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The Transformation of the Pharmaceutical Business Model – A Case Study of Roche

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Introduction

The pharmaceutical industry has been highly profitable for decades. The demand for pharmaceuticals has been strong as people grow older, following the post worldwar II baby boom generation. It can take billions of dollars to develop a new drug (most of which fail to produce a product), however a successful new prescription drug can be extraordinarily profitable. A single blockbuster could make up for all the investments as the drug was patent protected from direct competition. Thus, high profitability of the pharmaceutical industry rested on a handful of blockbuster drugs. Moreover, the high costs and risks associated with developing a new drug and bringing it to the market constituted a significant barrier to entry, limiting competition. Accordingly, the industry has been dominated by large, established companies that could bear the costs and risks (Ubel, 2016).

Nonetheless, the golden age of pharmaceuticals seems to be passé. Profits are declining and the industry is facing significant challenges, such as continued patent expiration, regulatory hurdles, access, pricing, and declining R&D productivity. It is becoming increasingly difficult to bring enough blockbusters to the market to make up for all the drugs that defaults (Ubel, 2016). In addition, there is likely to be a new breed of companies that will start to emerge from countries such as China, India, Korea and Brazil, to challenge the long-held leadership of US and European companies (Gautam & Pan, 2016).

The industry is about to mature, and pharmaceutical companies are experiencing a wave of competing challenges as part of the new digital era. The market is more informed and demanding now and expectations are rising with a different set of requirements. Not solely for great science, but for proof of effectiveness in the form of improved health outcomes at viable prices. In other words, it will be a more consumer-facing industry. Other industries have leapt forward, but healthcare systems are inching their way to the future (PWC, 2017).

The pharmaceutical industry has entered a new era and incremental adjustments are not likely to revolutionize the matured, traditional pharmaceutical business model. With the growing power of the payer, new commercial business models are required. Consequently, pharmaceutical companies are about to move away from unit-based product pricing to value-based initiatives that reward clinically and economically meaningful patient outcomes (EY, 2017).

The pharmaceutical industry has for a long time been dominated by big pharmaceutical companies, however the scene is changing. Companies from different industries are now entering the industry. Technology companies that specialize in IT, short-cycle innovations, big data analysis and consumer behavior are now entering the market. Leading actors like Apple and Alphabet are threatening the traditional structure. They have the lack of experience with the regulatory hurdles, timelines and risks of therapeutics R&D, however they are far ahead of understanding the areas that are shaping today's healthcare - and controls tremendous amount of data (Accenture, 2017).

It is estimated that the amount of health data is growing with approximate 48% each year (Stanford, 2017), however there are few companies that are actually utilizing this data, rather than only generating, and analyzing it (EY, 2017). Stanford Medicine (2017) claims that medical research is among the areas within healthcare where the power of big data has the most visible impact. A cluster of emerging tech companies is now starting to leverage the use of data by using artificial intelligence. By analyzing data from health systems and combining them with information from patients, they are trying to turn it into actionable recommendations (Stanford, 2017). Companies are attempting to revolutionize the R&D process by avoiding the standard hypothesis generation testing method, in a favor of a biology-led approach (Accenture, 2017).

The convergence of IT and healthcare is an area that is increasingly affecting the pharmaceutical business model. Technology firms and other non-traditional players awash in consumer and patient data, and they are entering the traditional pharmaceutical domain. Big data and mobile health are starting to transform healthcare and diagnostics in a significant way, with new players acting as increasingly disruptive catalysts. It is not hard to imagine a near future where a digital device can improve patient outcomes as well as traditional drug therapy, and with lower prices as well, it could be a highly disruptive threat to the traditional pharmaceutical companies (KPMG, 2017).

Roche

Roche is a Swiss multinational healthcare company that operates under two divisions: Pharmaceuticals and Diagnostics. The company is one of the world's largest pharma companies, and of the top 50 global pharmaceutical companies by prescription sales and R&D spending, Roche is the third largest in 2016 (Statista, 2017). In addition, Roche ranks second on enterprise value of global top pharmaceutical companies (Statista, 2017). Thus, Roche is a large incumbent in the industry and is one of the big players that are facing the challenges that arises with the new digital era, and has thereby initiated several engagements in order to meet these upcoming challenges.

- Research Question and Aim

As technology companies continue to implement digital innovations that potentially disrupt health care, there is a risk that the pharmaceutical incumbents lack the capabilities to control the data that are so important in demonstrating product value. Pharmaceutical companies have started to take use of data, however there are uncertainty whether they see a disruption from outside of the industry as a real threat, or whether they are solely concerned about using the data to make incremental changes. If the focus is on cost savings in the R&D process, a radical disruption from outside of the industry is likely to happen (Christensen, 1997).

The emerging digital technologies are reshaping the landscape, and a new generation of companies is utilizing big data, sensors and artificial intelligence to provide precise real-time monitoring of patients. A transformation of the pharmaceutical business model seems inevitable. There is a need to go "beyond the pill" and towards a more value-rich patient-centric service model (Nicholson, 2016). Moreover, pharmaceutical companies need to find strategies to improve patient outcomes and diversify revenue sources that go far beyond the pill.

The aim for this research is to evaluate the various factors that enables pharmaceutical companies to succeed in the new digital era. One of the drivers in the new digital era is the amount of data that are created. However, do the pharmaceutical companies have the necessary capabilities that are required to utilize the opportunities that lies in the data? The tech industry is undoubtedly experts at creating value out of data. Thus, do they represent an opportunity for the pharmaceutical companies, or are they threatening the very existence of the traditional players? If the leveraging of the data is the road to success, how will the pharmaceutical companies obtain them? What capabilities are in need in order to survive the digital era? Can they go it alone, or are there companies from other industries that are more suitable to take the pharmaceutical industry into the future? Are collaborations or M&As with tech companies the way to go? What is the right strategy in order to meet this potential disruption? With the above mentioned in mind, our research question becomes:

How are pharmaceutical companies, like Roche, leveraging data to cope with disruption in the new digital era?

Theoretical Framework

This section will provide elaborations on the three theories that will be the basis for our thesis: dynamic capabilities, networks, and disruptive innovation. The theories have been selected based on the relevance for the problem presented in the introduction, and they will be the means by which we investigate how pharmaceutical companies like Roche leverage data to cope with disruption in the new digital age.

- Dynamic Capabilities

The field of strategic management is largely concerned with how firms generate and sustain competitive advantage. The resource-based view (RBV) states that resources that are valuable, rare, imperfectly imitable and imperfectly substitutable, are a source of competitive advantage (Barney, 1991). The dynamic capability perspective extends the resource-based view argument by addressing how these valuable, rare, difficult to imitate and imperfectly substitutable resources can be created and how the current stock of valuable resources can be refreshed in changing environments (Ambrosini & Bowman, 2009). GRA 19502

Dynamic capabilities are a term used to analyze change in organizational capabilities, and is defined as "the firm's ability to integrate, build and reconfigure internal and external competences as to best address rapidly changing environments" (Teece et al. 1997). This is highly relevant for organizations within environments of rapid technological change, and organizations seeking to change themselves. As a result, dynamic capabilities enable organizations to create, deploy, and protect the intangible assets that support superior long-term business performance (Teece, 2007).

Dynamic capabilities involve adaptation and change, because they build, integrate or reconfigure other resources and capabilities (Helfat & Peteraf, 2003). Moreover, in a rapidly changing environment the capabilities that make a firm better able to adapt rapidly and repeatedly, can lead to strategic advantages (Teece et al. 1997). Further on, dynamic capabilities can be divided into three clusters of activities and adjustments: "(1) to sense and shape opportunities and threats, (2) to seize opportunities, and (3) to maintain competitiveness through enhancing, combining, protecting, and, when necessary, reconfiguring the business enterprise's intangible and tangible assets" (Teece, 2007). Hence, the key for organizations is to sense and identify potential opportunities, while adjusting organizational structures and processes in order to seize the opportunities, in addition to transforming the organization's intangible and tangible assets in order to best maintain a continued dynamic fit. Those that achieve sustainable competitive advantage in the market are the firms that can display efficient responsiveness and quick and flexible product innovation (Teece et al. 1997).

From a broader perspective, a firm's capabilities determine what it can or cannot do (Christensen, 1997). These capabilities extend out of three core areas of the firm: its resources, its processes, and its values. Further on, the need for a firm to strategically harness the abilities to reconfigure these capabilities in order to avoid the threat of market irrelevance brought about by turbulent and disruptive environments. In other words, an organization's capabilities become its disabilities when disruption is afoot (Christensen & Raynor, 2003).

Dynamic capabilities govern the alterations of operational capabilities through a

process of reconfiguration. This is done in an effort to anticipate changes in the environment as it relates to the competitiveness of the organization. From an exploration-exploitation perspective (March, 1991), dynamic capabilities aligns with exploration of new possibilities, whilst operational capabilities aligns with exploitation i.e. refinement of existing competences (Pavlou & El Sawy, 2011). Furthermore, dynamic capabilities branch out into nearly all aspects of the firm. It integrates and draws upon research in such areas as the management of R&D, product development, technology transfer, intellectual property, manufacturing, human resources, and organizational learning (Teece et al. 1997).

Other dynamic capabilities are related to the gain and release of resources. These include knowledge creating routines, a particularly crucial dynamic capability in industries like pharmaceuticals, where cutting-edge knowledge is essential for effective strategy and performance. Dynamic capabilities also include alliance and acquisition routines that bring new resources into the firm from external sources (Eisenhardt & Martin, 2000).

The concept of dynamic capabilities emerged in the 1990s, and the field has advanced considerably since. There has established a distinction around what defines the concept; "some are used to integrate resources, some to reconfigure resources; some are about creating new resources, while others are about shedding resources". Although the definition has been advanced, the notion remains the same: dynamic capabilities are those processes that impact upon resources (Ambrosini & Bowman, 2009).

-Network

Networks can provide access to key resources from its environments, such as capital, information and technologies (Gulati, 1998). Network structures in itself are unique, and competing firms can have trouble imitating these. Thus, a network by itself can be seen as a resource and a potential source of sustainable competitive advantage (Gulati & Gargiulo, 1999). Scholars have studied networks from several perspectives. In this review, we will look closer on network from a strategic and industrial view.

Strategic Network

The literature of strategic network contributes to the strategic research by

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addressing a relational view, rather than an atomistic (Gulati et al. 2000), and by this illustrates what position an actor have in a network will affect the economic performance (Gulati, 1998).

Jarillo (1988) argues that networks are important for firms' competitive position because of the generation of trust, which lowers the transaction costs and makes it easier to solve specific problems. He explains strategic networks as "long term, purposeful arrangements among distinct but related for-profit organizations that allow those firms in them to gain or sustain competitive advantage vis-à-vis their competitors outside the network".

Williamson's (1975) introduction of how economic activities are organized in, and between, markets and hierarchies, is arguably some of the most important work on transaction cost. Querying this, Powell (1990) introduced networks as a distinct way of organizing economic activities. He argued that networks have semi-strong incentives, an intermediate degree of administrative apparatus, and works out of a semi-legalistic law regime. Further, he stated that there is an indirect control within the network, with medium flexibility, and a high commitment between actors. Consequently, Powell implies that there exists a dependency between actors within the network. The strategic network is composed of enduring interorganizational ties, of strategic significance and includes strategic alliances in forms of joint ventures, R&D collaborations, partnerships, board interlocks, and clusters, among others (Gulati, 2000).

According to the network theory, every firm in the network have its own perceptions and own goals. The process of agreeing on a common goal or vision is not necessary to form a network. However, from a strategic management perspective, this could indeed help to improve the effectiveness and competitiveness of both individual partnerships and the total network. (Tikkanen & Halinen, 2003).

Industrial Network

The industrial network literature moves away from how the organization can form their own network and focuses on how business relationships form networks (Gadde et al. 2003). Johanson and Mattson (2015) defined the industrial networks as "complex arrays of relationships between firms". These relationships are established through interactions between firms, and the priority of relationship care were argued to be important for managers, as competing is a matter of positioning in networks". The industrial network consists of ties and nods where they are representing the relationship, or lack of relationship, between the nodes (Brass et al. 2004). The focus is on the relations between actors, whether they are organizations or individuals, and if they are creating opportunities or constraints for the firm (Gulati, 1998; Brass et al. 2004).

Powell (1990) highlights several industries that rely on organizational linkages, and contexts where organization boundaries becomes blurry. Scholars who address the strategic and industrial network are both arguing that their presence in the network both enhance and limit their opportunities (Harrison et al 2011), and how the network affects industries (Powell 1990; Gulati et al. 2000).

- Disruptive Innovation

Clayton Christensen introduced the concept of "disruptive innovation" in his book The Innovator's Dilemma in 1997. He defines a disruptive innovation as one that creates "an entirely new market through the introduction of a new kind of product or service" (Christensen, 1997). It characterizes an innovation that bring a very new value propositions into a new or existing market. As opposed to sustaining innovations, which foster improved performance of established products without changing the market as such. Christensen identified the two distinct categories of innovations based on the circumstances of innovations (Christensen, 1997).

The theory has had a significant impact on innovators, managers, and organizations and has made important contributions when explaining both successes and failures of innovations and organizations. In "The Innovator's Solution" (2003), Christensen and Raynor further developed the concept of disruptive innovation to include products, services and business models, in addition to the already mentioned technologies. Thus, the concept of disruptive and sustaining innovations would include not only technology, but also the actual products, services and business models that attach themselves to these innovations. In the Innovator's Dilemma (1997), Christensen explains how most established companies go up-market to where the most profitable tiers of the business exist, rather than attempting to retain its least profitable and price sensitive customers. This because large companies are more likely "to flee rather than to fight when attacked from below" (Christensen & Raynor, 2003). Further, he recommends new entrants to create a disruptive business idea, rather than to replicate the strategy of established competitors. Furthermore, a disruptive innovation can either attack the lower segments of an existing market or create a completely new market.

It is crucial to note that although several disruptive innovations are displacing the sustaining innovations in an existing market, disruptive innovations can also work side by side with the already established market and businesses (Schmidt & Druehl, 2008). Additionally, incumbents can survive the new market disruption and even take on the role as disruptors after reorganizing and restructuring the company to fit the new markets (King & Tucci, 2002).

Methodology

In this section, the research design and plans for data collection, data analysis and reporting will be presented. The purpose is to present our views and methods for conducting research in order to best answer our research question.

- Research Design

The research will be a qualitative analysis as we seek to use the point of view of the participant, and to understand how incumbents in the pharmaceutical industry addresses the challenges that arises with the digital era. Qualitative research addresses questions about how social experience is created and given meaning, and produces representations of the reality of individuals (Denzin & Lincoln, 2000). We wish to understand the perspective of Roche and other actors, and what they see as significant and noteworthy, and let this be our point of view. We also aim to be closely involved with our subjects to truly comprehend with their values and strategies. By additionally having a semi-structured approach we intend to obtain rich and deep data, which is in alignment with our qualitative approach.

As we are analyzing how the actors seek leverage data to cope with disruption in

the new digital era, we have decided to have an inductive approach. We will begin with an area of study and allow the theory to emerge from the data (Strauss & Corbin, 1998). Aiming to generate meaning from the data collected, we expect to identify reasons to build a theory. However, we use existing theory to explore the research area and to formulate our research question. By utilizing this "bottom-up" approach, we will allow the research findings to emerge without the restraints imposed by structured methodologies (Thomas, 2006).

We will conduct interviews of managers of Roche, who has a central position regarding strategic decisions, and consequently, our data will be affected by personal viewpoints and values. As we are integrating human interests into our study, we will have an interpretive approach. Thus, objectivity will not be obtained as the answers will mainly depend on the interviewees' perception. An interpretive approach will allow us to gain a greater insight into the actual drive and objectives of the actors.

In order to observe how pharmaceutical companies respond to present challenges, we decided to use a case study. Case study is a research design which allows you to study one single organization or location, with a system or a bounded situation as the focus, where the researchers wish to obtain insights into the specific case (Bryman & Bell, 2015). Advantages of choosing a case study as a research method, is that it allows for a detailed, in depth understanding of the object (Hodkinson & Hodkinson, 2001). Thus, we wish to provide an in-depth study of a large company in the industry, Roche. By looking deeper into this particular case, we hope that the findings from our study can be used to identify insights into how pharmaceutical actors are responding regarding uncertain future prospects, and what might be the best approach. We are concerned to identify the unique features of Roche, however at the same time we hope to use this case study as a means of understanding a broader aspect of the different business cultures (i.e. instrumental case study) (Bryman & Bell, 2015).

According to Stake (1995), researchers should choose cases where they expect to learn the most with regards to the phenomenon of interest. We believe to have found a suited case in Roche, as it is an incumbent company with old business models and processes which have not much evolved for decades. We would like to study to what extent Roche have a detailed and well-articulated strategy to attack the challenges ahead, and to what extent this plan could be groundbreaking for the industry as a whole.

- Data Collection

The data collection will consist of initially an exploratory phase, and subsequently primary and secondary data collection to obtain information, and analyze, the separate aspects of the negotiation process in the best way possible.

Exploratory Phase

Our research will start with an exploratory phase of collecting data. By seeking out to various specialists within the field of pharmaceutical, innovation and technology. We are aiming to collect primary data from Roche, AstraZeneca, Oslo Cancer Cluster and IBM.

With a qualitative approach in mind, we are open to the fact that a result of the data collection, and interview of industry experts and leaders, that we will by nature create hypotheses or hunches that will needed to be tested by quantitative research. To allow for an exploratory sequential design to take place, will also allow our scope and generalizability of the qualitative findings to be assessed (Bryman & Bell, 2015).

Collecting data directly from industry leaders in the pharmaceutical industry will give us a better understanding of the present situation. This will give us an insight of their view regarding competition, and what actions they take to address the continuous growing uncertainty within the pharmaceutical industry. We are in a process of gathering data from Roche, and aiming to gather data from AstraZeneca. Getting a perspective of two industry leading actors will give us a more balanced view of the industry, and with an accompanying insight from experts from different fields, we are hoping to obtain a more accurate view of the situation. In the following we will provide a brief presentation of the collateral contacts.

AstraZeneca is an Angelo-Swedish pharmaceutical industry leading company. The corporate headquarter is situated in Cambridge, and its research and development headquarters are situated in Södertälje, Sweden and in Warsaw, Poland.

AstraZeneca states they are innovation driven, and prioritizing their patients. We are in the progress of establishing contact with AstraZeneca.

Oslo Cancer Cluster (OOC) is part of the Norwegian Centre of Expertise (NCE) organization, with close connection to the Radiumhospitalet. With an expertise in the pharmaceutical industry and well embedded in the life science network of Norway, we are hoping that they can provide us with a more objective view of how the industry has changed during the last years. We have established contact with the General Manager, Bjørn Klem. With experience as Research Director in Photocure ASA and holding a master degree in Pharmacy from Oslo University, Klem has the noteworthy expertise in the field of life science, and experience from the industry to supply us with good anecdotal data.

Thomas F. Anglero - IBM. We are in dialog with the Director of Innovation for IBM Norway, Thomas F. Anglero. He is responsible for IBM Watson, innovation projects in Norway, and created the Watson Innovation Lab at the OCC. His position and extensive knowledge of the technology application can be an important source of data for our research. IBM have invested heavily on its artificial intelligence (AI) platform IBM Watson, to make it applicable to the health industry. Collecting data from IBM will give us the perspective of technological companies.

Primary Data Collection

We will conduct interviews of several managers and experts as an interview "has meaning to a researcher only in terms of other interviews and observations" (Whyte, 1953). The interviews will be semi-structured, and there will be some room for the interviewee to talk freely. This, to see the point of view through the participant's eyes, thus generate a better analysis of the cooperation. This type of structure is executed by means of an interview guide, containing a number of more specific questions and issues to be discussed. Semi-structured interviews are also a better choice when several people are conducting the fieldwork as in our case. As qualitative interviews are intended to be flexible, allowing for the interviewee to elaborate what he or she finds to be of importance, the interviewer should therefore be prepared to diverge from the interview guide (Bryman & Bell, 2015).

Both researchers will be conducting the interviews, in order to ensure that we are

able to comprehend as much information as possible. One will oversee the interview guide and ask the predetermined questions while the other will listen and ask follow-up questions where this seems appropriate. The interviews will be recorded in order to increase accuracy when interpreting the data. We plan to code the interviews continuously to have a clear picture on how our research is progressing, and to minimize the workload in the end.

Secondary Data Collection

We plan to collect archival data in terms of public relation memos, internal documents, newsletters from the different firms, and also documents and minutes of meetings regarding the strategic decisions. These types of data will hopefully provide us with a broader view and understanding concerning how the actors are coping with disruption. The secondary data obtained will then be used as a basis for the interview guide and questions asked, in order to not ask basic and general questions.

- Limitations

- Selection Bias

We recognize that our selection of one actor in the industry could possibly affect our findings, and if we were to choose another actor, the results could differ. An indepth study of only one player is a small and narrow sample and this will also be reflected in our findings. Even so, our research is not meant to be generalized. Consequently, we still see our research selection as valid.

- Influence of Researchers' Personal Beliefs

When researching cultural differences, it is important for the researchers to be aware of own perception and beliefs regarding the different cultures. This will be limited by the fact that the team consists of two researchers, and there are thus different opinions to consider. Nevertheless, we are aware of our own potential bias but by being aware we aim to eliminate it.

- Evaluation

When doing a qualitative study there are two primary criteria proposed by Guba and Lincoln (1985,1994) that can be used to evaluate the work. The first category is trustworthiness which contains four subcategories; credibility, transferability,

dependability and confirmability. All of these concerns the internal and external trustworthiness of the research and are criteria we will use when analyzing our work and especially our findings.

The second category is authenticity which contains fairness, ontological-, educative-, catalytic- and tactical authenticity. These criteria have not been influential but are thought-provoking (Bryman & Bell, 2015) which can broaden our thought process as researchers and thus improve our work.

- Ethical Considerations

As ethical issues may arise when conducting research, we now want to elaborate on considerations of our concern. We will explain possible transgression of ethical principles of our research, and particularly the ethical issues that arise in the relations between researchers and research participants when investigating the two cases.

- Harm to Participants

We acknowledge that it is our responsibility as researchers to assess carefully the possibility of harm to participants, and to take all reasonable precautions to ensure that the participants will not be harmed by our research. Additionally, we will emphasize for the interviewees that participation is voluntary, and about their opportunity to withdraw from the study.

- Lack of Informed Consent

It is of great interest for us to ensure that the prospective participants in our research have been given as much information as needed to make an informed decision about taking part in our study. We will by no means keep the purpose of our research covert from our participants, to strive for greater information.

We aim to inform the participants about the process of our study, what their participation entails, why their participation is necessary, how the data will be used, and how and whom findings will be reported. We will form a written consent that our participants will need to sign (Bryman & Bell, 2015). We are aware that it will be difficult to present absolutely all the information that might be required to make an informed decision. Thus, we need to take precautions to ensure that the

respondents are in no way harmed as a result of their participation in our research (Bryman & Bell, 2015).

- Invasion of Privacy

Another ethical issue of our concern is invasion of privacy. The participants may feel that they are not being treated with respect for their individual values and sense of privacy (Bryman & Bell, 2015). Transgressing the participants' privacy may have destructive consequences not only to them but also to us. They may resist future collaboration and key participants can boycott participating in our study and this could potentially damage our research. Therefore, we will treat every interview sensitively and individually and give every participant an opportunity to withdraw (Bryman & Bell, 2015).

- Deception

The last ethical concern we will address is causing deception. Our objective is not to represent our research as something other than what it is and mislead our participants. Deliberate deception of the participants as a matter of professional course is not in our interest.

Project Timeline & Management

To manage our project, we will be using a Gantt chart, as it provides a systematic way to keep track of our progress. The Gantt chart have received some critiques for sometimes being too detailed, and redundant information. We will eliminate this by making a simple Gantt chart, and include only the tasks that need to be done in a chronological order. We have implemented some slack in the timetable, in regard to unforeseen events. This could especially apply to collecting all necessary data.



Research question, aim and much of the design and methodology has already been developed. However, after the delivery of the Preliminary Thesis Report, we can adjust our current plan using the feedback from our supervisor. Additional alterations may be added as we continue exploring the field, nonetheless, we aim at finishing our Master Thesis in the beginning of July. Throughout the process, we will keep a continuous dialog with our supervisor.

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