up an excellent customer support service. Furthermore, the market segment the manufacturer aims to compete in with the chosen hearing aid also determines the amount of service that should be delivered with the hearing aid. Competing in a higher OTC segment, with a more expensive hearing aid, means a greater level of service is expected. Entering a lower OTC segment with a cheaper product means a lower level of service is expected. Thirdly, the hearing aid manufacturer should determine through what *channels* OTC hearing aids are going to be sold. In the case of company X, the aim is to sell OTC hearing aids mainly through the ecommerce website of its own brand. However, the problem is that hearing aids are a product that people generally do not buy online and like to see and feel in a store first before buying it. Getting consumers to buy OTC hearing aids OTC is a timely process, and not something that will happen easily. Therefore, a good balance should be sought between online sales channels and selling hearing aids through brick-and-mortar retail points. This brings us to the fourth point of how the hearing aid manufacturer can use different *actors* in its ecosystem in the OTC market. Party 1 and party 2 can be used to sell OTC hearing aid through. Again, the manufacturer should find an appropriate

way to use the actors in its ecosystem, keeping in mind the risks and opportunities each actor brings along.

5.1 Discussion

Adner (2017) states that business models are more about focal firm value creation and do not focus on the bigger constellation of actors, whereas his ecosystem-as-structure view does. However, he fails to mention, that using one of the two views does not rule out the use of the other, because in fact they can be complementary methods of capturing interdependence. In our research we use the ecosystem view to determine the actors and the links between them, and subsequently use business models to determine how value is created for the different customer segments of each actor. In this way we draw conclusions on the ecosystem and the business models of our case. We hereby prove that the two methods are complementary.

Furthermore, in previously mentioned literature by Mitchell & Coles (2004), Bucherer et al. (2012) and Foss & Saebi (2017), business model innovation is viewed as a straightforward process, where you simply think of how to innovate a business model and afterwards implement it. They fail to mention that it is a very timely process. According to our research, people are used to buying hearing aids while seeing and feeling them and not online: this transition towards online OTC sales of hearing aids takes time. This is a perfect example of the shortcomings of the current literature on business model innovation: time is not taken into account and an aspect of business model innovation that is underexposed.

6. LIMITATIONS AND FUTURE RESEARCH

There are some limitations to our study, which simultaneously offer possibilities for further academic research on this topic. First of all, the case study was conducted at company X, which is a representative case because it is a large hearing aid manufacturer, and therefore is a good representation for any big hearing aid manufacturer that wishes to enter the OTC hearing aid market. However, the case of company X may not be representative for smaller hearing aid manufacturers, or new entrants who wish to enter the OTC hearing aid market. Our research is focussed on mapping out the current business model and ecosystem of the hearing aid manufacturer, and what the consequences are of entering the OTC market, and how the manufacturer can use different actors in its ecosystem in the new OTC market. In the case of a smaller manufacturer or a new entrant, the ecosystem might be much smaller and look totally different, and the business model might be much less advanced. Our research on entering the OTC market assumes that a solid business model and ecosystem are already in place, whilst in the case of a new entrant it might be necessary to come up with a completely new business model. Therefore, future research could focus on analysing what the consequences are for a smaller hearing aid manufacturer to enter the OTC market, or how a new entrant can create a good business model for entering the OTC hearing aid market.

Another limitation of our research is that it only involves one case study. Although the case study is representative for big hearing aid manufacturers, external validity might be higher if multiple case studies are conducted. Therefore, another recommendation for future research would be research on the consequences of the OTC on a prescription based business model involving multiple case studies, thus increasing the external validity.

Our research can be viewed as a framework for how hearing aid manufacturers can adapt their business model for entering the OTC market. Based on our research, further research could focus on specifically analysing a certain aspect of entering the OTC market. Research can be conducted on how a hearing aid manufacturer can use servitization to enter the OTC market by developing a specific model of delivering service with OTC hearing aids. Alternatively, future research can focus on developing a strategy on what kind of hearing aid brand a hearing aid manufacturer can successfully enter the OTC market with, doing research on the specifics of such a brand and the willingness of potential consumers to buy such a brand.

7. ACKNOWLEDGEMENTS

I would like to thank my supervisors, Prof. Dr. Ir. Bart Nieuwenhuis, Xander Stegehuis MSc, and Dr. Raymond Loohuis for assisting me in writing this thesis, guiding me through the process, and providing me with good advice whenever it was necessary. Furthermore, I would like to thank my company supervisor from company X.

8. REFERENCES

- Adner, R. (2017). Ecosystem as Structure: An Actionable Construct for Strategy [Article]. *Journal of Management*, 43(1), 39-58. <https://doi.org/10.1177/0149206316678451>
- Amlani, A. M. (2019). Pricing in Hearing Healthcare: Which Race are You Running? <https://www.audiologypractices.org/pricing-in-hearing-healthcare-which-race-are-you-running>
- Blustein, J., & Weinstein, B. E. (2016). Opening the market for lower cost hearing aids: Regulatory change can improve the health of older Americans [Article]. *American Journal of Public Health*, 106(6), 1032-1035. <https://doi.org/10.2105/AJPH.2016.303176>
- Bucherer, E., Eisert, U., & Gassmann, O. (2012). Towards Systematic Business Model Innovation: Lessons from Product Innovation Management [Article]. *Creativity and Innovation Management*, 21(2), 183-198. <https://doi.org/10.1111/j.1467-8691.2012.00637.x>
- Carter, N., Bryant-Lukosius, D., DiCenso, A., Blythe, J., & Neville, A. J. (2014). The use of triangulation in qualitative research. *Oncol Nurs Forum*, 41(5), 545-547. <https://doi.org/10.1188/14.Onf.545-547>
- Donahue, A., Dubno, J. R., & Beck, L. (2010). Guest editorial: accessible and affordable hearing health care for adults with mild to moderate hearing loss. *Ear and hearing*, 31(1), 2-6. <https://doi.org/10.1097/AUD.0b013e3181cbc783>
- Edwards, B. (2020). Emerging Technologies, Market Segments, and MarkeTrak 10 Insights in Hearing Health Technology [Article]. *Seminars in Hearing*, 41(1), 37-54. <https://doi.org/10.1055/s-0040-1701244>
- Fischer, M. E., Cruickshanks, K. J., Wiley, T. L., Klein, B. E., Klein, R., & Tweed, T. S. (2011). Determinants of hearing aid acquisition in older adults. *American Journal of Public Health*, 101(8), 1449-1455.

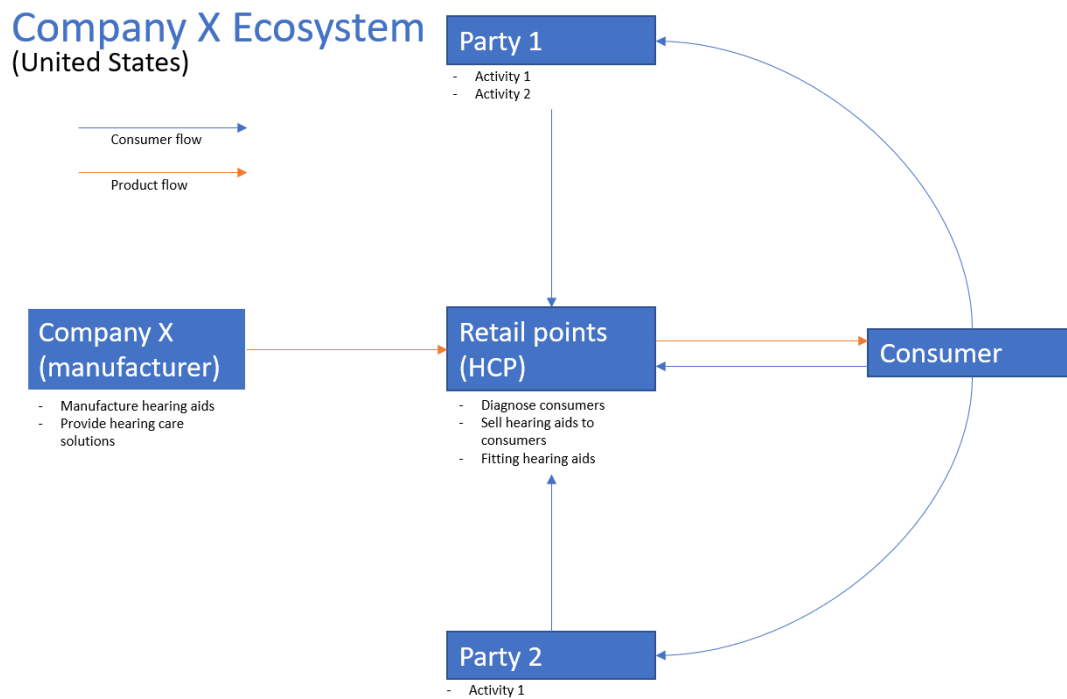
<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3134488/pdf/1449.pdf>

- Foss, N. J., & Saebi, T. (2017). Fifteen Years of Research on Business Model Innovation: How Far Have We Come, and Where Should We Go? [Article]. *Journal of Management*, 43(1), 200-227. <https://doi.org/10.1177/0149206316675927>
- Franck, K. H., & Rath, V. K. (2020). Regulation of over-the-counter hearing aids — Deafening silence from the FDA [Review]. *New England Journal of Medicine*, 383(21), 1997-2000. <https://doi.org/10.1056/NEJMp2027050>
- Grundfast, K. M., & Liu, S. W. (2017). What Otolaryngologists Need to Know About Hearing Aids. *JAMA Otolaryngology–Head & Neck Surgery*, 143(2), 109-110. <https://doi.org/10.1001/jamaoto.2016.3416>
- Humes, L. E., Rogers, S. E., Quigley, T. M., Main, A. K., Kinney, D. L., & Herring, C. (2017). The Effects of Service-Delivery Model and Purchase Price on Hearing-Aid Outcomes in Older Adults: A Randomized Double-Blind Placebo-Controlled Clinical Trial. *American Journal of Audiology*, 26(1), 53-79. https://doi.org/doi:10.1044/2017_AJA-16-0111
- Jilla, A. M., Johnson, C. E., & Danhauer, J. L. (2018). Disruptive Hearing Technologies and Mild Sensorineural Hearing Loss II: Current Research on Affordable Hearing Technologies and Direct-to-Consumer Models. *Seminars in Hearing*, 39(2), 146-157. <https://doi.org/10.1055/s-0038-1641741>
- Khanagha, S., Volberda, H., & Oshri, I. (2014). Business model renewal and ambidexterity: Structural alteration and strategy formation process during transition to a Cloud business model [Article]. *R and D Management*, 44(3), 322-340. <https://doi.org/10.1111/radm.12070>
- Kirkwood, D. (2013). Research firm analyzes market share, retail activity, and prospects of major hearing aid manufacturers. In: HearingHealthMatters.
- Kirkwood, D. H. (2009). Despite challenging economic conditions, practitioners in survey remain upbeat. *The Hearing Journal*, 62(4), 28-30.
- Kochkin, S., Beck, D. L., Christensen, L. A., Compton-Conley, C., Fligor, B. J., Kricos, P. B., & Turner, R. (2010). MarkeTrak VIII: The impact of the hearing healthcare professional on hearing aid user success. *Hearing Review*, 17(4), 12-34.
- Mitchell, D. W., & Bruckner Coles, C. (2004). Business model innovation breakthrough moves [Article]. *Journal of Business Strategy*, 25(1), 16-26. <https://doi.org/10.1108/02756660410515976>
- Nanof, T. (2020). Over-the-counter hearing aids: Be the change [Article]. *ASHA Leader*, 25(1), 18-19. <https://doi.org/10.1044/leader.AEA.25012020.18>
- Nielsen. (2021). *Bringing hearing aids to the over-the-counter market: Understanding the Category Drivers and Considerations for the Paths to Entry*.
- Omona, J. (2013). Sampling in qualitative research: Improving the quality of research outcomes in higher education. *Makerere Journal of Higher Education*, 4(2), 169–185-169–185.
- Osterwalder, A., & Pigneur, Y. (2010). *Business Model Generation*.
- Parvizi, N., & Woods, K. (2014). Regulation of medicines and medical devices: Contrasts and similarities [Review]. *Clinical Medicine, Journal of the Royal College of Physicians of London*, 14(1), 6-12. <https://doi.org/10.7861/clinmedicine.14-1-6>
- PCAST. (2015). *Aging America & Hearing Loss: Imperative of Improved Hearing Technologies*.
- Roblek, V. (2015). Impact of internet and social media on organisational change of OTC medicines marketing management [Article]. *International Journal of Electronic Marketing and Retailing*, 6(3), 239-258. <https://doi.org/10.1504/IJEMR.2015.070806>
- Stewart, C. (2020). *Global hearing aid market share by company 2019*. Statista. <https://www.statista.com/statistics/1087388/global-hearing-aid-market-share-by-company/>
- Talmar, M., Walrave, B., Podoynitsyna, K. S., Holmström, J., & Romme, A. G. L. (2020). Mapping, analyzing and designing innovation ecosystems: The Ecosystem Pie Model [Article]. *Long Range Planning*, 53(4), Article 101850. <https://doi.org/10.1016/j.lrp.2018.09.002>
- Teece, D. J. (2010). Business models, business strategy and innovation [Article]. *Long Range Planning*, 43(2-3), 172-194. <https://doi.org/10.1016/j.lrp.2009.07.003>
- Valente, M., & Amlani, A. M. (2017). Cost as a Barrier for Hearing Aid Adoption. *JAMA Otolaryngology–Head & Neck Surgery*, 143(7), 647-648. <https://doi.org/10.1001/jamaoto.2017.0245>
- Warren, E., & Grassley, C. (2017). Over-the-counter hearing aids: the path forward. *JAMA internal medicine*, 177(5), 609-610. https://jamanetwork.com/journals/jamainternalmedicine/articlepdf/2606426/jamainternal_warren_2017_vp_170004.pdf
- Weiss, R. S. (1995). *Learning from strangers: The art and method of qualitative interview studies*. Simon and Schuster.
- Yin, R. K. (2009). *Case study research: Design and methods*. Sage.
- Zamora, L. F., Gallo, M. P., & Cliquet, G. (2016). Selling OTC medicines in supermarkets: A challenge for the European market. In *Handbook of Research on Strategic Retailing of Private Label Products in a Recovering Economy* (pp. 469-490). <https://doi.org/10.4018/978-1-5225-0220-3.ch019>

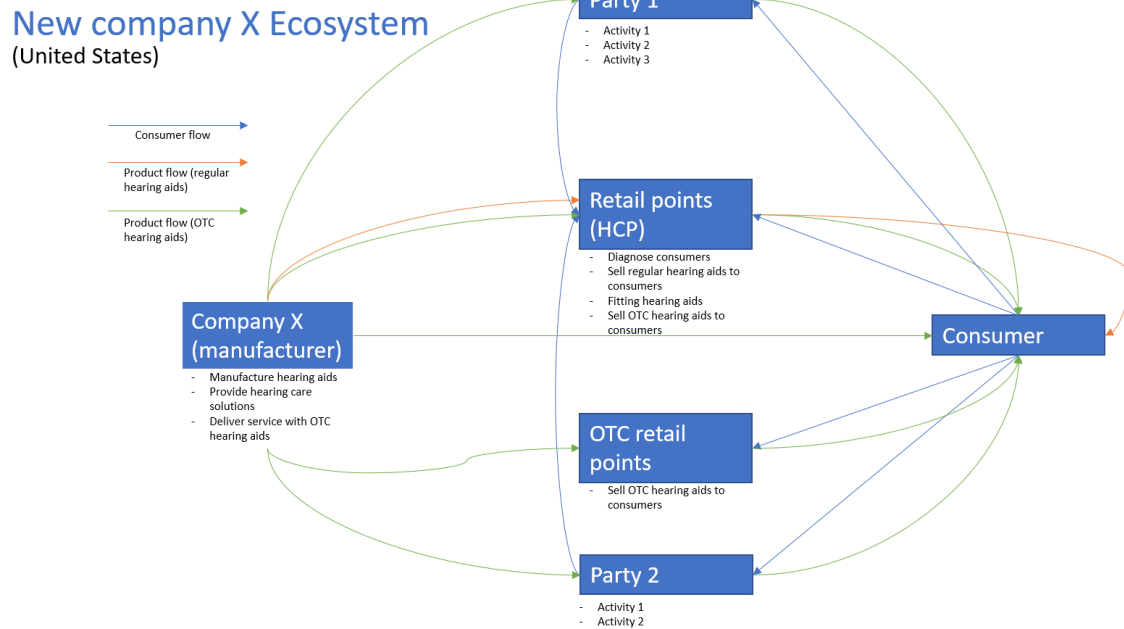
Zott, C., & Amit, R. (2010). Business model design: An activity system perspective [Article]. *Long Range Planning*, 43(2-3), 216-226.
<https://doi.org/10.1016/j.lrp.2009.07.004>

9. APPENDIX A

9.1 The current company X ecosystem



9.2 The new company X ecosystem



10. APPENDIX B: ECOSYSTEM PIE MODEL (EPM) OF OTC SALES

