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**THE IMPACT OF PATENT CLIFF RISK ON NOVO
NORDISK A/S: AN ERM ASSESSMENT WITH FOCUS
ON TWO MAIN PRODUCTS IN THE US MARKET**

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Introduction

Thesis purpose

The healthcare industry is a flourish and profitable business despite the constraints that affect its regulation; the importance of such sector is such that, innovation has a worldwide impact and determines the life change of millions of patients.

Large pharmaceutical companies drive innovation through investments in research and development activities for the creation of a new drug product that could represent a milestone for the whole world.

The worldwide pharmaceutical revenues amount to more than 1 trillion US Dollars and the industry is “responsible for the development, production and marketing of medications”¹, meaning that the sector has a broad and significant social scope, besides the monetary value.

Although the pharmaceutical industry is heavily regulated and with high barriers to entry, the competition in this market increased exponentially over recent years, given the high number of small pharmaceutical start-ups and biopharmaceutical products firms that try to enter the market, as well as the generic competition that arises with patents expirations.

The risk that a pharmaceutical company faces when the patent of a drug is about to expire, with consequent possible entrance from generic products firms and fall of revenues, is called patent cliff.

By definition², the word “risk” refers to any positive or negative deviation from expected, meaning both downside and upside volatility compared to the baseline (or expected) value.

A corporate risk assessment includes a mix of facts and personal opinions based on experience and it requires inputs from several sources to identify, quantify and monitor risks and their potential impact.

The purpose of the present paper is to identify and describe the impact of patent cliff risk on two main products of Novo Nordisk A/S. Novo Nordisk is a Danish founded pharmaceutical company that creates and manufactures 49% of the global insulin market. Novo Nordisk is

¹ The Statistics portal, Global Pharmaceutical Industry – Statistics & Facts

² Seagal. Corporate Value of Enterprise Risk Management. The Next Step in Business Management

mainly specialised in diabetes and obesity care, but also in hemophilia and growth hormone disorders.

The choice of this subject is driven by personal interest in the healthcare sector and specifically in Novo Nordisk, as it is one of the largest and oldest innovator in the diabetes segments and it is currently expanding in the obesity segment, which represent the main menace of the current modern lifestyle.

In fact, the population affected by diabetes and obesity was growing by 7%³ per year, while in 2015, people affected only by diabetes were 415 million worldwide, compared to 151 million of the previous year.

The US population is the most affected by those kinds of diseases, with a total adult population with diabetes of 30.2 million, in 2015. Only in the first half of 2017, the new cases of diabetes were 1.5 million, reflecting the fast growth of an unhealthy life style.

The business value of Novo Nordisk is highly dependent on social factors and trends, indeed the investment in diabetes and obesity sector became extremely profitable over the last five years, and this fact is reflected on the company's net sales, which increased by a CAGR of 11%, between 2010 and 2016.

Given the current market trends, it seems like the diabetes and obesity segment's sales are likely to growth at least proportional to the increase in illnesses caused by the diseases mentioned above; however, competition in the pharmaceutical industry can also impact the firm's sales and it is not to be underestimated. Even though, on one hand, barriers to entry obstacle the entrance of new companies on the pharmaceutical market, on the other hand, generic drugs firms have an easy way to access the industry, thanks to more loose regulations that encourage their presence, to increase competition and avoid monopoly.

Thesis structure

The present thesis consists of five chapters: Chapter 1 provides a broad understanding of the pharmaceutical industry and the main companies that operate in the diabetes and obesity sector,

³ National Diabetes Statistic Report, 2017

which are considered the direct competitors of Novo Nordisk. The first chapter, furthermore, includes a focus on intellectual property rights (IPR) as a driver of innovation in the industry. Chapter 2 provides a deep analysis of the company in scope from a strategic point of view, with the identification of the firm's segments and products, its position in the market and the strategy that Novo Nordisk is following to increase the company value, in the future.

Chapter 3 represents one of the steps in the Enterprise Risk Management process: The Risk Identification. Through a qualitative risk assessment, the author identifies the most important risks that affects Novo Nordisk's performance, how they are categorised and seen by the firm itself, which risks are the most likely to occur and which are the ones with the most impact on the company's profit margin.

The goal of Chapter 4 is to analyse the potential impact of the patent cliff risk on relevant metrics. For the purpose of this analysis, annual net sales and operating profit are the value drivers used to identify the impact of the patent cliff risk, given the expiration dates of Novo Nordisk patents.

This part of the paper focuses on quantifying the patent cliff risk, taking into consideration the last economic trends, the recent changes in regulatory authorities' norms and the competitors scenario that affects Novo Nordisk's performances.

Novo Nordisk's main business area is diabetes and obesity care; therefore, the analysis of the patent loss risk is narrowed down and limited to this sector only, which represents 80%⁴ of the company's sales.

In addition, the risk assessment is limited and narrowed further down to two of the main and most profitable products of Novo Nordisk - Victoza® and Saxenda® - in order to deeply understand how these products' patents expirations (expected by 2022) will influence the company's sales and performance.

The second part of the fourth chapter also includes the analysis of the mitigation actions already put in place by Novo Nordisk, to diversify and reduce the impact of the patent cliff risk.

Chapter 5 includes the key findings of the whole analysis and possible mitigation actions in order to reduce the impact of patent losses on Novo Nordisk's sales and profit margins are

⁴ Novo Nordisk Annual Report 2016

suggested. The last part of the present thesis gives an understanding of limitations and strengths of the firm in scope and the possible business changes that could be adopted by the firm's Risk Governance, to enable the patent cliff risk to be anticipated early, but also to be proactively responded in order to minimise its bearing on financials, assets and reputation.

CHAPTER 1

1.0 Pharmaceutical industry overview

This part presents the theoretical foundation of the thesis. Firstly, it provides a review of the pharmaceutical market to understand the characteristics and peculiarity of the industry. Secondly, it describes the main features of IPR, explaining the importance of such rights for a pharmaceutical company. Finally, this part is concluded by a discussion on innovation strategies and how they are linked with IPR protection.

1.1 The market

The pharmaceutical industry is one of the most complex and profitable markets.

Its complexity is due to two main reasons: the first is the particularity of the product itself, that must satisfy several specific requirements before being sold, the second reason is the regulatory environment, together with the need for intellectual property rights protection.

A brand name pharmaceutical company invests a lot of capitals in research and development for the discovery of new medical approaches, for the creation and production of a drug product, for clinical trials and for the regulatory authority approval.

The pharmaceutical industry is characterised by high innovation costs, but low marginal costs, therefore intellectual property rights - especially patents - are very important to cover those initial costs. Patents give the opportunity to create a monopolisation of the market, where a specific product is unique and can be sold at a high price, with zero-bargaining power for customers.

The peculiarities of the pharmaceutical industry are such that, it is very difficult for regulatory authorities to create a competitive market; in fact, the government is in favor of firms' development and industrialisation and it must guarantee intellectual property rights protection to incentivise companies to innovate. With this regime, price regulation is very difficult to

establish and patients are willing to pay as much as they can to assure themselves adequate cures.

For these reasons, the government is willing to increase competition in this sector, in order to ensure consumers' welfare and let the prices go down when patents expire.

Generic drug products represent the main competitors of brand products and they were introduced for the first time in 1984 with the Hatch-Waxman Act⁵.

In order to launch a new product on the market, it is mandatory to refer to the Food and Drug Administration (or European Medicines Agency) and submit an NDA, New Drug Application (MA, Marketing Authorisation, in Europe). With the introduction of the Hatch-Waxman Act, companies can submit an ANDA, or Abbreviated New Drug Application, and avoid the performance of clinical trials, ensuring that the product is bioequivalent to the branded one.

Bioequivalence means that the generic product must have the same effects on patients, therefore it is not necessary for a company to sustain high development costs when those have already been incurred for the very first time the bioequivalent product was developed.

Of course, on one hand, the state is willing to give incentives to businesses to innovate and to guarantee the development of the society and the economy; on the other hand, the state must guarantee welfare gains and let competition increase to reduce drug prices.

With the introduction of the Act, the number of generic drug products manufacturers increased exponentially, reducing consistently the market share of branded drug companies; in fact, nowadays almost every drug faces generic copies.

The Hatch-Waxman Act includes the following changes⁶:

- The product's bioequivalence can be guaranteed submitting an ANDA, instead of a NDA, meaning that generic firms do not incur in clinical and non-clinical trial costs, but they also do not face the risk of patent infringement;
- Submitting an ANDA is possible only for non-patented products;
- Generic drugs have also the benefit of exclusivity, but just for 180 days;
- A generic drug cannot be placed on the market until the branded drug expires (a positive aspect for branded drug products);

⁵ The Act was sponsored by Representative Henry Waxman of California and Senator Orrin Hatch of Utah

⁶ The Hatch-Waxman Act, US Food and Drug Administration

- Patent extension options can be guaranteed and last around three years when generic drugs are launched on the market.

The Act ensures competition in the pharmaceutical industry – to some extent - but also the safety and effectiveness of generic drugs.

Especially in the last years, there has been a big increase in pharmaceuticals competition, such that new generic products replace branded products even before the latter expire; therefore, branded companies can only count on customers' loyalty and misinformation to extend the products' selling period.

On top of that, the threat of competitors is even higher considering the low-cost rivals in the Asian market, but also the current uncertain regulation and the pressure from the healthcare system to reduce prices, pushing towards tenders and price discounts.

The economic impact of the pharmaceutical sector is enormous: in 2015, the total revenues of all pharmaceutical companies in the world were more than 1 trillion US dollars⁷. In fact, 415 million people worldwide are affected by diabetes, with 65% of the adults affected by diabetes living in big cities, where the illness is widely spread. Indeed, in big cities, it is more likely to develop an unhealthy lifestyle that leads to the development of type 2 diabetes – the so called “Urban Epidemic” phenomenon.

Talking about obesity disease, 1.9 billion adults (from 18 years and older) are overweight and 600 million of them have clinical obesity (meaning BMI >30).

Approximately 9.4% of the US population had diabetes in 2015, meaning 30.3 million of Americans, with the major spread among people aged more than 65 years old.

On top of that, 1.5 million of people in the US are diagnosed with diabetes every year; this is a dramatic data considering also that diabetes was among the main causes of death in the same Country, in 2015.

North America (especially US) is the country that leads the pharmaceutical industry, indeed the world's largest pharma company, Pfizer is based in NYC.

However, the Asian market is expanding very quickly, especially in China and Japan, that shows the highest growth rates over the previous years. Those countries are experiencing a huge

⁷ The Statistics portal, Global Pharmaceutical Industry – Statistics & Facts

urbanization, which leads to an increase in quality and mainly access of healthcare infrastructure and resources, making the market attractive for new pharmaceutical companies. For instance, in China adults with diabetes are 112 million people, while in Japan and Korea together, the number of adults affected by diabetes is 11 million.

Figure 1-Key regional facts

Key regional facts

	North America	Europe	International Operations	Japan & Korea	Region China
Population (million)	346	537	4,347	178	1,344
GDP per capita (USD) ¹	48,632	35,036	4,594	39,322	5,430
Healthcare spend per capita (USD) ¹	8,049	3,373	255	3,329	221
Physicians per 1,000 people ¹	2.4	3.3	1.1	2.1	1.4
Number of people with diabetes (million) ²	26	32	197	14	91
Diagnosis rate ²	78%	64%	46%	53%	43%
Diabetes national prevalence ²	11%	8%	8%	11%	9%
Novo Nordisk total sales (DKK billion)	34.2	19.7	11.1	6.6	6.4
Insulin value market share ³	38%	48%	51%	56%	60%
Insulin volume market share ³	42%	50%	58%	52%	60%

1. The World Bank. 2. International Diabetes Federation. 3. IMS Health, Midas Quantum, version November 2012.

Source: Novo Nordisk Annual Report 2016

The pharmaceutical market has several unique features that distinguish the sector from the others. To start with, the product pipeline is very long; this is true for every pharmaceutical firm, because the product must go through all the different phases and stages of development.

The regular pipeline is not always fulfilled because the Food and Drug Administration (or European Medicines Agency) can stop and shut-off the development process when a product might potentially be dangerous for patients. Intensive controls and strict guidelines are also the reason why the production process takes between 10 and 20 years.

Another particularity of the market is the way small and big companies “collaborate” with each other; in fact, to avoid competition big companies usually acquire or build partnerships with small ones, usually start-ups. Of course, this is also a positive way for start-ups to get access to big companies’ assets, as well as distribution channels.

Moreover, the pharmaceutical market shows that firms trade at a high price-earnings ratio, mainly because research and development expenses are paid up-front and it takes many years to recover those; on the other hand, return on equity is also very high, compared to other industries.

As in other markets, it is good to diversify to reduce the risk of investing in this industry, especially because of the long and complex drug development process, that causes uncertainty.

1.2 Intellectual property rights

Intellectual property rights should be the engine of welfare maximisation, since the application of those rights is different among countries and it depends very much on dissimilarities in income and on the elasticity of demand on prices.

However, differentiation of regulation among countries is a delicate debate that has pro’s and con’s; regulation variation among countries encourages the creation of a parallel market for drug products, which are easily transportable. Moreover, when exports are over imports, prices tend to increase in the exporting countries and they tend to decrease in importing countries, leading to unfair or uneven prices in lower income countries.

The demand in the pharmaceutical market is influenced by many variables, which are mostly difficult to predict; to begin with, the sector is highly regulated, with many actors influencing the market: the government tendency to control prices, public and private insurance schemes, limitations on marketing of the products and also the presence of professionals, like physicians and pharmacists.

On the supply side, there are also constraints, like the rigorous controls on product safety and so, on product manufacturing.

Differences among countries are visible, not only in the way IPR is applied by region, but they differ also because of number of applications made in each country, possible patent term

extension and patent pendency time. The tables below provide data on the countries that receive the highest number of applications and also on the possibility of extension of patents protection in Europe and US. It is important to state that generally and on average, the patent term is 20 years and this data should be considered as fixed; on top of that, there can be an extension of IPR depending on case to case and depending on national laws. Asia is currently growing a lot in terms of innovation, indeed patents applications are mostly present in China, Japan and Korea.

Table 1-EU and US patent protection conditions

Country	Patent protection (years)	Possible extension	Conditions
Europe	20	Possible under national law	If national law provides term extension to compensate for pre-marketing regulatory approval ⁸
USA	20	Possible under United States Patent and Trademark Office	If delayed response to an application request for patent; Exceeding 3 years to consider a patent application If delays due to a secrecy order or appeal ⁹

⁸ Article 63(2)(b) EPC

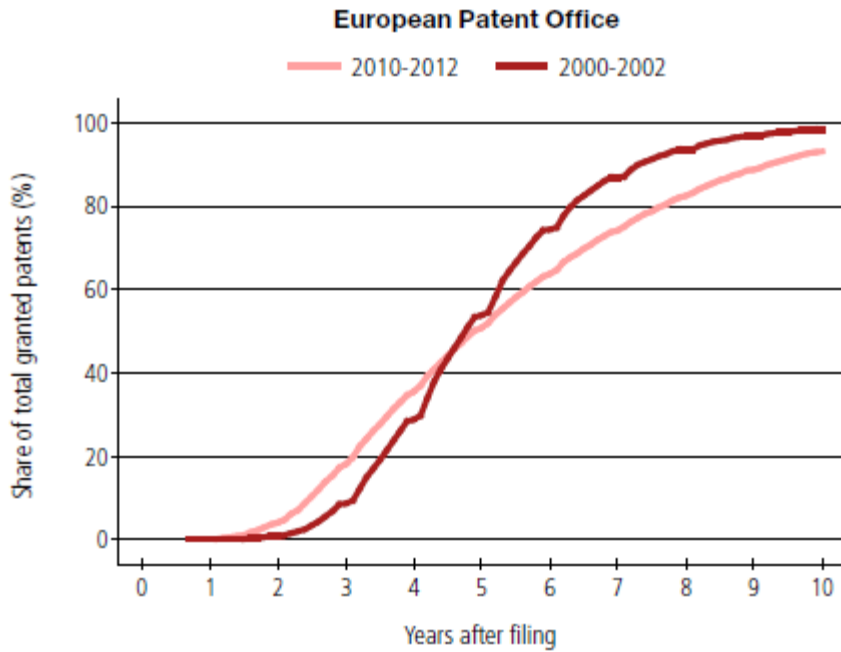
⁹ Patent Cooperation Treaty, PCT

Table 2-Patent applications

Country	Patent applications (as % of total applications in selected regions)
Europe	13.5%
North America	23.6%
Asia	58.4%
Latin America and Caribbean	2.5%
Oceania	1.4%
Africa	0.6%

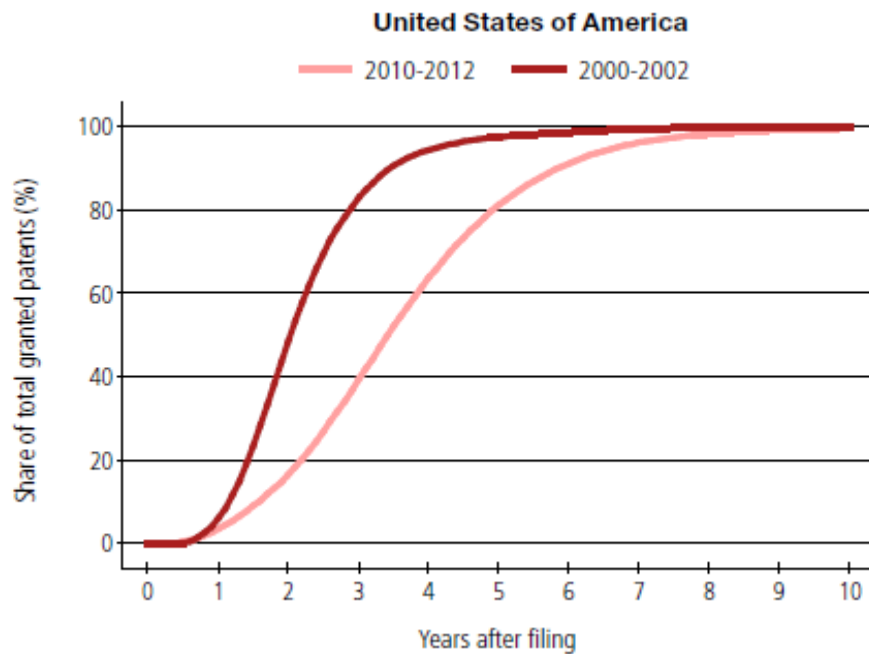
Going deeper on the patent requests timing it is clear that generally, the duration of patent protection is actually very similar to the patent pending time. Of course, if on one end this reflects the accuracy of the process (especially for medicines), on the other hand, it reflects some inefficiency in the regulatory approval process. The next graphs show the distribution of pendency time for some regions (or offices) and how those changed overtime from years 2000-2002 to years 2010-2012.

Figure 2-European Patent Office pendency time distribution



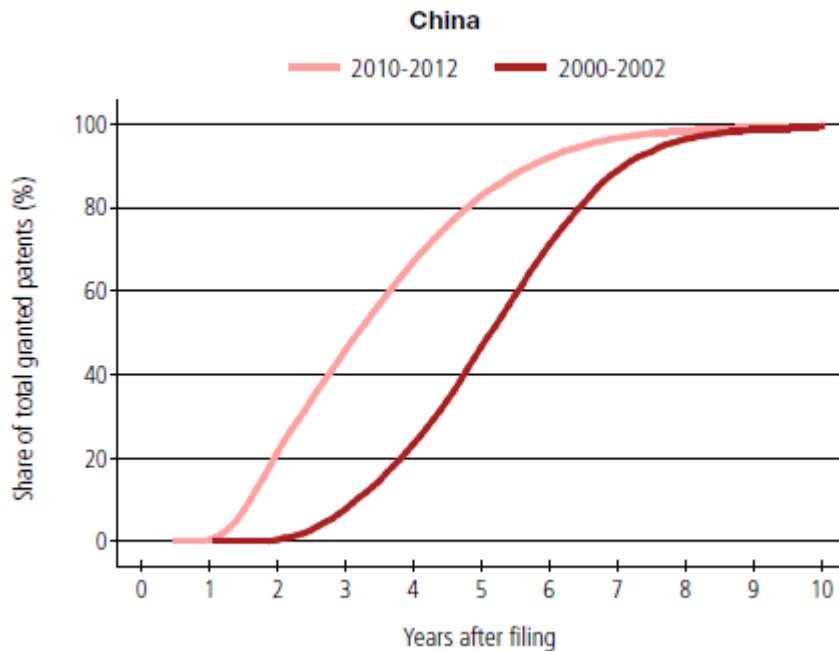
Source: World Intellectual Property Indicators

Figure 3-US Office pendency time distribution



Source: World Intellectual Property Indicators

Figure 4-Chinese Office pendency time distribution



Source: World Intellectual Property Indicators

The graphs identify the distribution of the pendency time of patents considering the years after filing the patent (on the x-axes) and the share of total granted patents (on the y-axes); it is visible the shift that Europe and US had in the patent pending duration. If between years 2000-2002 in order to grant 80% of the patents they used 6 years, from years 2010-2012 it takes on average 8 years; while for 100% of patents it takes more than 10 years. US office also worsened the average time of approval year after year; in fact, to grant 80% of patents between years 2000-2002, it took 3 years, while between years 2010-2012, the number goes up to 5; however, it takes around 9 years on average, to get 100% of the patent approval. China, instead shows an improvement compared to the past.

The impact of IPR on pharmaceutical companies is on market competition and innovation; market competition is supposed to be low thanks to the exclusivity – and basically the monopoly – of a drug manufacturing, selling and pricing. The other impact is on a company's innovation

capability, which should be incentivised by the opportunity of exclusivity and by the possibility to cover research and development costs, with also high profit margins.

The pharmaceutical industry is unfortunately threatened by the pressure from rising in research and development costs, together with the general decrease in the patent life; on top of that, many concerns arise because of the limited access to medicines from low-income groups and because of the general price increase of healthcare infrastructures.

Especially in the past, the scope of patents has been quite broad, but it definitely depends on countries; since innovation is increasing, especially with the development of biotechnology, the patent scope might even be larger than expected.

Patent protection issues are visible especially in high competitive markets. Talking about the patent life, in some cases, product exclusivity can be granted for additional periods, in order to promote actions on innovation in special diseases or particular cases.

From the patent owner's point of view, it is very important to offset research and development costs through the recovery of profit losses from infringers, as well as litigation proceeds.

On the other hand, from the new-comers prospective, it is important to have many patents not approved or declared invalid, or to go against the patents' requests.

Those facts rise up the problem of "patent quality", meaning the lack of high standards for patentability, which implies higher costs.

It is difficult to make a cross-country comparison when talking about this market, especially in terms of pricing, governments' regulations and agreement which are very much specific and complex. For instance, in the US there is an evidence¹⁰ of prices affected by regulation and intensity of rivalry among competitors; in markets with poor or little regulation, and with intense competition, when a patent expires the immediate consequence is the entrance of generic companies on the market and substantial profit losses of branded drug firms.

When generics launch their products, the price difference with the branded ones is very much visible, meaning that the price of dug products is meant to be high when patent protection occurs. Again, those evidences are based on the US market, but for instance, in other developed

¹⁰ Strategic Entry Deterrence and the Behavior of Pharmaceutical Incumbents Prior to Patent Expiration, studies of Caves, Whinston and Hurwitz (1991), Griliches and Cockburn (1995), Frank and Salkever (1997), Grabowski and Vernon (1992), Reiffen and Ward (2005), Scott Morton (2000), and others

countries with a different regulation and market, the generics entrance is less perceived and the price drop is also less impactful.

Patents protection is necessary to ensure the competitive advantage of a company; in fact, a survey on the impact of patents on R&D expenses¹¹ shows that if there was no secure exclusivity protection of a product, research and development investments would be much less – about 50% - than the current value.

However, patents protection has several effects, which – once again – have different impacts among countries; there are many variables that influence the research and development investment decision: for instance, the economy of scale and scope, work force skills and knowledge, but also government regulations, tax regimes and favorable subsidies.

Generally, the US has been the most attractive market for pharmaceuticals, mainly because the price regulation is very poor; on the other hand, in the EU governments' regulation has been tougher and it discourages research and development investments because of aggressive price control policies.

Furthermore, the investment decision is primarily driven by the presence of academic centers of excellence in some areas. This phenomenon implies also that pharmaceutical company infrastructures are basically close to each other and this means that they benefit from common access to skilled workforce and infrastructures, as well as from interactions with each other.

IPR have also effects on the composition of expenditures of a company.

Expenses in the pharmaceutical sector depend on the profitability of a certain market; the rarer the kind of disease, the more costly is the investment in the research phase. Moreover, companies are not willing to invest in a market where returns are low, or even non-existent. Those small markets are not attractive for pharmaceutical companies, so the innovation is mainly visible in big markets – meaning in common or most spread diseases – and in developed, or developing countries.

Usually, in less developed countries or low-income countries, the access to healthcare and medicines is problematic and costly; yet opportunities of developing and investing in those critical countries are coming up slowly.

¹¹ The impact of patents on R&D, Taylor and Silberston (1973)

1.3 Innovation in the pharmaceutical industry

The pharmaceutical industry is a particular knowledge intense sector, difficult to analyse and evaluate, but with a huge impact on the world economy, society evolution and also on the society welfare. Its expansion depends on intellectual property rights protection, governments' regulatory policies and on the degree of development of some areas.

The current business model of a pharmaceutical company is built up in a such a way that the innovator firm obtains its revenue stream from the product exclusivity, which is guaranteed by the patent protection for 20 years. The firm is then able to cover its R&D expenses.

The innovator firm suffers big losses when the patent expires, therefore usually the company invests to put new products into the pipeline, that can potentially offset the sales drop caused by generics.

1.3.1 The generic insulin

There are many generic drug products, in fact, the number of companies investing in generics is increasing a lot, however there is no generic insulin.

The introduction of generic insulin has been the object of many debates, especially in the US, but it is very difficult to develop. The invention of a generic insulin would certainly be a huge step ahead in the pharmaceutical industry for two reasons:

- There are 415 million of people affected by diabetes Type 1 and Type 2;
- The price of insulin is very high (especially in the US), it goes from \$120 to \$500. It was estimated to be \$274 for a 10ml bottle in 2017, increasing by 7.8% from the previous year.¹²

Normally, generic companies sell their products at much less price, because they do not incur the cost of discovering and developing a new product, but this is not the case for insulin.

First of all, branded companies usually renovate their patents, making some small improvements that make the drug “evergreen”; this does not mean that improvements are not valuable for

¹² The prices for life-saving diabetes medications have increased again, Business Insider Data source

patients, but the patent period expansion discourages the investment in discoveries and innovation of new type of products.

Moreover, also generic companies are not willing to work on the development of the insulin protein; because of the molecule complexity, insulin is very difficult to copy and very costly, therefore the generic insulin has never been developed in the past years.

Insulin is not just complex in its composition, but also in its approval; the approval process from the Food and Drug Administration is longer and more expensive than other drugs, meaning that it is not worth for generic companies to invest in such market.

Despite the facts just explained, the world's largest generic medicines producer, called Teva, announced in July 2017 that it has filed an ANDA with the FDA, for the approval of a generic version of Novo Nordisk best seller for the treatment of type 2 diabetes (Victoza®). Teva is the first company applying for a generic version of liraglutide and this can really change the competing scenario of the diabetes market.

1.3.2 Patent cliff escaping strategies

The patent cliff phenomenon is defined also as the revenues-cliff and one of the major risk for large pharmaceuticals because the innovator firm cannot avoid the entrance of generics on the market when patents expire. The traditional business model of the pharmaceutical firms is such that the company focuses on the development of a single drug for a wide target of customers; it is not a guaranteed that the company will succeed in covering the high R&D costs, thus if on one hand, this business model leads to important innovations and advances in the pharmaceutical industry, on the other hand, it is not always profitable and it is becoming outdated with the evolution of the market.

Many companies work in similar activities or products, so it is very important that they are quick in asking for patent permission for the drug candidate. Additionally, big companies do not have many products in their pipeline and it is becoming less sustainable for them to increase profit margin.

According to the current business model, new patented products must replace losses caused by patent expiration of the previous products, but there are many variables that obstacle this process:

- The cost of bringing new products to the market is becoming higher and the approval process is becoming longer, therefore pharmaceutical companies are now challenged by developing products which are more effective than those already on the market;
- The healthcare regulatory authorities are favoring the entrance of generics, changing the average price of products;
- Generic firms encourage branded companies to invest in innovation to keep up with competition, while generics have much fewer R&D costs and, of course, are willing to offer drugs at much less price.

For these reasons, branded companies need to find a way to defend their profit margins; for instance, acquisitions have been made from companies like Pfizer (that acquired Wyeth Pharmaceuticals in 2009), to offset the patent cliff phenomenon and to increase the assets portfolio.

To discourage generic competition and to fight the threat of patent shortage, firms must create new strategies to survive on the market.

The pharmaceutical industry is going toward the so-called “niche busters”, meaning markets with less exposure to substitutes. On one hand, this shifts the focus from more-common diseases, on the other hand it gives the possibilities for the firm to invest in specific assets, instead of focusing on the global market.

It is likely that – in the future - drugs will be paid based on the results and effectiveness that they deliver, so companies must reinvent new business models and abandon the traditional one. Among the new strategies that branded companies can adopt to fight competition, there are four important ones:

1. Prevention strategy;
2. Innovation strategy;
3. Extraction strategy;

4. Adaptation strategy.

In particular:

1. The prevention strategy aims at extending the patent protection creating “patent clusters”. Patent clustering means creating a portfolio of patents around the first one approved; it is related to the “evergreen” phenomenon of patents, with which companies create small improvements, linking secondary patents to the first one, increasing the exclusivity period of the product. There are several ways to apply a prevention strategy:

1.1 The secondary patent role is to incorporate inventions related to the primary patent, allowing the innovator to keep the market share, however generics that want to enter the market have the opportunity to challenge the validity of the primary patent, anyways. Obviously, this strategy is merely meant to escape the patent cliff, therefore, often secondary patents do not bring significant improvements to the patient’s life; in fact, sometimes it is difficult for the branded firm to get the approval of the secondary patents (especially in developing countries).

1.2 Another way to extend the patent life is to obtain a Supplementary Protection Certificate (SPC), this is a method applied in the EU – in the US it is named Patent Term Restoration. This mechanism allows the protection of the branded product up to five years from the expiration date, to compensate for the time spent during the regulatory approval process.

1.3 Firms can also apply for the orphan drug status, which instead is related to rare diseases, for which there are not so many effective treatments, thus this method allows companies to extend the patent period to cover the initial investment. Also in this last case, generics can enter the market challenging the validity of patents starting litigation processes.

2. The innovation strategy aims at focusing on impactful changes on an existing product. This means focusing on product-line extensions, new indications, or the creation of a new business model. Innovation means creating significant improvements to an existing product or creating a new one. The innovation strategy can also be applied through several ways:

- 2.1 A company can create new formulations or combinations of products to create a product-line extension, basically basing the product on the same active pharmaceutical ingredient than the previous one, but also reaching a different customers target; using this first method, a company can get three additional years of exclusivity.
- 2.2 A firm can also introduce new indications for the product, meaning that thanks to the improvements made, the drug can be used also for other purposes than the initial one – also with this method the firm has three years of exclusivity.
- 2.3 Another way is to create the so called follow-on product, which means introducing the same product on the market, but this time with the guarantee of it being more effective. This process is also difficult to demonstrate and it should bring significant changes on the product's effectiveness.
- 2.4 Moreover, a branded firm can expand the market switching the normal prescription to the one called Over the Counter (OTC). The main changes are just on the legal status of the product, in fact, the company's goal is to diversify the target and expand the market share. This last mechanism is also linked with the creation of an innovative business model, with which the company adapts and modify the business model according to the environment changes.

3.The extraction strategy's object is to avoid investments in innovation and to focus on the current market position through marketing and prices approaches.

Through this strategy, the firm can adopt several approaches:

- 3.1 Cutting costs related to the product, right before its expiration date, in order to compete with generics ready to enter the market. On the other hand, if the product is insensitive to the price, the company can also increase the price even more than the beginning price, before the patent expiration date. In this regard, branded firms must be very careful when applying the price to the product in the first place.
- 3.2 Another technique is to slowly disappear from the market, as soon as the expiring date is approaching; for instance, the firm can cut expenses on the product when it is likely that generics will take over the market, keeping the portion of customers that relates to the branded product.

3.3 A company can also license the drug or sell the product's exclusivity to other firms to take advantage of the other company's infrastructures and technology.

4. Finally, there is the adaptation strategy, which has already been implemented by many branded companies. This strategy aims at introducing generic drug products from the same company selling branded ones, developing synergies and diversifying the product portfolio, offsetting generic competition. Again, this approach can be implemented with different techniques.

4.1 The first one implies that it is the same company that owns the patent, that develops the generic product; this allows the company to reach several customers segments and apply a different price according to the customers' willingness to pay.

4.2 The second technique, instead, aims at offering the generic products through subsidiaries. In this case, it is very important for the subsidiary to be quick and get the first mover advantage on the market, before other generic competitors.

There are many ways to face competition and avoid the patent cliff phenomenon, however, this cannot be done for a long period of time; indeed, all those strategies just explained are effective in the short term and it can be very difficult to implement them, especially because the application of those approaches must be planned long time before the patent expiration date.

Moreover, the generic entrance erodes profit margins such that it is questionable for branded companies to keep sustain more costs, investing in some of these strategies.

The company must be ready to anticipate the changes in the business environment and also to get a deep knowledge of the regulatory authorities' norms.

On top of that, the decision to extend the life of the product depends on the product itself, meaning on its composition, complexity and its unique features, and of course, on the type of diseases that it is supposed to cure.

CHAPTER 2

2.0 Novo Nordisk company overview

This chapter provides a comprehensive view of Novo Nordisk A/S, starting from a description of the firm's facts and figures and the 3C framework; moreover, an analysis of the competitors' scenario is made using the Porter's Five Forces analysis and the SWOT analysis. The last part instead, gives an understanding of the growth strategy of Novo Nordisk in each segments in which the company operates.

2.1 Company analysis

Novo Nordisk is a leader in four main sectors and it has a global diabetes care value market share of about 27%:

1. Diabetes care
2. Obesity
3. Hemophilia
4. Growth disorders

According to the 2016 sales report, the amount of sales in that year is DKK 11.8 billion. Diabetes and obesity care account for 80% of 2016 sales and Hemophilia accounts for 9% of sales.

From 2000 to 2015 it was estimated¹³ that people affected by diabetes grew 7% per year (from 151 million to 415 million) and it is also projected that the people affected by diabetes in the year 2040 will be around 642 million. Given that, Novo Nordisk has huge opportunities to increase profitability and so do its peers (competitors).

The diabetes care market has three main categories: insulin therapy, glucagon-like peptide-1 (GLP-1) therapy, and oral anti-diabetic drugs. The prevalence of diabetes increased a lot, due to

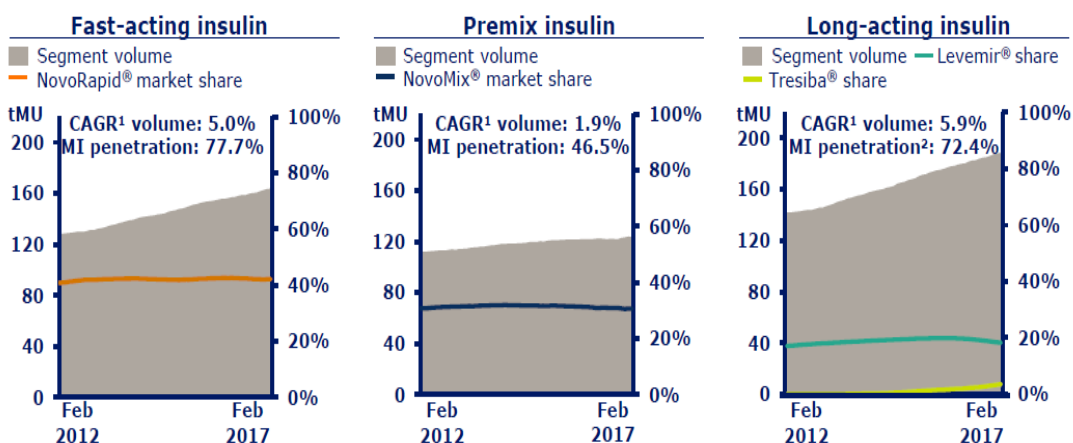
¹³ National Diabetes Statistics Report, 2017

rises in obesity and the aging population and it is consequently pushing up the demand for insulin therapies around the world. Moreover, the insulin market is divided into three segments: fast-acting or rapid-acting, premix, and long-acting therapies, depending on the time of the day when the patient takes the therapy.

Diabetes diseases lead to obesity; therefore, we might expect that the number of people affected by obesity will increase proportionally to the number of people affected by diabetes; or actually more than proportionally, considering that obesity does not necessarily mean being affected by diabetes.

As shown in Figure 5 and Figure 6 below, Novo Nordisk is focusing on the modern insulin segment: the new generation of modern insulin therapies, together with the high competitiveness of the company in the insulin pens, allows the firm to be a market leader in the modern insulin, while it is less strong in human insulin therapies.

Figure 5-Modern insulin segment volume



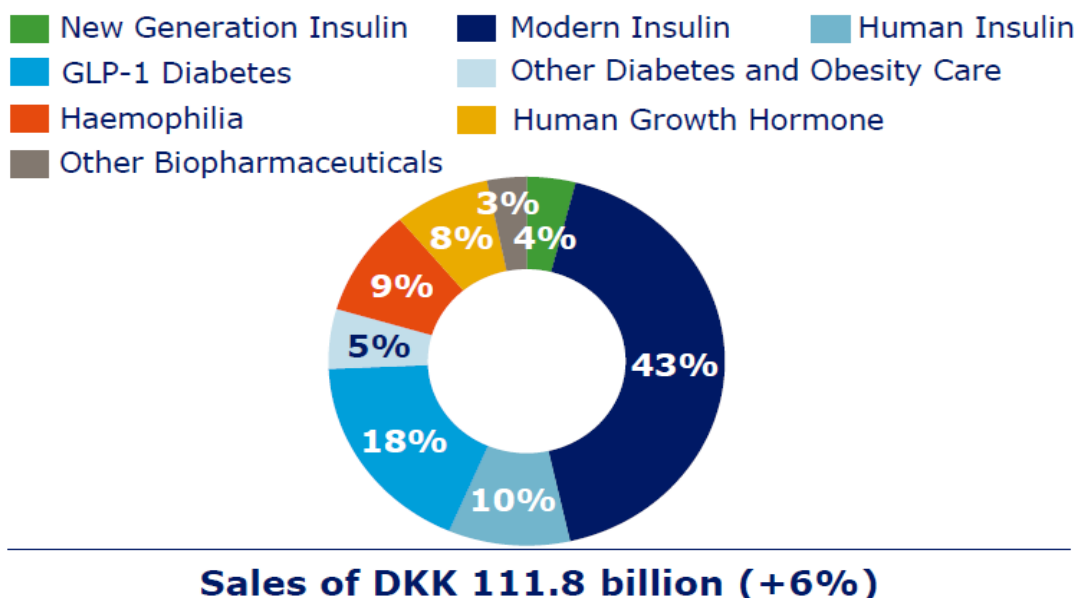
Source: IMS, Monthly MAT November 2016 value and volume figures¹⁴

¹⁴ Includes animal insulin. 2 Annual value of total insulin class. 3 Includes new generation insulin

Note: Data is sensitive to changes in IMS data collection and reporting methodology

Source: IMS, Monthly MAT November, 2016 value and volume figures

Figure 6-Sales division per specific segment of products



Source: 1 IMS Monthly MAT, figures in Novo Nordisk Investor Presentation 2016

Novo Nordisk market segments are also divided by diabetes type and geographical areas. Again, diabetes type 2 represents the biggest market segment. Talking about the geographical locations, the firm operates in 165 countries all over the world with more than 4 billion patients in North America, Europe, Japan & Korea, China and other International Operations. North America is the biggest market segment, followed by the European market; however, the Chinese market is becoming extremely important and is growing really fast.

Novo Nordisk products are Insulin syringes, Insulin pens, Insulin pumps, Insulin injectors; while Novo Nordisk end-users are hospitals and homecare.

Novo Nordisk sales growth is driven by new-generation insulin and Victoza®, which is part of glucagon-like peptide-1 (or GLP-1) market. In January 2016, the firm launched Tresiba® in US, a novel long-acting basal insulin; other major launches, by the same company, are Ryzodeg® and Xultophy® (the latter is a combination of Tresiba® and Victoza®). Novo Nordisk suffered losses due to high expectations coming from the launch of Levemir®, which was expected to be the sales growth driver in the modern insulin portfolio (as shown in Figure 7Figure 7).

At the same time, the competitor Sanofi launched Glargine® U300 or Toujeo®, which is a long-acting insulin with the same type of insulin of a former product of Sanofi: Lantus®. Lantus®

was the key product of Sanofi until it faced his patent expiration in 2015. Consequently, Novo Nordisk focus switched to another medicine: Tresiba®. Tresiba® represents a big innovation for Novo Nordisk since the product allows patients to take one injection that stabilises the insulin level for 42 hours. Tresiba® represents 4% of the sales in diabetes and obesity care segment, however, the highest amount of sales in 2016 is due to NovoRapid® and Victoza®.

Saxenda® represents another key product of Novo Nordisk, it was approved by the FDA in 2015 and it is an agonist of GLP-1. Saxenda® and Victoza® are both parts of GLP market, however the former is not used for the treatment of diabetes type 2, but for the treatment of obesity and it cannot be used at the same time as Victoza®. Since Saxenda® was recently introduced by Novo Nordisk, it still represents a small portion of sales, however, its sales are expected to boost in the next years. The main competitor product of Saxenda® is called Trulicity® and it is produced by Eli Lilly.

Figure 7-Focus on sales per product in 2016

Reported currencies	Sales (mDKK)	Sales split
Tresiba®	4,056	4%
Levemir®	17,083	15%
NovoRapid®	19,945	18%
NovoMix®	10,482	9%
Victoza®	20,046	18%
Saxenda®	1,577	1%
Diabetes and obesity care¹	88,949	80%
NovoSeven®	9,492	8%
Norditropin®	8,770	8%
Biopharmaceuticals¹	22,831	20%
Total¹	111,780	

Source: Novo Nordisk Annual Report 2016

2.2 The 3C analysis framework

The 3C analysis framework evaluates:

1. Customers
2. Competitors
3. Company

The strategic triangle is a key tool to identify the key success factors of the company.

The company analysis has been already implemented in paragraph 02.1 Company analysis, therefore this paragraph focuses only on customers and competitors.

Starting from the costumers, it is important to understand what are the customers' needs, the potential future needs, what is the demand trend and what it could possibly influence the consumers' choices in the future.

Looking at competitors, a deep analysis includes their market share, how it changed or it is going to change in the future, what is the market segment in which they operate, what they offer to the market and therefore, what their customers experience. In the special case of the pharmaceutical industry, a key element of the analysis is the patents allocation and the patents' expiration dates, which make a big difference in determining the competitive advantage. Patents expiration are publicly known and impact the company performances, making life easier for generic drugs businesses, which are prepared to take over the market and propose biosimilar drugs at price much lower.

Finally, the corporation analysis aims at identifying products, market share and target segments, which include a distinction by geographical area and product type. It is necessary to incorporate in the valuation, what are the strong points and pain points of the company, from the customers' point of view and what it could be the future challenge that the company might face, giving the consumer demand changes.

2.2.1 Customers scenario

Novo Nordisk customers are patients, therefore, the demand for products is inelastic. Generally, patients that use a specific product for a long time do not trust changes, even with generic drugs which come on the market at a price 80% less than branded drugs.

There is evidence of a possible new type of insulin - tablet format – that will come on the market. Companies are investing a lot in R&D to produce a kind of insulin which can avoid the daily injection for patients. Customers are prepared and they know that a change may come soon. However, firms have disclosure that the creation of a tablet form of insulin is particularly difficult, due to the possible dispersion of active pharmaceutical ingredient into the stomach, meaning that it is difficult for the tablet to be as effective as an injection, since the latter goes directly into the blood. Generally, those facts may prevent customers to trust the product at the beginning, even though the drug may be certified as 99% effective.

Once again, Novo Nordisk's customers are patients, therefore another company that sells the similar, but likely effective drug that patients need, may be mistrusted at the beginning. Especially old people are usually not willing to make those kinds of changes. At the same time, a drug that is likely effective and - if in a tablet form - sold at a lower price, might be trusted by customers after some time.

The tablet form is easier to take, less costly, practical to bring with you and do not causes the same pain as the injection, even though it may have collateral effects as any other drugs.

Given the particular nature of such customers, the main variable to take into consideration in this analysis is the potential patients' population growth in the short-future. Novo Nordisk's clients are going to growth and - other things equal - Novo Nordisk's sales are going to growth as well.

The short-future picture is pushing the diabetes care market to a next level because of two main reasons: the number of patients will be extremely high and the geographical focus of diabetes care companies is expanding in the Middle-East area. The geographical expansion, together with the increase in diabetes and obesity illnesses will significantly enlarge the customers' portfolio and boost sales.

2.2.2 Competitors scenario

Novo Nordisk's competitors are Eli Lilly, Sanofi, Pfizer, Leo Pharma, Jonson & Jonson, GlaxoSmithKline, AstraZeneca, Novartis, Merck, Takeda.

Competition affected the company a lot in the past five years, meaning that Novo Nordisk suffered big losses and the last year, it had to declare a considerable amount of people to lay off. Competition is expected to growth in the next years and this fact goes hand in hand with the increase in the number of patients affected by diabetes and obesity.

Given the increase in competition, pharmaceutical companies must innovate to survive on the market. Novo Nordisk has three products in phase 3 clinical trial. Phase 3 clinical trial aims at bringing the drug to the market and get the market authorisation form FDA (Food and Drug Administration) in the US or EMA (European medicine agency) in Europe. Clinical tests are made on more than 2000 patients affected by chronic disorders and they have a long-term scope, meaning that clinical trials must show the effectiveness of the active pharmaceutical ingredient (API) and the possible side effects when the drug is used continuously. If everything goes well, the drug shows effectiveness and normal and tolerable side effects, and then the company gets the market authorisation to bring the product on the market. Moreover, follows Phase 4, in which the product is finally launched on the market¹⁵. An explanation of the company's clinical trial phases and time frame is given by Figure 8, below.

¹⁵ NovoNordisk.com

Figure 8-Phases of clinical trials



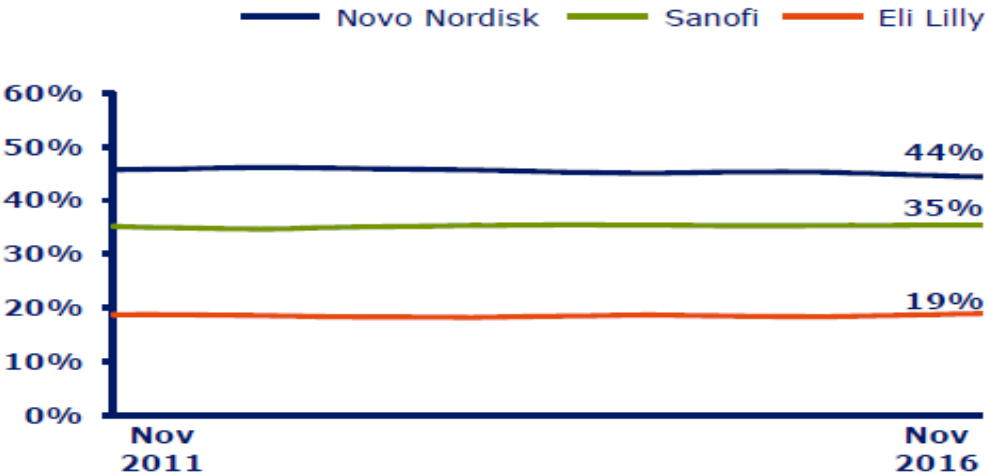
Source: Author's estimates

Referring to pharmaceutical companies' market segments, there is a distinction per diabetes type (type 1 and type 2) and a segmentation by geographical area (USA, Europe, AAMEO¹⁶, Japan and Korea and Latin America). Diabetes type 2 takes the most part of the market segment: it is a chronic metabolic condition caused by unhealthy lifestyle as well as genetic factors. Diabetes treatment is spread mainly in the US, which represents 77% of the overall insulin market and it is also expected to grow considerably in the next years.

Key insulin vendors are Sanofi, Novo Nordisk and Eli Lilly, which dominate the global insulin market and recently expanded in Asia. As visible from Figure 9, Novo Nordisk has the most part of the modern insulin market (44%), followed by Sanofi (35%) and Eli Lilly (19%).

¹⁶ Asia, Africa, Middle East and Oceania

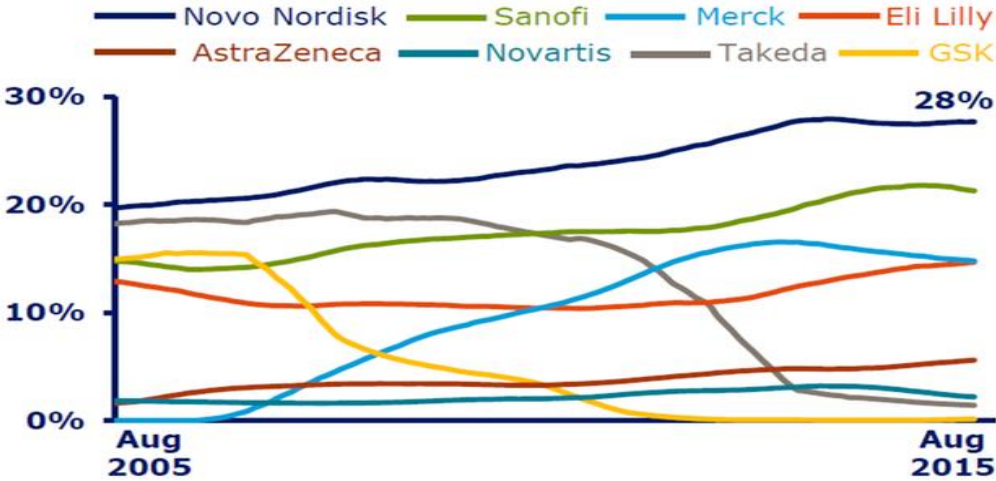
Figure 9-Market share in modern insulin, Novo Nordisk, Sanofi and Eli Lilly



Source: Novo Nordisk Q4 Results 2017

Competition in the diabetes segment is very high, but Novo Nordisk still holds a valuable position when related to its main competitors - as showed in Figure 10 – and it is placed as the 15th biggest pharmaceutical company in the world.

Figure 10-Nov Nordisk and competitors’ insulin market share



Source: IMS Monthly MAT, figures in Novo Nordisk Investor Presentation 2016

2.3 Porter's five forces analysis

A good picture of the industry strategic position is given by Porter's five forces analysis that describes the interaction of the main factors that influence a company's performance and decisions. Porter's analysis focus on: threat of new entrants, power of suppliers, bargaining power of buyers, availability of substitutes and intensity of rivalry.

The threat of new entrants is relatively low in the pharma industry, mainly because the entrance on the market requires a big initial investment, even though it usually leads to a very high payoff. However, there are many venture capital funds that are willing to provide capital to start-ups with innovative ideas in the pharma industry, but their exit strategy is to sell out to other big pharmaceutical companies, thus they do not represent a big threat to the big firms.

New entrants are also generic pharmaceutical companies, but they must wait until branded products' patents expiration date to have access to the market. Yet, they represent one of the biggest threat, because they can take over a big portion of the market share.

The power of suppliers is very low. Pharmaceuticals can get raw materials (and also equipment used for the production), from several different sources, since the manufacturing process entails commodity products in the chemical market.

The bargaining power of buyers is also very low. The lack of power regarding pricing is due to the fact that, only the insurance companies that acquire drug products from the pharma companies can somehow regulate the price of distributors, but they have no power with manufacturers' decisions. Also, professionals do not profit from the selling of drugs, on the other hand, pharmacies and medical institutions that accomplish patients' prescriptions have a margin of negotiations, but they are not incentivised to lower prices to customers.

Therefore, patients who represent the last step of the value chain, are in a very disadvantaged position, in which they have zero-negotiating power because of their need of being cured and having access to the drug products that they require.

On the producer side (specifically under the US regulation), the list price (the one set by the manufacturer) applies to patients without insurance, to patients with insurance with a good deductible or to patients that take advantage of Medicare coverage gap; from this initial price, rebates are subtracted (those are sum paid to insurance companies or to governments programs);

after that, the wholesalers payment is due to distribute the drug products to clinics, pharmacies and hospitals and after that manufacturers get the net or realised price.

The availability of substitutes is different among the type of drug and disease that it is supposed to cure; for rare diseases for which it is required a big initial investment, there are very few or there are any substitutes drugs, to the branded one. While, for very common diseases there are many substitutes, either created by big companies that are in competition, or by new generic firms.

Finally, the competitive rivalry is influenced by the lack of public information, because non-disclosure agreements and non-compete clauses represent a huge obstacle for competitors, that in such way, are not able to deeply analyse the industry and create substitutes.

That is also the reason why, the industry is made up of many big companies that acquire small ones, which are considered attractive because of their innovative researches.

2.4 SWOT analysis

A SWOT analysis is conducted to deep dive into the specific features of the pharmaceutical industry and to get a full understanding of Novo Nordisk's market and strategy.

Novo Nordisk is a leading pharmaceutical company, specialised in diabetes treatment (and also in other areas) that has more than 90 years of experience in the sector and that operates in almost 200 countries.

The expertise level of the company leads to one of its major strengths: a significant and deep knowledge on diabetes treatment, which results in an established position on the market, high reputation and also trustiness and loyalty of patients.

Novo Nordisk saved up a lot in the past months, in order to invest in new research and development projects and to keep up with competitors after a decline in profit margin in the past year; thus, the cash flow of the company can be either used for investments, acquisitions and expansions.

Another strength of Novo Nordisk is the presence of around 41 000 skilled and talented employees which also represent the expertise of the company – as mentioned before – together with its worldwide footprint.

The company is currently expanding its market portfolio, indeed it has invested a lot in Asian countries; it has also experienced business units and a good diversity in senior management, which calls for new and different perspectives and opportunities for improvements. Novo Nordisk recently reduced its labor costs to align with expected future revenues and it also increased its growth rate.

Talking about weaknesses, as any other pharmaceutical company, Novo Nordisk has huge R&D costs, as well as distribution costs, due to its worldwide presence.

The long time and the high cost to approve a product in its different development phases represent a big slowdown of the company performances; on top of that, competition is increasing very fast and Novo Nordisk does not have a big portfolio of products, meaning that it is not differentiated to mitigate the risk of generic entrants on the market.

To tackle this problem, many big firms are expanding their product portfolio and investing in generics, to keep up with coming up generics competitors. The company's performances are also affected by the high degree of complexity of the industry, which requires pharmaceuticals to constantly fulfill regulatory authorities' practices, as well as, to constantly uphold to government regulations in every different country.

On the other hand, Novo Nordisk has lots of opportunities to potentially exploit. First of all, the company is a leader in the diabetes treatment and nowadays, diabetes and obesity are very much threatening the society, because of the frenetic life style and the easy access to unhealthy food and drinks.

Consequently, the population affected by diabetes and obesity diseases will increase in a disproportionate amount in the next years, giving pharmaceutical companies the opportunity to increase revenues and profit margins; together with that, there is also a tendency in increasing of urbanisation and average life expectancy.

The growing demand is also due to the rise in the access to healthcare, as well as, the number of responsible and conscious people and the rise of income levels. The firm has opportunities to

growth, also because it has many products in its pipeline that are still in the development phase, but that can definitely increase profits in the following years.

The company's growth is also driven by the expansion in developing countries in which there is a high demand for insulin products and where the access to adequate cures is currently developing.

Among the threats that Novo Nordisk is facing, there are those regarding the changing government regulations (especially in the US). There might be negative consequences of some healthcare reforms approved by governments; regulation is also becoming more stringent and in periods of economic downturns, the public spending pressure often results in the decrease in healthcare investments.

For instance, the risk of rebates in the US, together with the risk of reducing drug prices for patients, increasing in interest rates, taxes and costs of raw materials, might reduce the margin of the company.

Besides the competition that arises after patent losses, there is also the risk of copied products, (bioequivalent products) that have the same active pharmaceutical ingredients of other products and the same velocity with which it is absorbed by the organism, but they are sold at a lower price. Finally, pharmaceutical companies face the threat of patent pending, or the risk of losing time and money during the patent's approval process.

Many variables can negatively influence the performance of a pharmaceutical company, but there are also several opportunities to develop the industry, mainly because of the fast changing society life style and because of the current emerging countries' need for healthcare infrastructures.

2.5 Novo Nordisk strategy

Novo Nordisk's corporate strategy is <Driving change to defeat diabetes and other serious chronic conditions>¹⁷.

¹⁷ Novo Nordisk Annual Report 2016

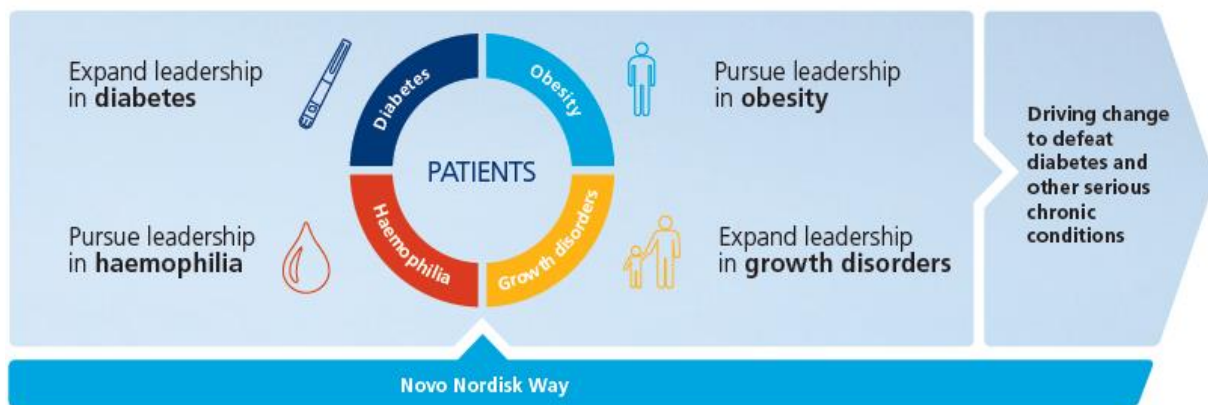
The company has unique capabilities and expertise in the diabetes and obesity market, however the strategic focus of Novo Nordisk is broader and refers to all its business segments.

Given the current economic condition of the pharmaceutical industry, Novo Nordisk has decided to adopt a different investment strategy from the past; in fact, with the increase in R&D costs and with payers less willing to pay for innovation, the investment projects must be better selected and scrutinised before arriving at the latest stages of the pipeline.

As a consequence, Novo Nordisk, from 2016 applied a more rigorous scanning of its products in the pipeline, but focusing on existing key products and on diseases with unmet patients' needs. This means that some of the projects in the early stages have been shut down, causing permanent losses.

The recent drawback pushed Novo Nordisk to a new defensive strategy to reduce the risk of patents expirations and new coming competitors; Novo Nordisk is indeed converging toward new markets in strong expansion, hence, it is focusing on reaching a new customers segment, expanding its leadership especially within the diabetes and obesity area.

Figure 11-Novo Nordisk's strategy



Source: Novo Nordisk Annual Report 2016

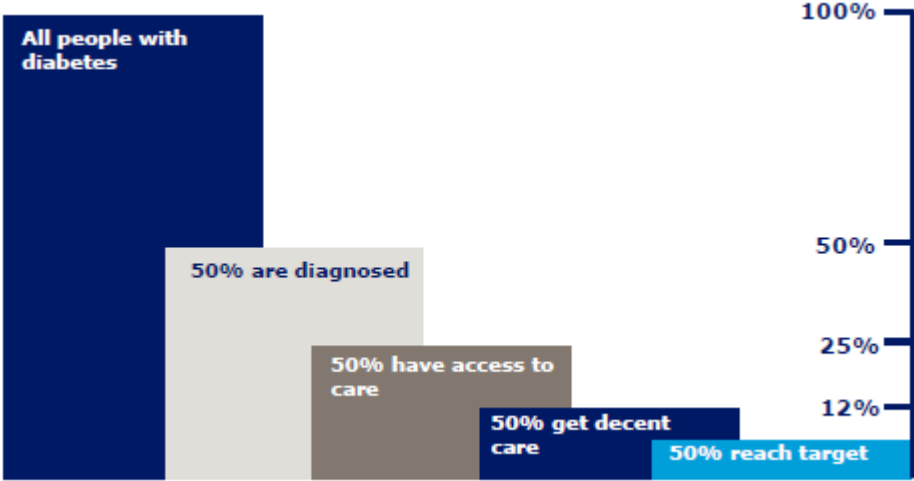
2.5.1 Diabetes

As the main driver of sales, diabetes sector is projected to boost profit margins even more, in the next years, thus the goal of Novo Nordisk is to expand the leadership in the diabetes segment.

From 2007, the company focused its attention on protein-based products (insulin and GLP-1) which are the also the main components of the firm’s sales ‘portion.

When talking about diabetes, it is important to mention the “Rule of Halves” (see Figure 12-The Rule of Halves Figure 12).

Figure 12-The Rule of Halves



Source: Novo Nordisk Q4 Results 2017

As shown in the figure, the amount of people affected by diabetes is much higher than the number of people effectively treated. The rule of halves explains that only 50% of people affected by the illness is diagnosed, meaning that the other half is not aware of having diabetes; only 50% of diagnosed people have access to care, in fact in less developed countries or low-income countries are not able to be cured; among the people cured, just half of them get an appropriate treatment, while another half of those people defeat diabetes.

How can Novo Nordisk improve the access to diabetes care? This is actually the goal of the company, in fact “Novo Nordisk Changing Diabetes” ambition is expected to reach in 2040, 40 million patients, such that the firm will contribute to decreasing the number of deaths caused by NCDs (Non-Communicable Diseases), by 25%, in 2025¹⁸.

¹⁸ Rabin Martin, Diabetes: Rethinking Novo Nordisk’s global strategy for access to care

Novo Nordisk's strategy to reduce the impact of patent expirations and increasing competition aims at focusing on new emerging markets, indeed the company is expanding its presence in urban areas ("Cities Changing Diabetes") and developing countries, thanks to contacts with policy makers, healthcare professionals and NGOs. China is also one of the main focus of the company, considering that the country has one of the highest rate of diabetes in the world.

Victoza® is the leading product for the cure of diabetes type 2 and it has been approved in the EU as the only GLP-1 product useful to prevent cardiovascular events. It is a product sold in 95 countries and treats more than 1 million patients¹⁹.

2.5.2 Obesity

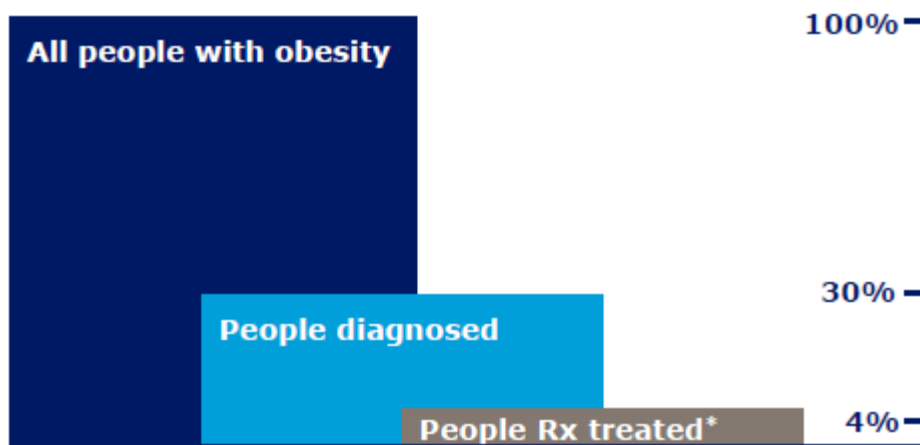
Obesity is not only a disease itself, but it is also the main cause of diabetes type 2, therefore Novo Nordisk wants to pursue leadership either in diabetes and also obesity care.

More than 600 million adults²⁰ suffer clinical obesity, however the percentage of people diagnosed is only 30% and the people treated* with AOM (anti-obesity medication) is only 4% of that.

¹⁹ Novo Nordisk A/S: Victoza® has been approved in the EU as the only GLP-1 with a label to include prevention of cardiovascular events

²⁰ Novo Nordisk Annual Report 2016

Figure 13-Obesity treatment



Source: Novo Nordisk Q4 Results 2017

As already mentioned, US is the market with the highest percentage of obesity and Novo Nordisk has already introduced Saxenda® has the leading product of Anti-obesity medications and it is confident about the long-term growth of the obesity market, as well as portfolio growth. It is part of GLP-1 products and it is demonstrated that it provides not only significant weight loss, but also improvements in blood glucose control after three years of usage²¹.

2.5.3 Haemophilia

Haemophilia is a rare bleeding disease, with unmet clinical needs. This disease comes in two forms: type A, which means having absent or defective production of blood clotting factor VIII, or it can be type B, meaning a difficulty in producing clotting factor IX.

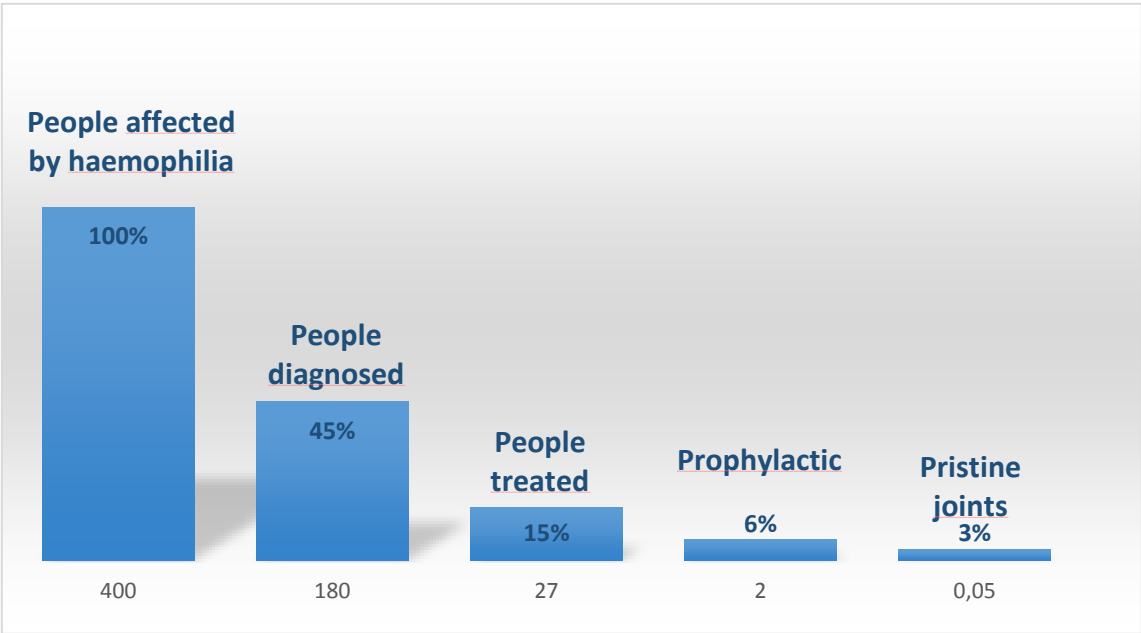
Novo Nordisk is already a leader in this segment, in fact the strategy of the company is to pursue the leadership in the market, however the number of patients is very small. People affected²² by Haemophilia type A are 350 000, while patients affected by type B are 70 000.

²¹ Novo Nordisk Press Release. Munich, Germany, 14 September 2016

²² Novo Nordisk Q4 Results 2017

Also in this segment, only less than half of the people affected by haemophilia are diagnosed, but Novo Nordisk has reached all patients with NovoSeven®, which obtained approval in most countries from 2014, but also and NovoEight®, from 2015.

Figure 14-Haemophilia treatment



Source: Author’s estimates, Novo Nordisk Q4 Results 2017

2.5.4 Growth disorders

Growth hormone deficiency is an inherited disease. Novo Nordisk has the highest market share in this segment (30%) compared to its competitors, but the strategic goal of the company is to expand even more its market presence.

Norditropin® will expire in 2017 and it has been the driver of sales in growth disorders in the past years, with a CAGR²³ of 10.4% from 2011 to 2016. However, the company has already Somapacitan (NN8640) in its pipeline and it is currently in phase III clinical trials, with high chances of being marketed.

²³ Novo Nordisk Q4 Results 2017

CHAPTER 3

3.0 Risk identification and qualitative risk assessment

The main purpose of this chapter is to develop a qualitative risk assessment of the risks that Novo Nordisk's Risk Governance must monitor and tackle. The first part of the chapter provides the risk categorisation and definition, with a focus on height main threats that menace the company's performances. The second part of chapter aims at deep dive on the most impactful risk among the ones categorised and at evaluating its impact on two main products of Novo Nordisk.

3.1 Risk categorisation and definition

The process-step ERM assessment includes the risk categorization and definition, to create a comprehensive list of the main risks that affect a company.

When evaluating corporate risk, there are many risk categories to take into account; governance, financial, operational, strategic, economic and political.

Depending on the company's performances, every firm faces some specific risks that the Risk Management Team should assess; however, there are some of them which are critical and shared among the whole pharmaceutical industry:

- Risk of rebates in the US (and other Countries) – political risk
- Risk of biosimilar competition – strategic risk
- Patent cliff – strategic risk

The US Government is taking actions to reduce drug products prices, since they are disproportionately high for patients; Medicare - the National Social Insurance program –is pressuring to drive prices down, especially on insulin products.

On top of that, biosimilar competition is also pressuring Novo Nordisk as a new competitor on the market, besides generic drug producers.

Finally, the patent cliff phenomenon is a risk that characterises the industry, because patents are the only way to ensure exclusivity of a product, but also to cover all research and development expenses and, obviously, every time the expiration date is met, generic competitors are ready to take advantage of the weak situation of branded firms and enter the market with new similar drugs.

Novo Nordisk is affected by the risks just mentioned above, but also by some other risks that might weakened the financial situation of the company because of their uncertainty in timing and financial impact. Some of them are also identified in the company’s annual report 2016:

1. Competition and global market
2. Biosimilar competition
3. Loss of intellectual property rights
4. Risk of rebates
5. Legal and compliance risk
6. Compromised operational quality and delay
7. Breach of information technology
8. Currency impact

There are many more risks that affects the company’s performances every day, but the ones mentioned above are taken into scope for the qualitative risk assessment, to deep dive later, on the main risk. In the table below, the risk categorisation and definition tool describes the risk just mentioned, dividing them in categories and subcategories.

Table 3-Risk categorisation and definition

Risk category	Risk subcategory	Risk	Definition
Strategic	Competitor	Competition and global market	Increase of competition and threat of new entrants
Strategic	Competitor	Biosimilar competition	Unexpected and aggressive changes

			in competitive landscape that bring the company a step behind its competitors
Strategic	Intellectual property	Loss of intellectual property rights	Loss of exclusivity of products
Political	Legal	Risk of rebates	General decrease in prices, with consequent unsustainable profit margin levels
Operational	Compliance	Legal and compliance risk	Inability of the company to comply with regulations
Operational	Compliance	Compromised operational quality	Inability of the company to comply with quality standards
Operational	Technology	Breach of IT	Inability to protect the firm from the loss of confidential information because of external attacks
Financial	Market	Currency impact	Unexpected changes in exchange rates

Before describing the risks just mentioned in Table 3, according to the Value-Based ERM approach, it is important to identify the risk scenarios to analyse.

When talking about risk, it is natural to think about the “negative” side of an event, even though it is not just that; an ERM analysis includes the credible worst-case scenario as a starting point, meaning “not the most unlikely of events, but neither it is a common event. It is somewhat in between, but still represents a fairly pessimistic scenario with a severe impact.” (Seagal, 2011). Besides that, there is also the credible best-case, which instead represents the optimistic scenario. After developing risk scenarios, the ERM process includes the quantification of the likelihood of the risk to occur, and the severity of its impact on net profit. Likelihood and severity are assigned according to the author’s opinion and his work experience in Novo Nordisk.

Table 4-Qualitative scoring criteria

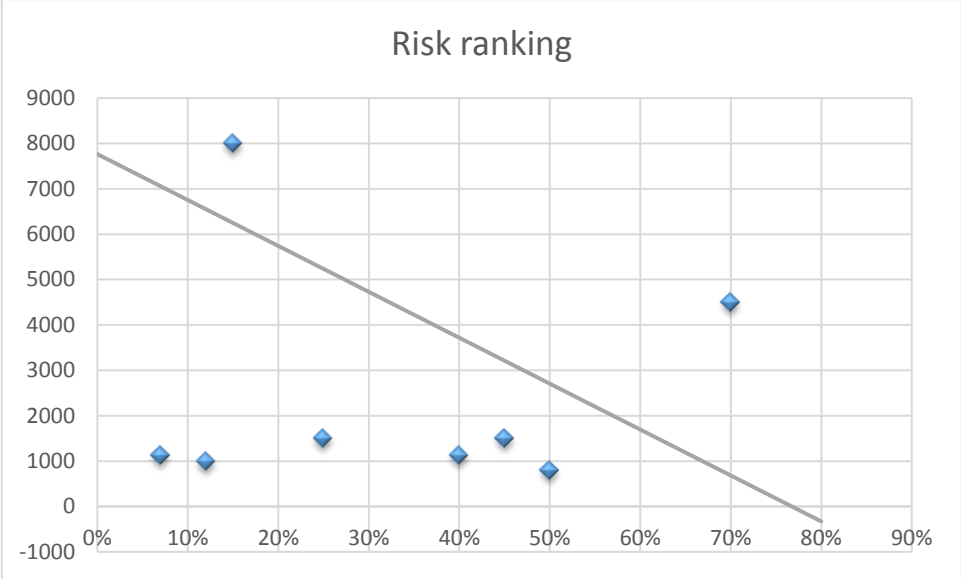
Likelihood	Qualitative scores	Severity (as a part of net profit)
Very likely >50%	Critical	>7500 mDKK
Likely 25-50%	Major	1500-7500 mDKK
Possible 10-25%	Moderate	750-1500 mDKK
Unlikely 0-10%	Minor	<750 mDKK

The table represents a qualitative scoring criteria from a critical to minor score, with likelihood and severity to assign to each risk. The likelihood (in the first column) represents the probability of the risk to occur and materialize; while, the severity (third column) is the impact of such risk on Novo Nordisk’s profit.

The score is assigned considering the worst-case scenario and a near-term horizon of 5 years, but before that, a deep analysis on the main risks affecting Novo Nordisk, is performed in the next paragraphs. As a result of the analysis, the outcome has been reported in a graph that displays the distribution of the risks, with likelihood on the x-axes, and severity on the y-axis. The dot in the upper left of the line seems to be a threat, but actually that represents the legal and compliance risk, which has a high impact, but it has also a low probability to occur. Moreover, the legal risk is based on legal cases, such as litigations, government investigations, patent disputes, supplier disputes, etc.; given the delicate nature of this risk, it is not possible to

proceed with a quantification of its impact, because of lack of internal information, since the legal risk in Novo Nordisk is handled by a specific Global Legal reporting system, which is strictly confidential. The quantification of the risk, is instead possible for the risk represented by the upper right dot; it is the risk of intellectual property rights loss and it has a significant impact on Novo Nordisk’s profit.

Figure 15-Risk ranking according to likelihood and severity



Source: Author’s estimates

In order to understand the graph just reported, it is necessary to proceed with the analysis of the risks, one by one.

3.1.1 Competition and global market

The competitive risk is the strategic risk associated with the chance that a competitor firm will prevent a company to achieve its goals. More specifically, the competitive risk may affect Novo Nordisk market share, revenues and margins, increasing the probabilities of losses due to competitive pressure. It is important to clarify that the risk in scope refers only to competition arising from new products entering the market, from existing products and new market

strategies. The risk of biosimilar competition is treated separately in paragraph 3.1.2 Biosimilar competition.

Branded products are originally discovered and branded by a company that incurs research and development costs to create the product, meaning that the new drug must be approved by FDA or EMA to be marketed and sold.

Generic products usually enter the market when a branded product is about to expire. A generic drug must have the same active pharmaceutical ingredient as the brand-name product, as well as the same dosage form and dose. Those requirements reduce a lot the costs and time spent when placing a new product on the market, merely because its composition has already been approved by the regulatory agency and, therefore does not require the same approval process.

Talking about the second type of competition, existing products represent a risk for Novo Nordisk, because they may still evolve. An existing drug can be stronger on the market because of three possible reasons:

- New clinical trials
- Contracting strategies
- Marketing strategies

New clinical trials are considered a threat, when a competitor decides to conduct new trials to generate a different outcome in a specific drug.

Any firm in this industry should also be aware of the possibility of a competitor to engage in a new contract (for instance, with a supplier) to gain almost exclusivity into the market; at the same time, marketing strategies are continuously used to increase the attractiveness of a certain product and therefore, the company's market share.

The competitive risk arises by the fact that drugs development takes many years, which in some cases, may be enough to let competitor affirm a good position in the market, moreover the increasingly market place and growing in the number of patients encourages the competitiveness of the industry.

Risk description: Existing and new competitors are pressuring to expand their market share with more competitive products, reducing Novo Nordisk's margins.

Impact and assumptions: It is necessary to understand which and how many are the variables to take into consideration if such risk occurs, therefore the questions to be asked are: Is that easy for a competitor to enter the market? How long does it take for a firm to access the market? Is it easy to acquire the trustiness of patients?

Whatever it is an existing product development, or a new product entering the market, Novo Nordisk might incur high costs anyways. Although it is not easy for competitors to get the trustiness of patients, a significant innovation can easily overcome this problem.

Moreover, the lack of information on the competitors' pipeline, creates unexpected changes in the competitive environment, and causes unexpected losses.

Likelihood: For the reasons explained above, it is likely that competition will arise even more in the next years (25%-50% likelihood) and the impact on Novo Nordisk's profit would be moderate (750-1500m DKK).

Implemented mitigation actions: Novo Nordisk's strategic plan is to keep performing clinical trials on products in the pipeline; in fact, the best strategy is to keep innovating, bringing new products on the market that can offset the impact of competitive market.

Table 5-Competition and global market risk

Risk title	Competition and global market risk
Objective	Sustaining Novo Nordisk's market share at the current levels and focusing on innovation to fight competition
Risk description	Existing and new competitors are pressuring to expand their market share with more competitive products, reducing Novo Nordisk's margins
Root causes	<ul style="list-style-type: none"> • Raising of chronic diseases' number, increased the market place • Generic competitors willing to enter the market • Tendency to sell on niche-markets

Risk consequences short term (0-3 years time horizon)	Profit margin erosion as a consequence of a decrease of revenues.	
Risk consequences long terms (on a 4-10 years time horizon)	Loss of market share and decrease of revenues.	
Mitigation actions currently in place	<ul style="list-style-type: none"> • Focus on customers' benefit when a new product is launched • Monitor of competitors and the possible drugs to be approved • Put products in the pipeline to ensure the continuity of sales 	
Net risk (<u>after</u> taking mitigating actions into account)	What is the impact (in DKK million)? Minor (<750m DKK)	What is the likelihood that the risk will occur? Possible (10%-25%)
Gross risk (<u>before</u> taking mitigating actions into account)	What is the impact (in DKK million)? Moderate (750-1500m DKK)	What is the likelihood that the risk will occur? Likely (25%-50%)
Next risk indicators	<ul style="list-style-type: none"> ▪ Increasing of pharmaceutical start-ups ▪ Social and demographic factors, like increase in chronic diseases and population ▪ Governments' prices regulations and actions 	

3.1.2 Risk of rebates

The competition risk goes hand in hand with the price war that the pharmaceutical industry is facing, in fact because of political pressure it may be that lower prices of products will be accepted in the US, that is also the biggest market for Novo Nordisk.

Increasing pressure from the US Government and from public healthcare insurance programmes (Medicare and Medicaid) to decrease drug prices is raising the probability of decrease in sales prices for Novo Nordisk. It is very important to clarify the role of the so-called <Payers>, which represent insurance organisations (like Medicare and Medicaid in US) which provide the payment of healthcare to people covered by their programs. These organisations basically “receive” and apply the list price suggested by manufactures companies. As explained before, only the insurance companies that acquire drug products from the pharma companies can somehow regulate the price of distributors, but they have no power with manufacturers’ decisions. In fact, a payer gets a sum, that from the manufacture point of view is called <rebate> and that is increasing exponentially in the last years, pushing manufacturers to a decrease in the price applied out of their sales.

The current US President - Donald Trump - met with leaders of the biggest pharmaceutical companies in the world, to push for price decrease either using competition, or creating a “bidding war”. Being US the biggest market for the pharmaceutical industry, it is probably difficult to start a bidding war, but the price pressure is still very high.

Risk description: Government price regulation in US might push drug prices down with a consequent decrease in the sales prices.

Impact and assumptions: Which Novo Nordisk’s product would be affected the most by a decrease in price? How fast this would happen? And how much would be the price decrease? How long it will take before a new regulation is applied? 80%²⁴ of sales come from diabetes and obesity care, and Novo Nordisk has a leading position in the modern insulin market in the US. Lower down drug prices in this market can easily be achieved through political pressure, if this was a free-market.

On top of that, in other markets, prices could also go down if other countries’ governments follow the US model.

If the risk occurs, the risk’s impact is directly on patients: if the company, for the reasons explained above, is not able to launch a product on the market, patients will not be able to benefit from those products.

²⁴ Novo Nordisk Annual Report 2016

Likelihood: For the reasons explained above, it is likely that a price decrease will happen in the US (25%-50% likelihood) and if the price decrease occurs in the biggest diabetes market, then the impact would be moderate (750-1500m DKK).

Implemented mitigation actions: Innovative contracting (negotiation) with payers are very difficult, but Novo Nordisk is trying to put in place this policy, which means that the value of the innovation is paid out because the price of a pharmaceutical product is set based on the actual benefit or improvement that it brings to patients. This situation, together with exclusivity contracts of some products makes difficult for a price policy to be implemented, at least in the short-medium term. Together with that, Novo Nordisk keeps public affair and lobbying activities to all the relevant stakeholders, including negotiation with payers.

Table 6-Rebates risk in the US

Risk title	Rebates risk
Objective	Sustaining insulin prices on the current level in US in order to avoid a decrease in net sales.
Risk description	Government price regulation in US might push drug prices down with a consequent decrease in the sales prices
Root causes	<ul style="list-style-type: none"> • US government prices regulations causes the pressure on lowering insulin prices • The US situation may influence other Countries with high insulin prices • High bargaining power of payers because of decrease in insulin prices level • Generic competitors willing to enter the market
Risk consequences short term (0-3 years time horizon)	Price downsized affects volumes, but they will almost equalise human insulin price levels, causing a sort of value equalisation of the products

Risk consequences long terms <i>(on a 4-10 years time horizon)</i>	In the long-term, a price reduction may considerably decrease revenues because it not only affects modern insulin price, but also human insulin price. On top of that, prices down may encourage competitors to became more aggressive and discourage R&D.	
Mitigation actions currently in place	<ul style="list-style-type: none"> • Focus on customers' benefit when a new product is launched • Public affair and lobbying activities to all the relevant stakeholders, including negotiation with payers (governments, KOLs, etc.) 	
Net risk <i>(after taking mitigating actions into account)</i>	What is the impact (in DKK million)? Minor (<750m DKK)	What is the likelihood that the risk will occur? Possible (10%-25%)
Gross risk <i>(before taking mitigating actions into account)</i>	What is the impact (in DKK million)? Moderate (750-1500m DKK)	What is the likelihood that the risk will occur? Likely (25%-50%)
Next risk indicators	<ul style="list-style-type: none"> ▪ International price comparisons on insulin ▪ National price/value comparisons of human and analogue insulin ▪ Governments' prices regulations and actions 	

3.1.2 Biosimilar competition

Biosimilar products vary from generics because they differ in the biological composition, in fact they are more complex and they require large clinical trials on patients. The threat of biosimilars is to be considered an emerging risk because of the current uncertainty in the regulatory agency approval process, that makes this threat difficult to predict: while it is simpler in Europe or Asia to face competition from biosimilar products, the FDA has not yet made any evidence of approval.

Biosimilar companies are just starting the market penetration and they represent a small portion of the pharmaceutical industry; nevertheless, biosimilar competition is considered one of the emerging warnings for Novo Nordisk, for two reasons:

- It represents an additional way (besides generic drugs) for small pharmaceutical companies to gain market share and penetrate the pharmaceutical market offering products at a lower price;
- Large pharmaceutical companies are already developing and commercialising biosimilar drug products to prevent emerging competition.

An important consideration is the fact that the impact of biosimilar is currently unknown and ambiguous, because of the unclear or inexistent government regulation in many countries.

Risk description: Government facilitation in accessing the market to biosimilar products, increase competition in the pharmaceutical industry, with consequent sales decrease and profit loss.

Impact and assumptions: Which of Novo Nordisk products may be affected by biosimilar competition? What regulations are proposed? Which biosimilars are available? Is it easy for them to gain market share? Many biosimilar products are commercialised, however there are many obstacles for biosimilar companies which are their difficulties in getting the approval of similarities with branded drugs, capacity constraints, necessity to import the active pharmaceutical ingredient from other countries (meaning that it is costly) and finally the fact that they do not have a solid brand to sustain competition from firms established in the industry. Governments' actions are likely to sustain the biosimilar products, especially in less regulated countries (in Asia), but they are currently not clear in developed countries.

Likelihood: For the reasons explained above, it is possible (10-25% likelihood) that biosimilar will penetrate the market, facilitated by regulators with a major impact in around 4-5 years from now. The impact associated with the following risk is moderate, meaning that the profit loss amount is between 750 and 1500 million DKK.

Implemented mitigation actions: Novo Nordisk constantly monitors the competitors' scenario and it is confirming its presence in the Asian countries, limiting biosimilar competition. Moreover, one of the company benefit from capacity and implements clinical trials to ensure

the high quality and safety standards of his products, which is a great competitive advantage over biosimilar firms.

Table 7-Biosimilar competition

Risk title	Biosimilar competition	
Objective	Sustaining insulin market share, limiting access of biosimilar drug products from biosimilar companies.	
Risk description	Governments regulations might encourage the entrance of biosimilar companies on the market, to increase competition in the pharmaceutical industry.	
Root causes	<ul style="list-style-type: none"> • Government of some countries willingness to decrease drug prices • Small pharma companies found a different way to access the market, different from generics 	
Risk consequences short term (0-3 years time horizon)	In the short term, biosimilar is not a big threat, because it currently represents a small portion of the market.	
Risk consequences long terms (on a 4-10 years time horizon)	In the long-term, regulations especially in emerging countries may sustain the biosimilar products, increasing competition in the industry.	
Mitigation actions currently in place	<ul style="list-style-type: none"> • Constantly monitor of competitors' scenario • Established brand in emerging countries 	
Net risk (after taking mitigating actions into account)	What is the impact (in DKK million)? Minor (<750m DKK)	What is the likelihood that the risk will occur? Possible (10%-25%)
Gross risk (before taking mitigating actions into account)	What is the impact (in DKK million)? Moderate (750-1500m DKK)	What is the likelihood that the risk will occur? Possible (10%-25%)
Next risk indicators	<ul style="list-style-type: none"> ▪ Competitors' products development 	

- | | |
|--|---|
| | ▪ Governments' prices regulations and actions |
|--|---|

3.1.3 Loss of intellectual property rights

The risk of losing intellectual property rights is one of the major threats for a pharmaceutical company. The patents' permission is necessary to avoid generics from taking over the market and to recover the research and development costs that the company faces when producing a new drug.

Considering also the fact that returns from R&D investments are visible just in the long term, pharmaceutical products must be protected to ensure a proper financial return.

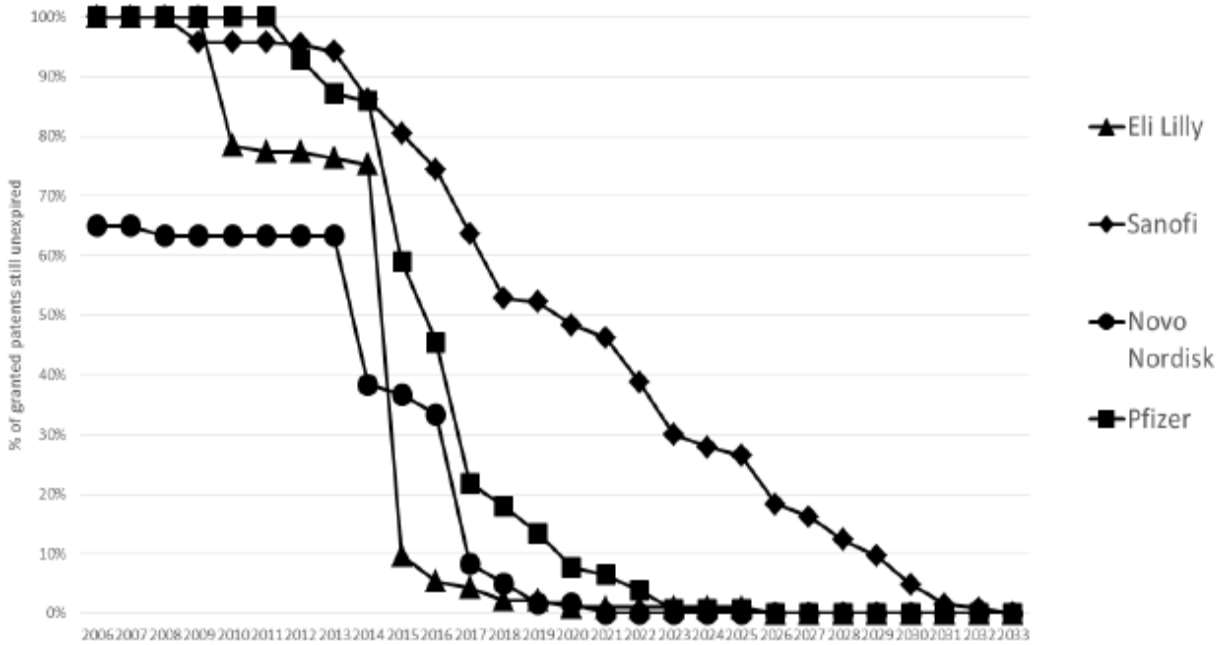
In the short term, the loss of exclusivity of a product causes financial losses and decrease in market share.

Novo Nordisk recently launched new generation insulin and combination products, such as Tresiba®, Xultophy®, Ryzodeg®, Fiasp®, Saxenda® and Victoza®; especially the launch of Tresiba® represents a competitive advantage for the company, because it not only has a safety cardiovascular profile, but it also helps reducing severe hypoglycaemia events, which is an impactful innovation for patients. Victoza® also shows a big reduction in cardiovascular events, stroke, blood glucose levels and body weight. When launching a new patented product, a company have a competitive advantage because it acquires the exclusivity to sell that product on the market.

INPADOC²⁵ International Patent Documentation identified - in April 2016 - the cumulative percent worldwide patent expiries of the four main companies operating in diabetes in US and Canada. The figure below represents the status of all granted patents of those companies, as stated in the Orange Book/HC, which includes drug products approved on the basis of safety and effectiveness, by the Food and Drug Administration.

²⁵ Insulin Patent Profile, April 2016 World Health Organization, study on insulin patents was undertaken as part of Addressing the Challenge and Constraints of Insulin Sources and Supply (ACCISS) Study

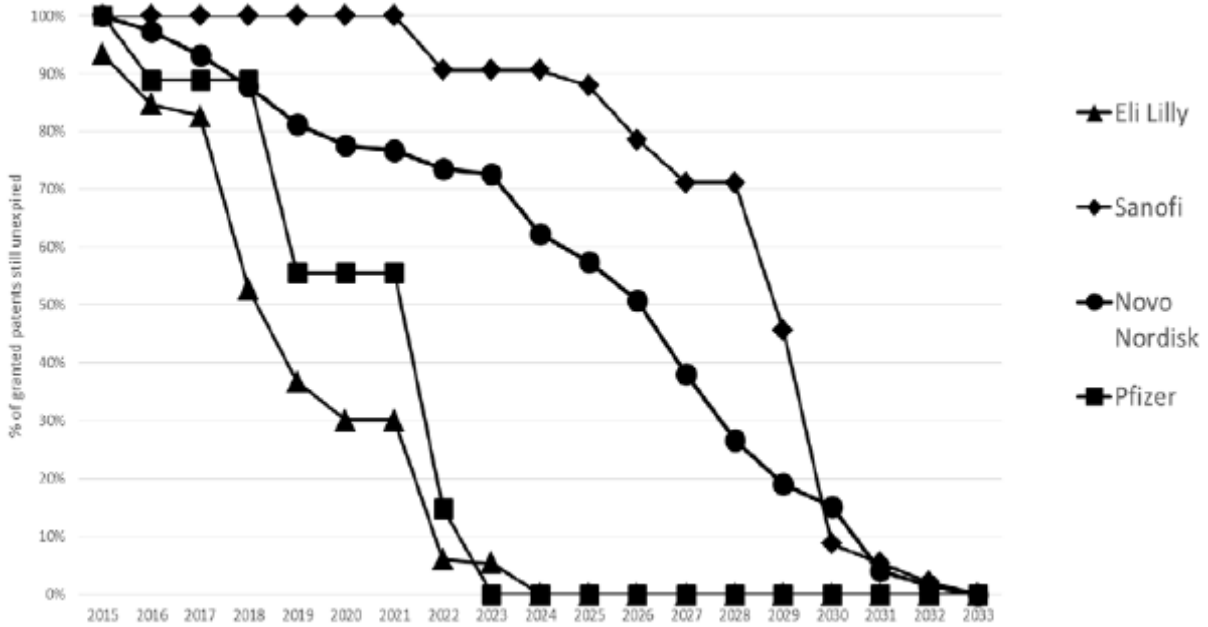
Figure 16-Granted patents expiration dates



Source: ACCISS factsheet insulin patent, World Health Organization

It is visible from the graph that Sanofi has a good advantage compared to the other companies in terms of expected expiration dates of insulin-related patents. However, the graph below shows the cumulative percent worldwide of patent expiries of the four main companies operating in diabetes, of product still in the development stage or not marketed in US and Canada, but instead in European countries.

Figure 17-Patent expiration dates in European countries



Source: ACCISS factsheet insulin patent, World Health Organization

The figure shows that Sanofi and Novo Nordisk seem to have acquired patents almost in the same period, even though the advantage of Sanofi is still visible, also in Europe. Considering the products which are currently in phase of approval and the public information available in terms of expiration dates for Novo Nordisk’s patents and its competitors, it seems that the company will face the expiration of many of its products in the next 2-4 years in US, Europe, Japan and China. Moreover, the patent cliff threat is likely to materialise in the years between 2021 and 2024, even though the products that Novo Nordisk is about to launch, or that are now during the last clinical phases, they will expire in around 15-20 years.

In particular, two of the main products of Novo Nordisk -Victoza® and Saxenda® - face patent expiration in 2022. Historically, Victoza® has been the driver of sales and Saxenda® was launched later on the market has an “equally profitable” product.

Given the former considerations, the patent cliff risk is to be considered a threat for Novo Nordisk, at least in the short-medium period. The company already experienced this phenomenon during years 2015 and 2016, in which most of its patents expired during the financial crisis and this brought the company to a downturn period.

Patents' expiration will occur in the next few years and increases Novo Nordisk vulnerability to competitors entering the market and to existing competitors gaining market share.

Risk description: Loss of exclusivity of Victoza® and Saxenda® causes a decrease in sales and profit margin, with potential entrance of new generic medicines on the market.

Impact and assumptions: What is the time frame to take into consideration? Is it easy for a generic to enter the market if Novo Nordisk loses exclusivity of its products? How long does it take for a competitor firm to enter the market?

Patents' expiration in the next 4 years relates to diabetes drugs. This situation makes Novo Nordisk sensitive to competition and may affect the ability of the company to face competitors, due to the easier entrance of generic drugs into the market. Moreover, patent expirations dates are known and competitors can easily try to expand their presence in countries where Novo Nordisk will lose its products' exclusivity.

A series of product will go off patents, in the next 2-4 years: the company will lose exclusivity of Levemir® for diabetes in US and Europe, as well as the obesity drug product Saxenda® and the diabetes drug Victoza® in Us, Europe, China and Japan. On top of that, expiration of other diabetes products like Tresiba®, Ryzodeg® and Xultophy® will occur in China and subsequently in Us, Europe and Japan.

Generic drug companies are very aggressive and fast in monitoring brand drug companies' performances and pushing their discounted products into the market, as soon as patents reach the expiration date. Existing brand drug companies are instead focused in developing their own innovation and get products exclusivity, continuously monitoring competitors' performances and acquiring intellectual property rights before them, to ensure their presence in the market.

The table below shows some of the main marketed products of Novo Nordisk with the correspondent expiration years in US, Europe, Japan and China. For the sake of clarity, the legend under the table identifies the years in scope using different colours.

Table 8-Novo Nordisk's patents expiration dates

Product type	Product Name	US	EU	JP	CN
Insulin	<i>NovoMix</i> [®]	Exp	Exp	Exp	Exp
Insulin	<i>NovoRapid</i> [®]	Exp	Exp	Exp	Exp
Insulin	<i>NovoNorm</i> [®]	Exp	Exp	Exp	Exp
Insulin	<i>Levemir</i> [®]	2019	2019	2019	Exp
Insulin	<i>Ryzodeg</i> [®]	2029	2028	2024	2024
Insulin	<i>Tresiba</i> [®]	2029	2028	2027	2024
GLP-5	<i>Saxenda</i> [®]	2022	2022	2017	2017
GLP-2	<i>Victoza</i> [®]	2022	2022	2022	2017
Combination	<i>Xultrophy</i> [®]	2029	2028	2024	2024
Biopharmaceuticals	<i>Norditropin</i> [®]	2017	2017	2017	2017
Biopharmaceuticals	<i>NovoSeven</i> [®]	Exp	Exp	Exp	Exp
Biopharmaceuticals	<i>NovoEight</i> [®]	N/A	N/A	N/A	N/A
Biopharmaceuticals	<i>NovoThirteen</i> [®]	2021	Exp	Exp	N/A
Biopharmaceuticals	<i>Vagifem</i> [®] 10 mcg	2022	2021	2021	N/A

Source: Novo Nordisk Investor Presentation 2016

Table 9-Legend: Novo Nordisk's patent expiration dates

Scope	Colour range			
0-4 years	2017	2018	2019	2020
4-8 years	2021	2022	2023	2024
8-12 years	2025	2026	2027	2028
12-14 years	2029	2030	2031	2032
14-18 years	2033	2034	2035	2036

Source: Author's estimates

It is clearly visible that the orange, which includes the years between 2021 and 2024, is prevalent across the key markets in the table, followed by the red colour, which instead represents the years between 2017 and 2020, however the risk assessment's scope includes just the time frame between 2021 and 2024.

Likelihood: For the reasons explained above, it is very likely (>50% likelihood) that this phenomenon will occur, with a major impact between years 2021 and 2024. It is important to mention that, even though the expiration date of patents is a fact, the request of an expansion

period of the patent and the presence of many different patents covering the same product, might alter the current planned expiration dates.

The impact on profit can be also considerable, even though the expiration of patents in the “orange period” may be offset by profits generated by new products recently launched on the market (or about to be launched) and of which the expiring period is represented by the light green area in the table (years from 2029 to 2032). Given this fact, the impact associated with the following risk is major, meaning that the profit loss amount is between 1500 and 7500 million DKK.

Implemented mitigation actions: Given the fact that patent expiration can’t be avoided, it is very difficult for Novo Nordisk to exploit efficient mitigation actions. The company continuously monitor and analyse its competitors and make internal controls that aim to minimise its vulnerability to other players. After taking mitigation actions, Novo Nordisk can alleviate the impact on profit of new generics entering the market or anticipate existing competitors’ move.

Table 10-Loss of intellectual property rights

Risk title	Loss of intellectual property rights
Objective	Defend NN intellectual property rights to ensure sustainable market share and to protect products candidates in the R&D pipeline.
Risk description	Patent cliff : NN patents’ expiration of Victoza® and Saxenda® in 2022 threatens the company’s market share and profit.
Root causes	<ul style="list-style-type: none"> • Patent expiration represents a prerequisite to cover R&D costs and to gain exclusivity of the products • NN is already in a downturn period due to patents expired in the past 3 years • It is predictable that patents will expire during the next few years, encouraging competitors to take over the market • Profit from drug products are visible in the long term • Generic competitors willing to enter the market

Risk consequences short term (0-3 years time horizon)	Loss in sales due to expired drugs and low profit because it will take few years before getting income from new launched products. Moreover, generic competitors will take over the market.	
Risk consequences long terms (on a 4-10 years time horizon)	In the long term, some of the NN patents are likely to expire and this will keep reducing profit margin.	
Mitigation actions currently in place	<ul style="list-style-type: none"> • Internal controls aim to minimise vulnerability • Monitor and analysis of competitors 	
Net risk (after taking mitigating actions into account)	What is the impact (in DKK million)? Moderate (750-1500m DKK)	What is the likelihood that the risk will occur? Likely (25%-50%)
Gross risk (before taking mitigating actions into account)	What is the impact (in DKK million)? Major (1500-7500m DKK)	What is the likelihood that the risk will occur? Very likely (>50%)
Next risk indicators	<ul style="list-style-type: none"> ▪ Generics becoming more aggressive in the US ▪ Competitors' marketed products and expiration dates ▪ Market trends and sales level of new launched products 	

3.1.4 Currency impact

Novo Nordisk's financial operations account for the main financial risk associated with those, and Novo Nordisk foreign exchange rate fluctuations. The financial exposure that Novo Nordisk faces can be divided in three types:

- Transaction exposure
- Translation exposure
- Economic exposure

Transaction exposure refers to the fact that the company is influenced by exchange rate fluctuation because of payment received or due in a different currency than the home country currency and it typically has an impact in the short-medium term.

Translation exposure impacts directly the financial statement of foreign subsidiaries of a company and it generates a financial impact in the medium-long term.

The economic or operating exposure, instead, is the risk of unexpected fluctuations in foreign currencies and it has a significant long-term effect, usually difficult to predict.

Risk description: Exchange rates fluctuations cause financial losses if foreign currencies depreciate against the Danish krona.

Impact and assumptions: Which currencies are expected to oscillate the most? What is the impact on the financial statements? Foreign exchange risk has to be considered in USD, CNY and JPY, while EUR does not represent a significant risk due fixed exchange rate policies between DKK and EUR.

Risk of profit losses may occur if one of the currencies mentioned above loses value (depreciate) compared to the Danish krone currency.

Likelihood: Market fluctuations depend very much on the general economic situation of a Country; instable policy systems causes up and down of stock markets and exchange rates.

Considering USD, CNY and JPY and the currency fluctuation in the short-term, those represent a risk likely to occur (with 25%-50% likelihood) and moderate impact on Novo Nordisk profits (between 750 and 1500 million DKK).

Implemented mitigation actions: 99% of Novo Nordisk income comes from operation outside Denmark; therefore, the company already stipulated hedging contracts of existing assets and liabilities and so of future cash flows, to avoid the impact of currencies oscillations.

Table 11-Currency impact

Risk title	Currency impact
Objective	Avoid and reduce short-term negative impact of exchange rates fluctuations.
Risk description	Financial losses occurs if there are unexpected or unpredicted substantial exchange rates fluctuations.
Root causes	<ul style="list-style-type: none"> Novo Nordisk operates globally

	<ul style="list-style-type: none"> • Global economic environment is continuously changing and those changes are difficult to predict • Depreciation of foreign currencies against Danish krone causes increase in liabilities and costs 	
Risk consequences short term (0-3 years time horizon)	Increase in liabilities and costs, with consequent decrease of profit and profit margins	
Risk consequences long terms (on a 4-10 years time horizon)	Long-term consequences are visible just in case of unexpected operation exposure and they may cause a considerable decrease in profits.	
Mitigation actions currently in place	<ul style="list-style-type: none"> • Hedging contracts of current assets and liabilities • Hedging contracts of expected future cash flows of a maximum of 24 months forward 	
Net risk (after taking mitigating actions into account)	What is the impact (in DKK million)? Minor (<750m DKK)	What is the likelihood that the risk will occur? Possible (10%-25%)
Gross risk (before taking mitigating actions into account)	What is the impact (in DKK million)? Moderate (750-1500m DKK)	What is the likelihood that the risk will occur? Likely (25%-50%)
Next risk indicators	<ul style="list-style-type: none"> ▪ Instable political situation of a Country ▪ Economic agreement between countries ▪ Specific events that may change the market or the political-social environment of a Country 	

3.1.5 Legal and compliance risk

A company faces a legal risk when it fails complying with regulation and legal obligations. For a pharmaceutical company breach of legislation represents one of the major risks because of the complex quality requirements to fulfil when producing a drug; indeed company's policies are aligned with company's stakeholders like healthcare professionals and Novo Nordisk must

ensure the application of those policies to respect laws and authorities. The legal risk can include also the price paid for tax disputes, in fact, loss of tax cases results in unexpected and substantial expenses and it also happen quite often, considering that most of the time generic companies try to open disputes to get the approval of launching a product before the expiration date of a branded one.

Legal requirements are needed to ensure the integrity of the people part of Novo Nordisk and that the company itself respects quality standards.

Of course, failing in complying with regulation, policies and procedures has a substantial impact on financial performances, as well as on reputation; however, the most significant impact may occur on patents health and lives, if the product does not respect quality standards and it has already been launched on the market.

The compliance risk is increased compared to the past, if we consider that Novo Nordisk operates in emerging markets and it must comply with several regulatory standards, from the research phase, to the production process and to the launch of the product. Moreover, regulation is different among countries and regulatory authorities, for instance FDA in US, and EMA in Europe, CFDA in China and so on. On top of that, constant controls and audits (internal or external) are put in place to ensure the continuous respect of safety standards.

Also, Novo Nordisk's Quality Assurance Department scope is to ensure standards' respect of new equipment to be integrated in the production pipeline and from there, that the whole production process follows the Standard Operating Procedures (SOPs).

Risk description: Risk of a production facility or production process to be in non-compliance threatens health and lives of patients and causes financial losses and affects the company's reputation.

Impact and assumptions: What are the people affected by the risk of non-compliance? How does it affect the company? What would be the impact on reputation? Does it affect the company's performances in the long, medium or short term? Patients are affected by the risk of assuming a drug that does not respect quality standards and that, in the worst case, could injure them. Therefore, the risk impact of putting into the market a product that does not respect quality standards has a series of implication that affect the whole supply chain process.

Firstly, if this happens, patients need to be repaid for the injuries received, or simply for the cost of buying the product; then there are costs associated with withdrawing the product from the market (transportation costs), opportunity costs of producing another drug product, cost of destroying batches that does not respect quality standards and all production costs (machinery work, equipment use and salaries). Secondly, there are losses from sustained costs like COGS, administrative costs, distribution and marketing. As one can notice, the consequences of such risk are of a considerable amount; however, Novo Nordisk applies a number of quality assurance procedures to avoid this risk and the consequences of this specific situation would have a short-medium term impact if correctly and proactively handled.

The other component of legal risk is the tax disputes; this is also considered a source of losses because the money transfer to tax authorities due to tax disputes may have an impact on profit due to the high amount of tax and fines that must be paid on top of that. If the consequences for Novo Nordisk are either on financials and reputation, the consequence for patients is that they stop benefiting from a product which is taken off from the market.

Likelihood: Novo Nordisk has a functional quality management system that ensures that such a negative situation will not threat the company and also the facilities and equipment are up-to-date; therefore, the probability of such risk to occur are low, (possible 10%-25% likelihood), but of course the impact on profits would be critical (above 7500 million DKK).

Implemented mitigation actions: Novo Nordisk quality assurance management, a authority inspections, internal and external quality audits aim at ensuring the respect of safety and quality of products, processes and facilities. In fact, issues are usually found before the product is put on the market and the impact in terms of costs is considerably low.

Table 12-Legal and compliance risk

Risk title	Legal and compliance risk
Objective	Avoid and reduce non-conformities to comply with quality and safety policies.
Risk description	Health and lives of patients are at risk when production facilities or production process are in non-compliance; this

	also causes financial losses and bad reputation. Moreover, taxes disputes due to non conformities occur with considerable fees to pay on top of taxes.	
Root causes	<ul style="list-style-type: none"> • Novo Nordisk operates globally • The pharmaceutical industry requires high and complex quality and safety standards 	
Risk consequences short term (0-3 years time horizon)	Increase in liabilities and costs, with consequent decrease of profit and profit margins.	
Risk consequences long terms (on a 4-10 years time horizon)	In the long-term, reputation of the company may be affected, with consequences on sales.	
Mitigation actions currently in place	<ul style="list-style-type: none"> • Quality Assurance Management • Internal and external audits • Continuous monitor and controls form regulatory authorities • The non-compliances are tackled during the production process 	
Net risk (after taking mitigating actions into account)	What is the impact (in DKK million)? Minor (<750m DKK)	What is the likelihood that the risk will occur? Unlikely (0-10%)
Gross risk (before taking mitigating actions into account)	What is the impact (in DKK million)? Critical (>7500 million DKK)	What is the likelihood that the risk will occur? Possible (10%-25%)
Next risk indicators	<ul style="list-style-type: none"> ▪ Unconformities during inspections ▪ Change in regulations ▪ Competitors initiating issuing procedures 	

3.1.6 Compromised operational quality and delay

The legal and compliance risk is very much connected with the risk of compromised operational quality. Compromised operational quality refers to the risk of failures, breakdowns and delay to the standard production process; many variables contribute to the materialisation of this risk and it is possible to classify them in internal and external.

Internal causes of compromised operational quality are: machinery breakdowns, human errors, skills and expertise of human resources, aging of facilities and equipment, delay of upstream material, delay of suppliers, delays in distribution and planning; while external causes refer to all external factors that could influence the standard flow of the production process.

The materialisation of external causes is difficult to predict, as well as the impact that this could have on financial performances, however it is much easier and useful to quantify the impact of internal causes.

Once again, the impact of such risk is on patients who may suffer from delays in the products' delivery, while Novo Nordisk impact is on reputation, but also on financials.

In order to ensure the respect of quality standards, as mentioned before, it is important to apply Standard Operating Procedures (SOPs), which are part of Good Manufacturing Practices (GMPs). The aim of SOPs is to ensure that the work related to the drug product production is performed correctly and as exactly showed in the documentation. Most of the time, SOPs are many into an organization, either because of the complexity of the process or because of the particularity of a product, since they describe the job task that needs to be performed in a specific production step.

Nevertheless, equipment breakdown represents one of the main causes of delay in the manufacturing process, but it can also be predicted more accurately, calculating equipment and facilities aging and depreciation.

Risk description: Failures in the production pipeline causes delays in product delivery and affect the whole production process, causing inconveniences for patients and losses for the company.

Impact and assumptions: Is the failure in production pipeline likely to occur? How does it affect the company? What would be the impact on reputation? Does it affect the company's performances in the long, medium or short term? Supply chain failure may occur, but a failure percentage buffer is already planned in Novo Nordisk, therefore there is a percentage of risk

which it is likely to occur and that could increase the company's costs, from R&D costs, to the cost of used machinery and lost batches to produce the product. On top of that, delays in production cause reputation costs and may affect contract with stakeholders.

Likelihood: It is possible that the risk materialises (10%-25% likelihood), because the production process of drug products is very difficult and it implies a high level of skills and expertise; the impact on profits, if such risk occurs, would be moderate (between 750 and 1500 million DKK).

Implemented mitigation actions: Novo Nordisk complies with regulatory standards and it fulfil annual regulatory inspections that ensure production compliance with Good Manufacturing Practices. Moreover, back-up facilities and special agreement with suppliers are in place to avoid and limit delays in the delivery of drugs to patients.

Table 13-Compromised operational quality and delay risk

Risk title	Compromised operational quality and delay risk
Objective	Avoid and reduce delays in products' production and delivery to comply with quality and safety policies.
Risk description	Failures and delays in production causes inconveniences for patients, but also financial losses and bad reputation for NN.
Root causes	<ul style="list-style-type: none"> • Production of drug products require specific and complex Standard Operating Procedures • Novo Nordisk operates globally • The pharmaceutical industry requires high and complex quality and safety standards
Risk consequences short term (0-3 years time horizon)	Increase in liabilities and costs, with consequent decrease of profit and profit margins.
Risk consequences long terms (on a 4-10 years time horizon)	In the long-term, reputation of the company may be affected, with consequences on sales.

Mitigation actions currently in place	<ul style="list-style-type: none"> • Quality Assurance Management • Internal and external audits • Continuous monitor and controls form regulatory authorities 	
Net risk <i>(after taking mitigating actions into account)</i>	What is the impact (in DKK million)? Minor (<750m DKK)	What is the likelihood that the risk will occur? Unlikely (<10%)
Gross risk <i>(before taking mitigating actions into account)</i>	What is the impact (in DKK million)? Moderate (750-1500 million DKK)	What is the likelihood that the risk will occur? Possible (10%-25%)
Next risk indicators	<ul style="list-style-type: none"> ▪ Unconformities during inspections ▪ Unskilled or unexperienced employees ▪ Aging facilities and equipment 	

3.1.7 Breach of information technology

Internal information technology systems are necessary to protect the firm from external cyber treats. Every day Novo Nordisk collect plenty of information that go through all over the world and those are, of course, very much sensitive and confidential. Confidentiality is a strict rule of the company and it is meant to prevent the spread of data, processes, projects and facts that may change either the financial position of the firm, and the future of patients.

Since Novo Nordisk has a global value chain, the risk of being exposed to such breaches is even higher and well functioning IT systems are a necessary condition to ensure the smooth and safe flow of information across the organisation.

There are basically two types of information that can be spread:

- Private, sensitive and confidential patients' data;
- Sensitive and confidential data about financials, production capacity and stakeholders' contracts.

Consequences coming from this risk are also on two specific sides:

- Patients privacy violation;

- Ability of third parties to predict Novo Nordisk strategy and deteriorate the financial position of the company, with also effects on patients as drug products consumers.

Technology breach is one of the main concerns of the last years, since many cyber organisations are already acting to get access to those highly sensitive information.

Given this situation, Novo Nordisk must protect itself and patients from such risk and it has implemented a very strong and effective IT Security System, that continuously seek for improvements to keep up with “innovative” cyber-crimes.

Prevention systems had also been put in place to ensure safety and prevent intruders to steal confidential data.

Risk description: Breach of information systems causes the spread of high sensitive, private and confidential information that violates patients ‘privacy and put the firm in a weak position compared to the rest of the market.

Impact and assumptions: Is the breach of IT information likely to occur? How does it affect the company? What would be the impact on patients? Does it affect the company’s performances in the long, medium or short term?

The breach of IT information can occur and it is also difficult to predict, basically because it is a cyber-crime act; Despite the numerous negative consequences on patients and firm’s strategy, cyber-crime is not likely to prevent the company’s daily activities and to weak the company’s performances in a frequent way. Indeed, it can be an isolated episode and it may not be effective on his purpose.

Therefore, the consequences of such a risk are very difficult to quantify, since the cyber violation may be effective or not and it is also very complicated to disclosure the number of information that could potentially be stolen or affected by the attack, as well as the number of information that has been stolen, in case this happens.

Likelihood: Generally, the risk is unlikely to arise (<10% likelihood), because of continuous changing and advanced technology systems and tool also to prevent it; the impact on profits, if such risk occurs, would be moderate (between 750 and 1500 million DKK).

Implemented mitigation actions: Novo Nordisk has a robust IT systems and it currently ensures also the prevention of external cyber attacks or threats, thanks to frequent internal audits of IT security.

Table 14-Breach of IT

Risk title	Breach of information technology risk	
Objective	Prevent external intruders to access the firm's systems and ensure the safety of patients' and company's information.	
Risk description	Security breaches causes the privacy violation of patients and the actual steal of sensitive information about the firm's strategy and performances.	
Root causes	<ul style="list-style-type: none"> • Novo Nordisk operates globally • The pharmaceutical industry is an attractive business for cyber-crimes • Novo Nordisk handles many sensitive and confidential information • Novo Nordisk handles privates' data 	
Risk consequences short term (0-3 years time horizon)	Increase in liabilities and costs, with consequent decrease of profit and profit margins. On top of that, patients information are violated and NN should carry the consequences of that.	
Risk consequences long terms (on a 4-10 years time horizon)	In the long-term, reputation of the company may be affected especially if sensitive information are disclosure by ackers, with negative impact on sales.	
Mitigation actions currently in place	<ul style="list-style-type: none"> • Internal audits of IT Security • Robust IT Systems • Continuous IT improvements • Skilled workers 	
Net risk (after taking mitigating actions into account)	What is the impact (in DKK million)? Minor (<750m DKK)	What is the likelihood that the risk will occur? Unlikely (>10%)
Gross risk (before taking mitigating actions into account)	What is the impact (in DKK million)? Moderate (750-1500 million DKK)	What is the likelihood that the risk will occur? Unlikely (>10%)

Next risk indicators	<ul style="list-style-type: none"> ▪ Unconformities during audits ▪ Unskilled or unexperienced employees ▪ Advanced technology systems creations to help hackers
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3.2 Key findings of the qualitative risk assessment

Given the analysis of the main risks provided in the previous paragraphs, the risk of intellectual property rights loss and patent cliff phenomenon result as the major risk to deep dive in.

The IPR risk analysis shows that two main products of diabetes and obesity care segment- Victoza® and Saxenda® - will expire soon, exposing Novo Nordisk to the risk just mentioned. Therefore, the next step of the risk assessment process is to analyse the impact of this risk. For the purpose of this theses, the focus is limited to the impact on sales of Victoza® and Saxenda® in US, that is most profitable market of Novo Nordisk.

CHAPTER 4

4.0 IPR loss risk and patent cliff quantification

This chapter aims at quantifying the risk of expiration of patents of Victoza® and Saxenda®, in terms of the impact on Novo Nordisk's sales and operating profit. To develop the analysis - that has a scope of 6 years (until 2022, the expiration date of the products' patents) – it is first identified the baseline value, as the value of the products' sales when no risk occurs. Secondly, it is calculated the individual risk exposure and its impact on Novo Nordisk's revenues and EBIT.

4.1 Implementation of the baseline company value

The baseline company value is defined as the operating profit of Novo Nordisk, that comes from the evaluation of the long-term growth of sales of two main products, Victoza® and Saxenda®, based on current expectations. Sales amount is one of the relevant metric used for the quantification of the shocks, which are described as changes to the expected value or as any deviation from the baseline.

Sales, or revenues are a component of profit:

$$\textit{Profit} = \textit{Revenues} - \textit{Costs}$$

Revenues are given by *Number of unit sold * Sales price*, however an increase or decrease in revenues is either caused by a change in volume of unit sold, or by a change in price.

Those sub-components of revenues may vary for many reasons, however the variable that mostly influence the sales' value is the social and demographic trend; more specifically, the US' population growth and the spread of diabetes and obesity illnesses.

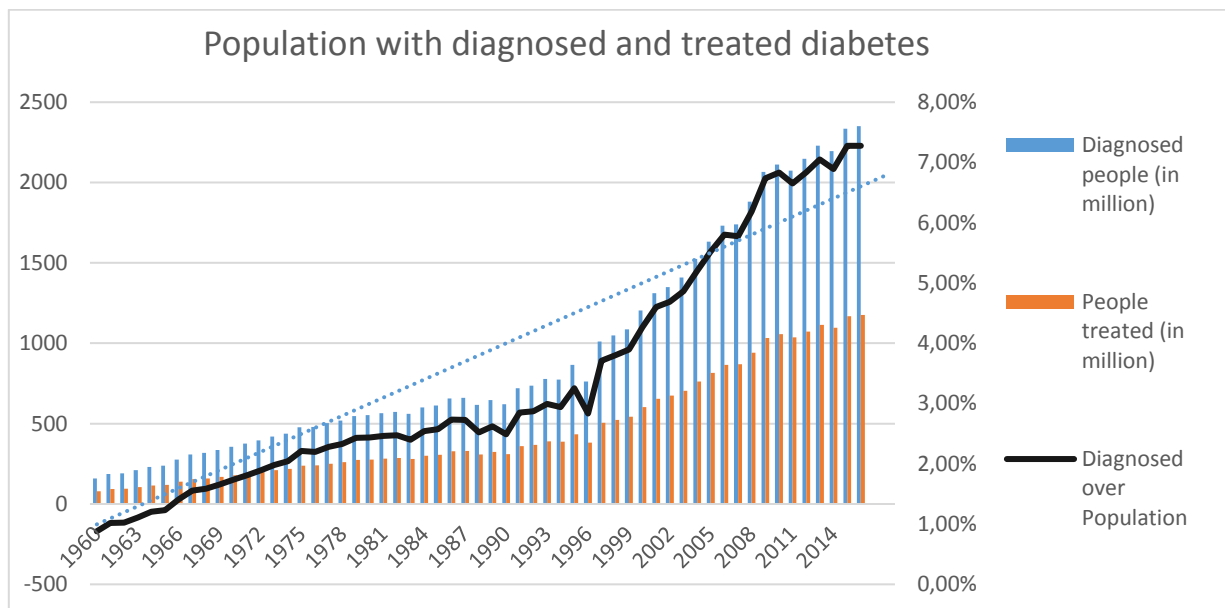
Given the different scope of Victoza® and Saxenda®, their sales growth in the US is analysed separately.

4.1.1 Victoza® long-term growth

Victoza® is specifically used for the treatment of diabetes type 2.

The calculation of Victoza® baseline value incorporates demographic trends and diabetes growth in US. An analysis of the US population has been done, to recognise if there is a trend and a correlation between the growing population and the people affected by diabetes, as well as people treated.

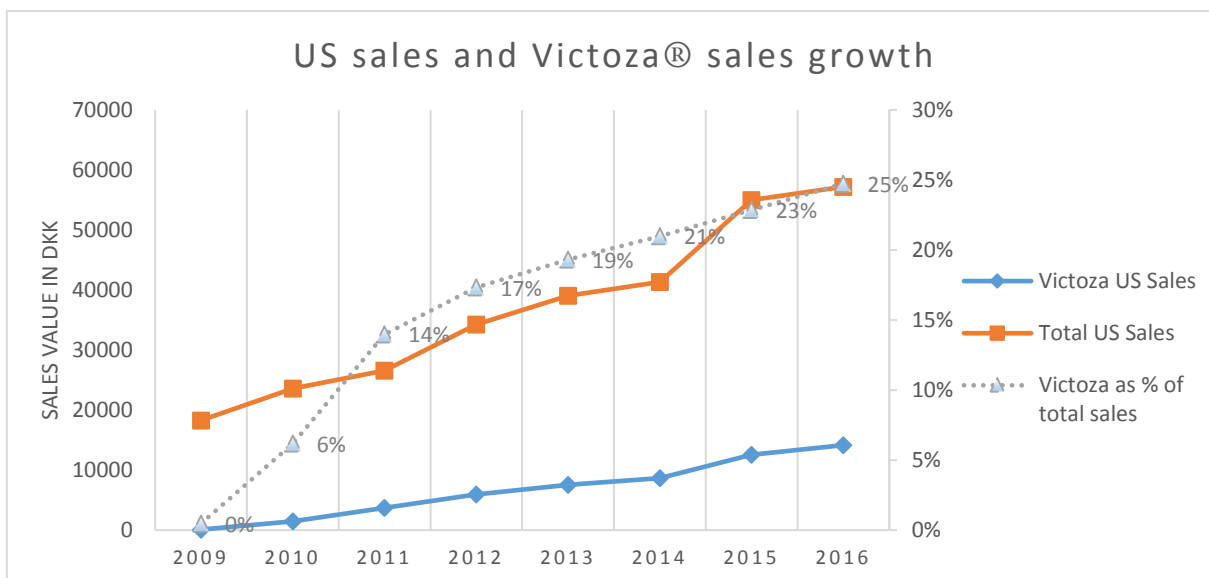
Figure 18-Growth of population affected by diabetes in USA



Source: Author's estimates, Long-term Trends in Diabetes April 2017 CDC's Division of Diabetes Translation. United States Diabetes Surveillance System

The blue line in the graph is the growth of people with diagnosed diabetes and the black line is the percentage of people with diagnosed diabetes over the total US population. The orange line is the number of people treated, while the dotted blue line represents the estimated growth of diagnosed people, beyond year 2016. Diabetes presence in US is expected to growth a lot in the next years, together with the increase in population; people treated, though, are just half of the people diagnosed.

Figure 19-USA total sales and Victoza® sales growth



Source: Author's estimates, Novo Nordisk Annual Reports

From the launch of its fifth patent in 2009, Victoza® sales steadily grew at a CAGR of 107%²⁶ and represented 25% of US sales in 2016. From the analysis results a strong positive correlation index equal to 0.866²⁷ between the number of people with diagnosed diabetes and Novo Nordisk US sales' portion, however it is important to mention that the correlation value obtained suffers from small sample bias.

Two important assumptions have been made when estimating Victoza® sales' growth:

- The product's expected expiration date is year 2022, however, the sales growth is estimated assuming the continuity of sales also after the expiration date;
- Data from Novo Nordisk Annual Reports are presented in Danish Krona, however since the values showed in this paper refer to US sales, calculations are reported in USD; a comparison with the company's financial statements is made applying the current exchange rate²⁸ between the two Countries, even though this causes small errors in calculations.

The sales forecast of a pharmaceutical product is made considering three main variables:

²⁶ Author's own estimates based on Novo Nordisk Annual Reports

²⁷ Author's own estimates

²⁸ The exchange rate applied for the whole analysis is the one of the 7th August 2017, 1 USD=6.31 DKK

- Number of people affected by the illness and people treated;
- Price per unit sold, per person;
- Market share of the company.

In the specific case of Victoza®, the calculation of the people affected by diabetes must include also the number of people affected by diabetes type 2. In high income countries, it is estimated²⁹ that between all people with diabetes, 87% and 94% suffer of diabetes type 2; while 7% to 12% have diabetes type 1 and between 1% and 3%, other types of diabetes. In the US, the percentage of people with diabetes type 2 is 90%³⁰.

The data available from CDC³¹ includes the current number of people diagnosed and the expected number in 2040, which is 351 million people³²; given these data, the number of people diagnosed between years 2017-2040 has been calculated with a simple linear interpolation. The percentage of people treated is calculated applying the “Rule of Halves”, that has evidence of existence in the US and on top of that, it is known that 90% of those people have diabetes type 2. The price per unit of product is calculated using the National Drug Acquisition Cost³³, in USD; pricing is made per milligrams: Victoza® is sold in quantity of 18mg per 3ml pen, in a pack including three pens for the injection. Its dosage is generally 0.6mg per day the first week of treatment, then 1.2mg per day the second week and from the third week the dosage per day is 1.8mg.

For the sake of simplicity, in this model the assumption is that the dosage used by patients is directly the one at the third week of treatment, meaning that a pack of Victoza® lasts 10 days. In year 2017³⁴, the price per unit (ml) of Victoza® is \$86.10857, therefore the price sustained by a single patient per year in 2017 is \$9429.

²⁹ International Diabetes Foundation, Atlas Seventh Edition 2015

³⁰ American Diabetes Association, Statistics about Diabetes

³¹ Center of Disease Control and Prevention

³² Long-term Trends in Diabetes April 2017 CDC’s Division of Diabetes Translation. United States Diabetes Surveillance System

³³ Medicaid USA Drug Prices

³⁴ Medicaid USA Drug Prices, price at 19th July 2017

Novo Nordisk's market share in US in the baseline scenario is fixed at 37%³⁵; the company's market share in US grew a lot in the past years, but the increase in competition and the political scenario stabilised the percentage at that level, in the last five years. The market share used for the analysis is not only the diabetes care value market share in the US, but also the US GLP-1 products market share and Victoza® market share, which are fixed respectively at 12% and 54%³⁶, the assumption is that these values will be the same as year 2016. Finally, the increase in the product's price is estimated considering an inflation rate of 2%³⁷, however the increase in price is very much dependent on Novo Nordisk's policies -given the freedom in price allocation- therefore, in this thesis the assumption is that the company decides to not increase the price for any other reason but the inflation. The market share and inflation varies according to the given scenarios.

The tables below show Victoza®'s price estimations and its sales value, which grows at around 4% per year after 2017, reflecting two main observations: Victoza® is still a leading product in US, keeping a quite high growth rate, however it was launched in 2009, meaning that the boost of sales manifested already in the first 4-5 years of marketing.

Table 15-Victoza® price per unit in USD

Years	2016	2017	2018	2019	2020	2021	2022
Victoza® Price	240	258	263	269	274	280	285

Table 16-Victoza® baseline scenario assumptions, sales in Million USD

Years	2016	2017	2018	2019	2020	2021	2022
Victoza® Sales	2.224	2.441	2.540	2.642	2.747	2.855	2.966
Sales growth		9,78%	4,05%	4,01%	3,97%	3,94%	3,90%

4.1.2 Saxenda® long-term growth

Saxenda® is a product used for the treatment of obesity in adults and it belongs to the product class of Anti-Obesity Medications, used to control and reduce the feeling of hunger.

³⁵ Novo Nordisk Q4 Results 2017

³⁶ Novo Nordisk Q4 Strategic Results 2016

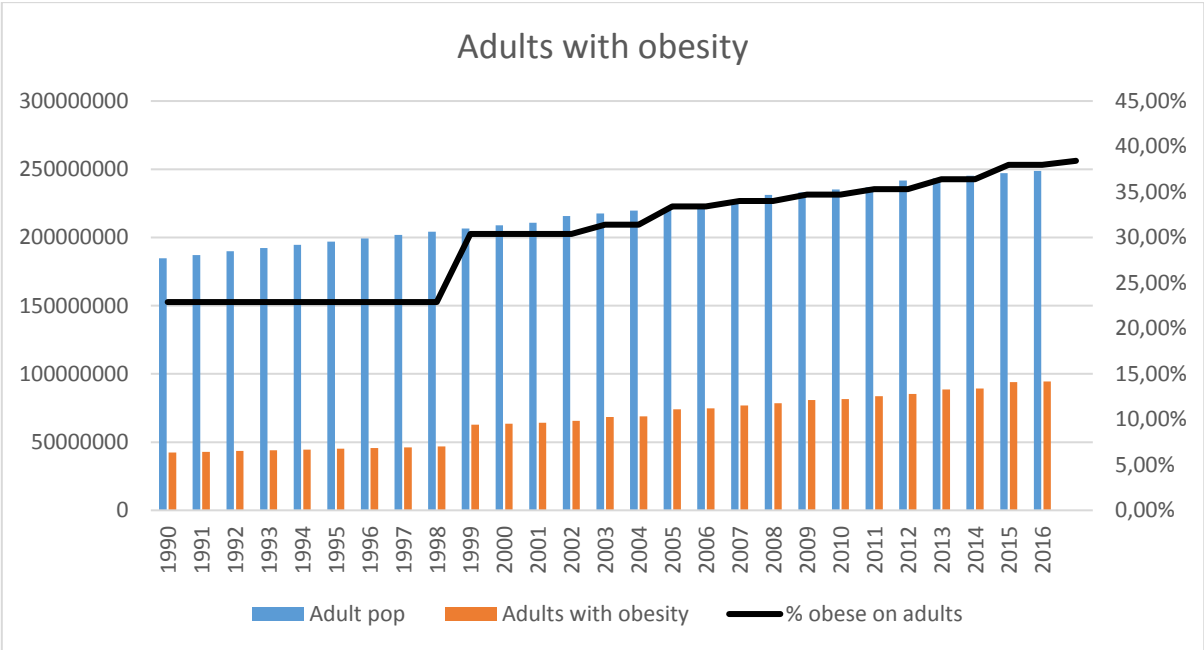
³⁷ Bureau of Labor Statistics, Data and Statistics, CPI index

It is important to mention that Saxenda® does not represent big portion of Novo Nordisk sales, however it is interesting to analyse the product’s sales growth because Saxenda® represents the first step of the company toward the obesity segment and because AOM market value grew very quickly in the past years, also thanks to the recent launches from competitors; indeed, AOM market is expected to grow more in the next years, with the increase of competition.

Calculation of the baseline value of Saxenda®’s sales starts with the identification of people affected by obesity (defined as BMI>30) among US adult population.

Adult population, as well as data about obesity among adult population are obtained from CDC; people with diagnosed obesity that receive a treatment are just 4% of those, while people treated with AOM are around 1%³⁸. Those percentages are assumed to be fixed overtime.

Figure 20-US adult population with obesity



Source: Author’s estimates, CDC, obesity in US

Once known the population in scope and its growth over time (see graph above), the next step is the calculation of the product’s price. The price per unit of product is calculated using the

³⁸ Novo Nordisk Q4 Financial Results

National Drug Acquisition Cost³⁹, in USD. Like Victoza®, pricing is made per milligrams: Saxenda® is sold in quantity of 18mg per 3ml pen. Its dosage goes from 0.6mg per day the first week until 2.4mg the fourth week of treatment; after that the dosage per day is 3mg.

The assumption is that the dosage used by patients is directly 3mg of treatment, meaning that a pack of Saxenda® lasts 6 days. In year 2017⁴⁰, the price per unit (ml) of Saxenda® is \$73.68222, therefore the price sustained by a single patient per year in 2017 is \$13653.

Given the set of data analysed, the market share needed for the calculation of expected sales of the product, is the market share of Saxenda®, among AOM treatments; that is 56%⁴¹ and it is fixed in the baseline scenario. Finally, the increase in product prices is expected to keep up with inflation. Saxenda® has been on the market just from 2015, therefore the sales growth between 2015 and 2016 is very high: 202%. From the analysis results a strong decrease in sales growth from 2017, reflecting the fact that Saxenda® covers a small segment of the obesity market and also the fact that the product is considered less attractive because of the injection needed; in fact, competitors sell AOM products in tablet form. The tables below show the expected prices and sales of Saxenda®.

Table 17-Saxenda® price per unit in USD

Years	2016	2017	2018	2019	2020	2021	2022
Saxenda® Price	224	221	225	230	235	239	244

Table 18-Saxenda® baseline scenario assumptions, sales in Million USD

Years	2016	2017	2018	2019	2020	2021	2022
Saxenda® Sales	289	295	307	320	333	347	361
Sales growth		1,91%	4,17%	4,16%	4,14%	4,13%	4,12%

³⁹ Medicaid USA Drug Prices

⁴⁰ Medicaid USA Drug Prices, price at 19th July 2017

⁴¹ Novo Nordisk Annual Report 2016

4.2 Risk impact

For the calculation of the risk there are two main variables to take into account:

- The strategy that pharmaceutical companies use to prevent the impact of the risk;
- The fact that the patent expiration of a product shows its effect in sales decrease, usually starting from one year before the expiration date and releases its effect until two years after the expiration date.

For the identification of the company's strategy, an analysis of competitors is made considering the main patent loss that they experienced in the past and the strategy that they used to prevent the loss in sales.

Novo Nordisk has two main products in its pipeline, which are supposed to offset the patent loss risk of the products in scope. The potential strategies used to face the patent loss risk have been already mentioned in the first Chapter of this thesis; the strategy that Novo Nordisk is using to contrast the patent loss risk is defined as second generation strategy, because the drugs in the pipeline contain a fairly different active ingredient which makes the drug work longer and faster than the products already on the market. A second generation strategy (which can be seen as part of the prevention strategy category) aims at creating important and meaningful improvements on a product, selling to the same customers' segment. For these reasons, timing is an important variable to avoid the cannibalisation effect.

The competitors in scope are four, each of them experienced in different years the patent loss of some products which had a strong impact on their income statements; therefore, once identified the companies that applied the second generation strategy, data on their products sales are taken from their financial statements.

For the quantification of the risk, Pfizer is also used as term of comparison, either because it is the biggest pharmaceutical company worldwide and because the company experienced in 2014 a large downturn period, in which six of its products expired, causing sales and profit losses. The average sales loss of the companies using the same strategy and the average sales loss of Pfizer are compared to verify the effectiveness of the estimated loss on Novo Nordisk.

The companies used for the quantification of the risk are: Wyeth (now acquired by Pfizer), Eli Lilly, Astra Zeneca and Schering-Plough (now acquired by Merck & Co.).

Every company introduced a substitute product (or two substitutes) for the same customers' segment between two years before the first product's patent expired and three years after its expiration; the tables below show the revenues (worldwide) coming from the principal product and its substitute. The expiration date of the principal product is highlighted in blue; values are in USD.

Table 19-Wyeth sales and second generation strategy

Wyeth	Year	2007	2008	2009	2010	2011
Effexor XR	1 st Product (exp 2010)	2.464	2.658	2.386	1.431	391
Pristiq	Substitute		54	267	412	523
	Tot sales	2.464	2.711	2.652	1.843	914
	Tot sales growth		10%	-2%	-31%	-50%
	Sales growth Effexor XR		8%	-10%	-40%	-73%
	Sales growth Pristiq			398%	54%	27%

Wyeth was acquired by Pfizer in 2010, consequently, data on the new products introduced are shown in Pfizer annual reports after that year; the company introduced Pristiq two years before the expiration of Effexor XR; the strategy used caused a sales loss of -31% for the combined products in 2010, however it is not correct to say that the strategy did not work, because a decline in total sales after expiration cannot be avoided. Indeed, in 2010 total sales represent 75% of Effexor XR's sales prior to the introduction of the new products, therefore it is reasonable to say that Wyeth effectively implemented its strategy.

Table 20-Eli Lilly sales and second generation strategy

Eli Lilly	Year	2000	2001	2002	2003	2004	2005
Prozac	1 st Product (exp 2001)	2.610	1.990	734	645	559	
Symbyax	Substitute 1					70	53,9
Cymbalta	Substitute 2					93	636
	Tot sales	2.610	1.990	734	645	722	690
	Tot sales growth		-24%	-63%	-12%	12%	-4%
	Sales growth Prozac		-24%	-63%	-12%	-13%	-100%
	Sales growth Symbyax						-23%
	Sales growth Cymbalta						586%

Eli Lilly is famous for its Prozac, which made the company boost its sales when it was introduced; the expiration date of Prozac was 2001, however the introduction of two substitutes was too late to offset the loss of sales and therefore the second generation strategy has to be considered ineffective.

Table 21-AstraZeneca sales and second generation strategy

AstraZeneca	Year	2000	2001	2002
Prilosec	1 st Product (exp 2001)	6.260	5.578	4.623
Nexium	Substitute	17	568	1.978
	Tot sales	6.277	6.146	6.601
	Tot sales growth		-2%	7%
	Sales growth Prilosec		-11%	-17%
	Sales growth Nexium			248%

AstraZeneca, instead, introduced Nexium one year before the expiration of Prilosec's patent; in this case, the sale's decrease was only -2% in 2001 and from the year after, the combined sales of the two products increased up to 7%. Moreover, the combined value of sales at the expiration date is almost equal to Prilosec's sales prior its expiration date, showing the effectiveness of the strategy.

Table 22-Schering-Plough sales, second generation and OTC strategies

Schering-Plough	Year	2001	2002	2003	2004
Claritin	1 st Product (exp 2002)	3.158	1.800	370	321
Clarinex	Substitute 1		598	694	692
Claritin OTC	Substitute 2		105	415	419
	Tot sales	3.158	2.503	1.479	1.432
	Tot sales growth		-21%	-41%	-3%
	Sales growth Claritin		-43%	-79%	-13%
	Sales growth Clarinex			16%	0%
	Sales growth Claritin OTC			295%	1%

The last company to analyse used two different strategies to mitigate the IPR loss; however it is interesting to see how only with the second generation strategy - with the introduction of Clarinex - the company already achieved a good result in sales in 2002; indeed, sales of Clarinex and Claritin combined (without considering Claritin OTC), were already 76% of the individual sales of Claritin one year before its patent's expiration.

Table 23-Pfizer sales value and growth rate of six products after patent expiries

Pfizer Medicines	2013	2014	2015	Sales growth 2013-2014	Sales growth 2014-2015
Detrol	428	87	35	-80%	-60%
Viagra	310	120	76	-61%	-37%
Rapamune	253	254	129	0%	-49%
Inspra	150	160	74	7%	-54%
Lyrica	1.458	1.634	1.048	12%	-36%
Celebrex	2.084	1.872	189	-10%	-90%

Finally, also Pfizer's income statement is analysed considering its products' sales at their expiration date and one year after. The average sales drop of these product is -22% at the expiration date and -54% afterwards. The percentage is actually close to the average sales drop calculated among the other four competitors that used the same strategy as Novo Nordisk, therefore it is considered realistic to use those percentages as a proxy for the risk quantification. From the competitors' analysis, it is possible to take out two key findings:

- The average sales loss at the patent’s expiration year of the first product introduced is -29.42%; while its loss one year after the expiration date is -58.09%. After that, the sales loss is assumed to be -100%;
- Since a decline in sales is inevitable, it is reasonable to state that the second generation strategy is effective if the combined sales level after the expiration date of the first product is maintained at least close to the sales of the product prior patent’s expiration and before the introduction of its substitute⁴².

The next step is attributing the impact of the risk on the products’ sales in the baseline-case scenario.

4.2.1 Assessing the gross impact of the risk on Victoza®

Firstly, the percentage of sales loss just calculated using the competitors’ analysis are applied to the projected sales of Victoza® during years 2022 – patent’s expiration date – and years 2023 and 2024⁴³.

Table 24-Victoza® sales value after patent loss

Victoza®	0	1	2	3	4	5	6	7	8	9
Years	2016	2017	2018	2019	2020	2021	2022	2023	2024	2025
Baseline sales	2.22 4	2.44 1	2.54 0	2.64 2	2.74 7	2.85 5	2.966	3.081	3.199	3.32 0
Loss percentage	0,00	0,00	0,00	0,00	0,00	0,00	- 29,4%	- 58,1%	- 100,0%	0,00
Sales loss		0	0	0	0	0	-840	1.171	-844	0
Sales value after patent exp effect	2.22 4	2.44 1	2.54 0	2.64 2	2.74 7	2.85 5	2.015	844	0	0

⁴² Approach developed by Henriette, A.C. van Looveren in her Master Thesis, Pharmaceutical companies and their patent expiries, what do pharmaceuticals do to maintain their sales value?

⁴³ The period is extended beyond 2022 to show the effect of sales drop after the expiration date

Applying the percentage estimated, in year 2022 there is a drop of sales from \$2966 to \$2015; in 2023, sales drop even more until \$844, to become zero in year 2024. The new projected sales after the patent's expiration effects are very much different from the projected sales if the risk did not materialised.

4.2.2 Assessing the gross impact of the risk on Saxenda®

The same assessment is done for Saxenda®. The product shows a sales drop in 2022, from \$361 to \$245; in year 2023, the drop is from \$376 to \$ 103, until zero in 2024⁴⁴.

Table 25-Saxenda® sales value after patent loss

Saxenda®	0	1	2	3	4	5	6	7	8	9
Years	2016	2017	2018	2019	2020	2021	2022	2023	2024	2025
Baseline sales	289	295	307	320	333	347	361	376	391	407
Loss percentage	0,00	0,00	0,00	0,00	0,00	0,00	-29,4%	-58,1%	-100,0%	0,00
Sales loss		0	0	0	0	0	-102	-142	-103	0
Sales value after patent exp effect	289	295	307	320	333	347	245	103	0	0

It is important to recall that Saxenda® does not represent a big portion of Novo Nordisk sales, nevertheless, it represents the entrance of the company to a new market, therefore there is no other AOM product produced from Novo Nordisk to cure obesity. Its sales loss -due to the expiration of the patent protecting the active pharmaceutical ingredient- can still have a large impact on the company's sales in US, because of two reasons: US is the biggest market in terms of obesity and, more important, the first product launched in a new segment is significant to establish a strong position as leader in the obesity market.

4.2.3 Combined sales value before mitigation actions

Once calculated the sales value after the patent expiries of Victoza® and Saxenda®, it is calculated the combined net sales value. The cost of goods sold is fixed at 15%, the number

⁴⁴ The period is extended beyond 2022 to show the effect of sales drop after the expiration date

results from an historical analysis of Novo Nordisk's income statements; the analysis provides a fixed COGS percentage on sales, which is also expected to be the same in the next years⁴⁵. Applying this percentage on sales, it is established the net sales value of the two products combined. The row "Net sales" represents the new sales value with attributed shocks. In order to guarantee an estimation of the value added from sales, the net sales value is further broken down to get the EBIT. EBIT represents the operating profit of a company; it ignores tax and interest expenses; however, it shows the ability of a company to gain earnings from its operations. To get the EBIT, from the net sales value are subtracted R&D costs and SG&A costs. In a pharmaceutical company's financials, one would expect that R&D represents the main portion of operating expenses, since it is basically the engine of sales; but looking at Novo Nordisk's financial statements, selling, general and administrative expenses absorb the main part of the company's sales. It is important to recall the main components of SG&A, to get an understanding of why is this the case: SG&A include items that typically represent a fixed cost for a company, such as overhead, salaries and benefits, building rents, insurance but also equipment depreciation and amortisation. Given the fact that Novo Nordisk's fixed expenses mainly relate to facilities and equipment, it is clear that SG&A costs represent a large portion of expenses.

Given the assumptions made in the previous chapters and recalling that the pharmaceutical industry is facing an increase in R&D and SG&A costs, it is reasonable to think that those will increase overtime. To calculate the rise in value, it is used a simple extrapolation, using the R&D percentage of sales in the past 6 years, the average percentage in the past 6 years is 14%⁴⁶, however the extrapolation reflects the increase in costs of the past, over the next years. The same calculation is made for SG&A costs, which are also calculated as percentage of sales, using values from the past 6 years and the linear interpolation to estimate the same percentage until year 2022. The average SG&A as percentage of sales, in the past 6 years is 29%⁴⁷, however, also in this case, it is visible an ascend trend. Using Net sales as a valuation metric, the risk is

⁴⁵ COGS is expected to be fixed overtime according to the pasts Novo Nordisk's annual reports

⁴⁶ Novo Nordisk Annual Reports

⁴⁷ Novo Nordisk Annual Reports

to overestimate the value of sales with the patent cliff occurrence; indeed, the EBIT reflects the earnings ability of the company, after sustaining the costs.

Table 26-Operating profit before mitigation actions

Operating profit EBIT	0	1	2	3	4	5	6
Years	2016	2017	2018	2019	2020	2021	2022
Total sales	2.513	2.736	2.847	2.962	3.080	3.202	2.260
<i>Total sales growth</i>		8,88%	4,07%	4,03%	3,99%	3,96%	-29,42%
<i>COGS as % of sales</i>	15,00%	15,00%	15,00%	15,00%	15,00%	15,00%	15,00%
COGS	377	410	427	444	462	480	339
NET SALES	2.136	2.325	2.420	2.517	2.618	2.721	1.921
<i>R&D as % of sales</i>	13,03%	12,61%	15,50%	14,04%	13,97%	14,82%	15,34%
<i>SG&A as % of sales</i>	28,90%	29,81%	30,17%	32,17%	31,86%	33,07%	34,70%
R&D costs	278	293	375	353	366	403	295
SG&A costs	617	693	730	810	834	900	667
Operating profit EBIT	1.240	1.339	1.315	1.354	1.418	1.418	960
EBIT Ratio	49,37%	48,95%	46,18%	45,72%	46,05%	44,30%	42,47%

The table above shows, in year 2022, operating profit of \$960. The main costs to subtract to get the operating profit is given by SG&A costs, which in year 2022 are expected to account for 34,70% of sales, while R&D costs are expected to take 15,34% of the sales portion. Finally, the EBIT Ratio - which is the operating profit as percentage of Gross sales – is 42,47%.

4.3 Risk scenarios

Once assessed the gross impact of the risk on the baseline value, the different assumptions on the *Pessimistic* and *Optimistic* scenarios are shown.

The variables used for the different scenarios are the ones used for the calculation of the sales growth of the two products, as well as for the calculation of the main costs of the company: inflation, market shares, R&D costs and SG&A costs. More specifically, the common assumptions for both products are the following:

- The inflation rate is applied to both products prices (recall that the price variation based on company's opinion/projection is not taken into account in this valuation); the inflation rate in the baseline case scenario is 2.0%; while in the pessimistic and optimistic cases,

inflation rate are respectively the worst (1.1%) and the best cases (2.4%) experienced in the last ten years in US⁴⁸ (between year 2007 and 2017);

- R&D costs are expected to increase over the next years; as stated in the previous paragraphs, the rise in value is calculated with a linear extrapolation. The assumption for the baseline value and for the pessimistic case are the same, while for the optimistic scenario, the R&D costs as percentage of sales are assumed to be stable overtime at the current level of 13,03% (year 2016 is taken as a proxy);
- The same assumptions and calculation are made for SG&A costs, which percentage in the baseline and optimistic scenario are the same – calculated with linear extrapolation – but for the optimistic scenario, the percentage over sales is 29,90%.

Victoza® deserves some unique assumptions, given its medical structure; since Victoza® is part of a class of products (GLP-1), the market shares used are three: US market share, GLP-1 class products market share and Victoza® market share among its class products. A deep dive into these three variables is made to better explain the identification of the percentages assigned to each scenario:

- US market share is 37%⁴⁹ either in the baseline-case and in the optimistic case because it is not likely that the percentage will go up, due to the intensification of competition⁵⁰; in the pessimistic case, instead, for the same reasons it is reasonable to think that US market share can decrease up to 30% from year 2018, in fact, even though Novo Nordisk is leader in the diabetes sector in US, the strong competitive environment challenges the company's position.
- US GLP-1 market share is 12%⁵¹ in the baseline case scenario and also in the pessimistic case because this segment of products is in strong

⁴⁸ National Bureau of Labor Statistics, CPI Index

⁴⁹ Novo Nordisk Q4 Results 2017 and Novo Nordisk Annual Report 2016

⁵⁰ In Novo Nordisk Annual Report 2016 it is also stated that the increase in competition will not encourage the increase in market share in the next years

⁵¹ Novo Nordisk Q4 Results 2017 and Novo Nordisk Annual Report 2016

expansion due to the clinical tested effectiveness of the GLP-1 receptor agonists; indeed, in the optimistic case, US GLP-1 market share can go up to 15% from year 2018.

- Finally, Victoza® market share among GLP-1 class products is set at 54%⁵² either in the baseline case and in the optimistic case, in fact, Victoza® market share decreased compared to 2015, and even more if compared to 2014 (when it was respectively 60% and 66%⁵³), that is because the competitive product Trulicity® was introduced by Ely Lilly and took most of the GLP-1 market. Consequently, in the pessimistic case the product's market share can decrease until 50% starting from year 2017.

The analysis of Saxenda® includes just one variable, which is Saxenda® market share, because data on population already incorporates Novo Nordisk customers' portion and number of people using AOM medications. Hence, in the baseline and pessimistic case the product's market share is 56%⁵⁴ and it is reasonable to think that it cannot go down because of non-existent equivalent injectable AOM (injectable are also considered more effective on weight loss); in the optimistic case, instead the market share can go up to 60% from year 2018 because of the spreading of AOM treatment use.

Values for Victoza® and Saxenda®, with the *Pessimistic* and *Optimistic* scenarios are shown in the tables below: the operating profit in the *Pessimistic* case is \$720, with an EBIT Ratio of 42,47%; while in the *Optimistic* case it is \$1.395, with an EBIT Ratio of 49,37%.

⁵² Novo Nordisk Investor presentation 2017 and Novo Nordisk Investor Presentation 2016

⁵³ Novo Nordisk Annual Reports

⁵⁴ Novo Nordisk Annual Report 2016 and Novo Nordisk Q4 Results 2017

Table 27-Sales valuation: Pessimistic scenario

Years	2016	2017	2018	2019	2020	2021	2022
Victoza sales valuation							
<i>Inflation rate</i>	2,00%	1,10%	1,10%	1,10%	1,10%	1,10%	1,10%
Price paid per unit	240	258	261	264	267	270	273
Price paid per year	8765	9429	9533	9637	9743	9851	9959
People treated	105805 49	107978 18	110150 86	112323 55	114496 24	116668 93	118841 62
<i>US Market share</i>	37,00%	37,00%	30,00%	30,00%	30,00%	30,00%	30,00%
NN patients	391480 3	399519 3	330452 6	336970 7	343488 7	350006 8	356524 8
<i>US GLP-1 Market share</i>	12,00%	12,00%	12,00%	12,00%	12,00%	12,00%	12,00%
<i>Victoza Market share</i>	54,00%	50,00%	50,00%	50,00%	50,00%	50,00%	50,00%
Expense per patient	34314	37670	31501	32475	33468	34478	35506
Sales	2224	2260	1890	1949	2008	2069	2130
Sales loss		0	0	0	0	0	-609
Sales value after patent exp effect	2224	2260	1890	1949	2008	2069	1460
<i>Total sales growth</i>		1,65%	- 16,38%	3,09%	3,06%	3,02%	- 29,42%
Saxenda sales valuation							
<i>Inflation rate</i>	2,00%	1,10%	1,10%	1,10%	1,10%	1,10%	1,10%
Price paid per unit	224	221	223	226	228	231	233
Price paid per year	13.653	13.447	13.595	13.744	13.896	14.049	14.203
People treated	37.819	39.130	39.962	40.808	41.666	42.537	43.421
<i>Saxenda Market share</i>	56,00%	56,00%	56,00%	56,00%	56,00%	56,00%	56,00%
NN patients	21.179	21.913	22.379	22.852	23.333	23.821	24.316
Sales	289	295	304	314	324	335	345
Sales loss		-	-	-	-	-	- 98
Sales value after patent exp effect	289	295	304	314	324	335	236
<i>Total sales growth</i>		1,91%	3,25%	3,24%	3,23%	3,21%	- 29,42%
Combined sales							
Total sales	2.513	2.555	2.194	2.263	2.332	2.403	1.696
<i>Total sales growth</i>		1,68%	- 14,11%	3,11%	3,08%	3,05%	- 29,42%
<i>COGS as % of sales</i>	15,00%	15,00%	15,00%	15,00%	15,00%	15,00%	15,00%
COGS	377	383	329	339	350	360	254
NET SALES	2.136	2.172	1.865	1.923	1.982	2.043	1.442

<i>R&D as % of sales</i>	13,03%	12,61%	15,50%	14,04%	13,97%	14,82%	15,34%
<i>SG&A as % of sales</i>	28,90%	29,81%	30,17%	32,17%	31,86%	33,07%	34,70%
R&D costs	278	274	289	270	277	303	221
SG&A costs	617	647	563	619	632	676	500
Operating profit EBIT	1.240	1.251	1.013	1.034	1.074	1.065	720

Table 28-Sales valuation: Optimistic scenario

Years	2016	2017	2018	2019	2020	2021	2022
Victoza sales valuation							
<i>Inflation rate</i>	2,00%	2,40%	2,40%	2,40%	2,40%	2,40%	2,40%
Price paid per unit	240	258	265	271	277	284	291
Price paid per year	8765	9429	9655	9887	10124	10367	10616
People treated	105805 49	107978 18	110150 86	112323 55	114496 24	116668 93	118841 62
<i>US Market share</i>	37,00%	37,00%	37,00%	37,00%	37,00%	37,00%	37,00%
NN patients	391480 3	399519 3	407558 2	415597 1	423636 1	431675 0	439714 0
<i>US GLP-1 Market share</i>	12,00%	12,00%	12,00%	15,00%	15,00%	15,00%	15,00%
<i>Victoza Market share</i>	54,00%	54,00%	54,00%	54,00%	54,00%	54,00%	54,00%
Expense per patient	34314	37670	39350	41090	42890	44752	46680
Sales	2224	2441	2550	3328	3474	3625	3781
Sales loss		0	0	0	0	0	-1066
Sales value after patent exp effect	2224	2441	2550	3328	3474	3625	2559
<i>Total sales growth</i>		9,78%	4,46%	30,52%	4,38%	4,34%	29,42%
Saxenda sales valuation							
<i>Inflation rate</i>	2,00%	2,40%	2,40%	2,40%	2,40%	2,40%	2,40%
Price paid per unit	224	221	226	232	237	243	249
Price paid per year	13.653	13.447	13.770	14.100	14.439	14.785	15.140
People treated	37.819	39.130	39.962	40.808	41.666	42.537	43.421
<i>Saxenda Market share</i>	56,00%	56,00%	60,00%	60,00%	60,00%	60,00%	60,00%
NN patients	21.179	21.913	23.977	24.485	24.999	25.522	26.053
Sales	289	295	330	345	361	377	394
Sales loss		-	-	-	-	-	111
Sales value after patent exp effect	289	295	330	345	361	377	266
<i>Total sales growth</i>		1,91%	12,05%	4,57%	4,55%	4,54%	29,42%
Combined sales							

Total sales	2.513	2.736	2.880	3.674	3.835	4.002	2.825
<i>Total sales growth</i>		8,88%	5,28%	27,55%	4,40%	4,36%	-
<i>COGS as % of sales</i>	15,00%	15,00%	15,00%	15,00%	15,00%	15,00%	15,00%
COGS	377	410	432	551	575	600	424
NET SALES	2.136	2.325	2.448	3.122	3.260	3.402	2.401
<i>R&D as % of sales</i>	13,03%	13,03%	13,03%	13,03%	13,03%	13,03%	13,03%
<i>SG&A as % of sales</i>	28,90%	28,90%	28,90%	28,90%	28,90%	28,90%	28,90%
R&D costs	278	303	319	407	425	443	313
SG&A costs	617	672	707	902	942	983	694
Operating profit EBIT	1.240	1.350	1.422	1.813	1.893	1.976	1.395

4.4 Implemented mitigation actions

As anticipated in the previous chapters, the strategy that Novo Nordisk is using to offset the sales loss of Victoza® and Saxenda® is called second generation strategy. More specifically, the company is planning to launch two similar products for the same segment of customers.

The substitute of Victoza® is called Semaglutide NN9535 and it currently is in the last phase of development⁵⁵. The most significant improvement on Victoza® is the possibility of once-weekly injection, in fact Semaglutide NN9535 has the same characteristics of Trulicity®, the Eli Lilly product launched in 2014. So far, the emerging product gave many positive signs in clinical trials, increasing the expectations about its effectiveness and its future sales; assuming that there are no problems with the FDA approval, Semaglutide NN9535 is expected to be launched on the market in year 2020.

Regarding Saxenda®, a substitute of this product is currently in Novo Nordisk's pipeline and it is called Semaglutide NASH 9931. The product showed in 2016 excellent efficacy, meaning a percentage of NASH (Non-Alcoholic Steatohepatitis) resolution of 39%. This product is just in phase II development; thus, it is expected that – if the product overcomes positively all clinical trials – it will be launched in year 2024.

⁵⁵ Novo Nordisk Pipeline, Novonordisk.com

4.4.1 Assessing the net impact of the risk on Victoza®

In order to offset the impact of the patent loss of Victoza® in year 2022 (risk mitigation), the new product Semaglutide NN9535 combined with Victoza® has to sell almost like Victoza® alone before its patent’s expiration date.

A sales projection for a product that currently does not exist on the market is not easy, however there are two main considerations that are useful to quantify the expected sales of the emerging product:

- The first point is that Semaglutide NN9535 is considered the substitute of Victoza® because it takes the same customers’ segment; indeed, its sales are expected to reach at least the same value of Victoza®. For these reasons, the assumptions are that the future market share of Semaglutide NN9535 will grow at the same pace as Victoza®’s market share when it was launched on the market and that the new product will reach the same customers as Victoza® (patients’ figure is already calculated with the projected sales growth of Victoza®);
- The second consideration is that Semaglutide NN9535 is exactly the same clinical treatment as Trulicity® (manufactured by Eli Lilly), therefore to estimate the potential price applied to this product, Trulicity®’s prices⁵⁶ (from its launch in 2015 to year 2017) are taken as a proxy for the sales projection.

For Semaglutide NN9535’s market share there are two other scenarios besides the baseline value, which are resumed in the following table.

Table 29-Semaglutide NN9535 projected market share

Semaglutide NN9535	Scenarios	2020	2021	2022	2023	2024	2025
Market share	<i>Pessimistic</i>	2%	5%	7%	15%	50%	50%
	<i>Baseline</i>	2%	5%	10%	17%	57%	57%
	<i>Optimistic</i>	2%	5%	10%	17%	57%	57%

⁵⁶ Medicaid USA Drug Prices, prices are reported per Mg. Since Trulicity® is sold in a pack with 1,5Mg/0,5MI pen for a once-weekly use, the price per year, per patient is calculated just multiplying by 48 (weeks)

The baseline product's market share is the same as Victoza® from its introduction until its stabilization on the market⁵⁷; the expansion of the market is already included in the population treated, however with the increase in competition there are no other positive scenario than the baseline; while in the pessimistic case, the product's market share will not go above 50% -again- due to competition.

Given these assumptions it is calculated the expected sales value of Semaglutide NN9535 from year 2020, which should offset the sales loss caused by Victoza® expiration.

Table 30-Mitigated risk of patent loss of Victoza®

Combined Sales	0	1	2	3	4	5	6	7	8	9
Years	2016	2017	2018	2019	2020	2021	2022	2023	2024	2025
Semaglutide NN9535					125	374	821	1.450	5.050	5.241
Victoza®	2.224	2.441	2.540	2.642	2.747	2.855	2.015	844	0	0
Total sales	2.224	2.441	2.540	2.642	2.871	3.229	2.837	2.295	5.050	5.241
Sales growth		9,8%	4,1%	4,0%	8,7%	12,4%	-	-	120,0%	3,8%

From the table, it is visible how the new product partially covers the sales drop of Victoza®, shifting the loss percentage in 2022 from -29,42% to -12.1%. the following year the sales drop goes from -58.09% to -19.1% showing again a significant reduction of the expected losses.

4.4.2 Assessing the net impact of the risk on Saxenda®

The same consideration is done for Saxenda®: in order to offset the impact of its patent loss in year 2022, the new product Semaglutide NASH 9931 combined with Saxenda® has to sell almost like Saxenda® alone before its expiration date. In this case, the situation is very much different from Victoza®, in fact Semaglutide NASH 9931 is not expected to be launched before year 2024.

⁵⁷ Data available on Novo Nordisk Annual Reports and Investor Presentations

Given this fact, the estimation of the future sales of the emerging product is not in scope; indeed, the metric used for the valuation is the amount of sales in year 2022, which does not incorporate the effect of future sales of Semaglutide NASH 9931. Novo Nordisk's mitigation action for the patent loss of Saxenda® is to be considered ineffective, since the retarded launch of the product does not contribute to offset the sales loss.

Table 31-Mitigated risk of patent loss of Saxenda®, ineffective strategy

Combined Sales	0	1	2	3	4	5	6	7	8	9
Years	2016	2017	2018	2019	2020	2021	2022	2023	2024	2025
Semaglutide NASH 9931					x	x	x	x	N/A	N/A
Saxenda®	289	295	307	320	333	347	245	103	0	0
Total sales	289	295	307	320	333	347	245	103	0	0
Sales growth		1,9%	4,2%	4,2%	4,1%	4,1%	-29,4%	-58,1%	-100,0%	0,0%

4.3.3 Combined sales value after mitigation actions

The sum of the sales after implementing the mitigation actions is showed in the table below. Again, the COGS of 15% is applied to obtain the net sales value of the two products combined. Net sales in year 2022 are much higher than the value obtained with pre-mitigation actions: the net sales value without mitigation is \$1.921, while with mitigation the value goes up to \$2.619, showing the positive effect of the actions put in place by Novo Nordisk.

Table 32-Operating profit after mitigation actions

Operating profit EBIT	0	1	2	3	4	5	6
Years	2016	2017	2018	2019	2020	2021	2022
Total sales	2.513	2.736	2.847	2.962	3.204	3.575	3.081
<i>Total sales growth</i>		8,88%	4,07%	4,03%	8,20%	11,58%	-13,82%
<i>COGS as % of sales</i>	15,00%	15,00%	15,00%	15,00%	15,00%	15,00%	15,00%
COGS	377	410	427	444	481	536	462
NET SALES	2.136	2.325	2.420	2.517	2.724	3.039	2.619

<i>R&D as % of sales</i>	13,03%	12,61%	15,50%	14,04%	13,97%	14,82%	15,34%
<i>SG&A as % of sales</i>	28,90%	29,81%	30,17%	32,17%	31,86%	33,07%	34,70%
R&D costs	278	293	375	353	380	450	402
SG&A costs	617	693	730	810	868	1.005	909
Operating profit EBIT	1.240	1.339	1.315	1.354	1.476	1.584	1.309
EBIT Ratio	49,37%	48,95%	46,18%	45,72%	46,05%	44,30%	42,47%

In 2016, Victoza® and Saxenda® represented together 27% of Novo Nordisk total US sales, with the major impact attributed to Victoza®.

Even though the strategy applied for Saxenda® does not work, its sales value is so minimal that does not influence that much the sales level in year 2022. Indeed, the sales drop at the expiration date of the two products is -13.82%, compared to -29.41% without mitigation actions. In year 2022, the EBIT is \$1.309, it is much higher compared to its value before mitigation actions (it was \$960), however, the EBIT Ratio is the same as the pre-mitigation value 42,47%.

The next step in the analysis is the calculation and comment of the individual risk exposure pre and post mitigation actions.

4.5 Individual risk exposure

The individual risk exposure is the “quantification of multiple deterministic scenarios for the key risk, in terms of its potential impact on the baseline value” (Segal, 2011).

It is important to recall that in this thesis, the valuation of the individual risk exposure is not on the enterprise value, but it is narrowed down to the net sales value and operating profit of two products of Novo Nordisk; moreover, a pharmaceutical company must necessarily steadily maintain high the value of sales to cover the R&D investments of the products. Hence, the mitigation actions put in place by the company should raise the net sales value in order to maintain the leading position of the firm.

First of all, the probabilities of each scenario to occur are set as follows:

-75% likelihood for the baseline scenario because it is a fact that the expiration of the two products will occur;

-15% likelihood for the pessimistic scenario and 10% for the optimistic, because even though Novo Nordisk is growing very fast with many products in its pipeline, the increase in competition and R&D costs make the optimistic case less likely to occur than the pessimistic one.

The shocks on the baseline value are applied for the variables already identified and explained during the Risk Scenario development (inflation, R&D costs, SG&A costs and market share); subsequently the combined sales value of Victoza® and Saxenda® in year 2022 and the operating profit in the same year have been calculated prior the application of mitigation actions and afterwards. At this point, with the individual risk exposure the first variable to assess is the *Delta* from the baseline value pre and post mitigation actions, considering the different scenarios.

Table 33-Individual risk exposure

Individual Risk Exposure (USD million)		Pre-Mitigation Actions		Post-Mitigation Actions	
<i>Scenarios description</i>	Probability	EBIT 2022	Delta from Baseline	EBIT 2022	Delta from Baseline
<i>Pessimistic</i>	15,0%	720	-239	918	-390
<i>Baseline</i>	75,0%	960	0	1.309	0
<i>Optimistic</i>	10,0%	1.395	435	1.901	593

The *Delta* from the baseline gives already a strong sign about the implementation of Novo Nordisk strategy: the *Delta* obtained pre-mitigation actions is smaller than the one obtained post-mitigation actions. The reason is that Novo Nordisk's strategy covers just the product Victoza®, because the substitute product of Saxenda® will be introduced too late to offset the sales loss at the patent's expiration date; therefore, there is a large gap from the baseline value – especially in the pessimistic scenario – when implementing mitigation actions. This means that, in the pessimistic case, the strategy that the company will apply gives a higher amount of sales and operating profit, but it is actually more risky than its non-execution.

The individual risk exposure includes also the calculation of summary statistics that give an explanation of the effectiveness of Novo Nordisk's strategy.

Table 34-Summary statistics: Individual risk exposure

<i>Summary Statistics</i>	Pre-Mitigation	Post-Mitigation	Delta from pre-mitigation	% delta from pre-mitigation
<i>Baseline</i>	960	1.309	349	36%
<i>Expected Value</i>	967	1.309	342	35%
<i>Std dev. from Baseline</i>	166	241	75	45%
<i>Std dev. from Exp. Val.</i>	166	241	75	45%
<i>Range</i>	674	983	309	46%

Looking at the table above and going through the summary statistics it is estimated that:

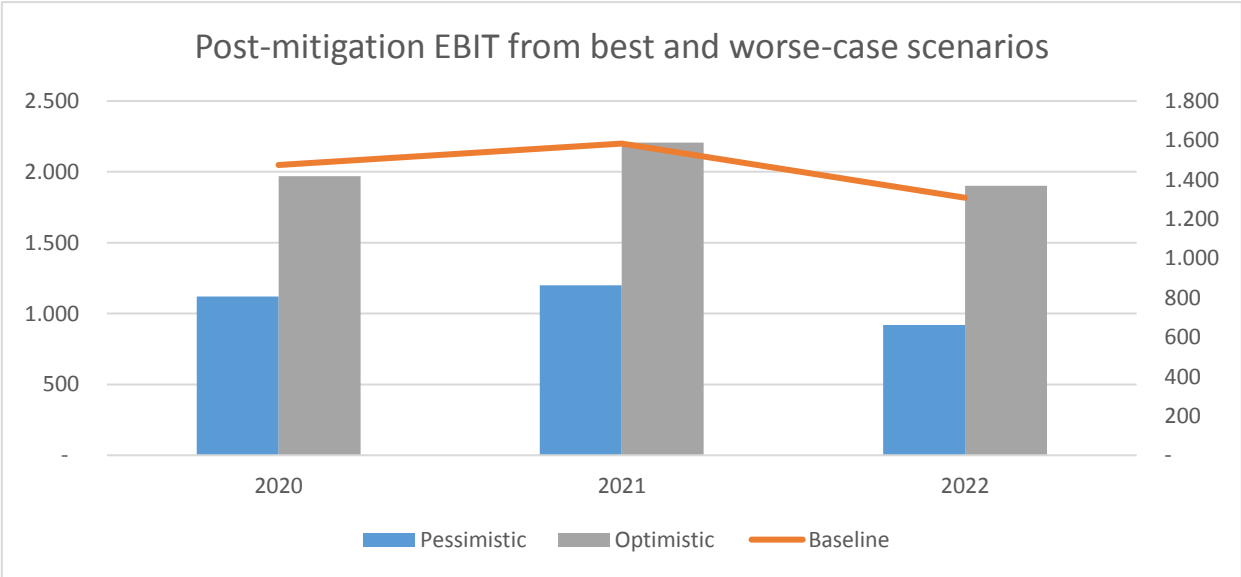
- The post-mitigation baseline value is to considered high enough to efficiently offset the patent cliff risk. The baseline value is 36% higher when implementing the mitigation actions, even though these covers just one of the two products in scope;
- The expected value is the sum of the possible sales value in 2022, multiplied by the likelihood of each sales value to occur, given the different scenarios; the post-mitigation expected value is 35% higher than the pre-mitigation expected value. This means that the mitigation decision increases Novo Nordisk’s sales even though the introduction of a new product raises the total COGS, R&D and SG&A costs and it is considered risky.
- The standard deviation from the baseline and from the expected value shows the degree to which the pre and post mitigation results are considered risky. The value obtained from both (45%) shows that the second-generation strategy is very risky; indeed, with a higher amount of operating profit there is also a higher risk connected to the investment in a new product, which is reflected in raising of R&D and SG&A costs. When the standard deviation is a positive value it is called “upside volatility”, meaning that the company is producing results that exceed its strategic plan, however even upside volatility means a high degree of instability and uncertainty of the mitigation actions put in place, as well as a high dispersion of values from the baseline operating profit. The range confirms the statements just above, in fact the range of values from the optimistic to the pessimistic scenarios with post-mitigation actions is higher compared to the value with pre-mitigation, this means a number that goes from \$674 to \$983.

This assessment on Novo Nordisk’s patent cliff risk and on the strategy that the company is planning to apply suggests that a drop in sales is inevitable when such risk occurs, however the mitigation actions that Novo Nordisk is planning can help in keeping a high value of revenues. The introduction of a new product to offset the sales loss of another one is a very risky decision, but a pharmaceutical company does not have cheap options to contrast the effect of patents’ loss. Indeed, the cost of mitigation is very high, in fact the increase in sales means also a raise in selling and distribution costs, as well as R&D costs.

Moreover, Novo Nordisk does not have an effective plan to cover the sales loss of Saxenda®, in fact the strategy aims only at covering the loss of Victoza®, resulting in postponed sales that will be capitalised after two years the expiration of Saxenda®’s patent.

It is important to mention that, when applying the same summary statistics on the Net sales value, the standard deviation from the baseline is 53%, meaning 800 bps higher than using as a metric the operating profit. The reason is that, limiting the analysis on the net sales value, the risk is to overestimate the actual value added to the balance sheet, because it does not take into account the costs occurring from the new strategy put in place by the company.

Figure 21-EBIT from best and worse-case scenario post-mitigation actions



Source: Author’s estimates

In conclusion, Novo Nordisk achieves a good result in increasing revenues after the patent cliff effect, indeed the combined (gross) sales in 2022 are \$3.081 and – considering the assumptions made – this amount should be close or above the sales value achieved by the combined products before introducing their substitutes; the substitute for Victoza® is launched in 2020, so the total (gross) sales in 2019 are \$2.962. This means that the company is using an effective second generation strategy, when considering its combined effect on both products.

On the other hand, the fact that the strategy is applied just on one product increases a lot the volatility of the baseline value. To conclude, another important metric used in the analysis is the EBIT Ratio, that calculates the earning ability of Novo Nordisk; this percentage is the same pre and post mitigation actions (42,47%), but it changes compared to the different scenarios. The reason is that the second-generation strategy aims at launching a new product that will be the perfect substitute of the previous one, meaning that the costs sustained to implement mitigation actions offsets the higher value of net sales obtained.

Indeed, if the costs amount before applying mitigation actions is in total \$1.300, the cost sustained after mitigation actions is \$1.733, which reduces the earning ability of Novo Nordisk.

Table 35-Total costs variance

<i>Total Costs</i>	Pre-Mitigation	Post-Mitigation	Delta from no mitigation	% delta from no mitigation
<i>COGS</i>	339	462	123	36%
<i>R&D</i>	295	402	107	36%
<i>SG&A</i>	667	909	242	36%

In the next chapter, there author gives some suggestions to decrease the volatility associated with the strategy adopted by Novo Nordisk and the possible mitigation actions that can be applied to reduce the patent cliff risk.

CHAPTER 5

5.0 Wrap-up

The last Chapter of this thesis is made up of two parts: the first one highlights the main findings of the ERM model applied to Victoza® and Saxenda®; the goal of this paragraph is to understand limitation and strengths of the ERM model developed and the transmission channels useful to develop the analysis. The second part of the chapter, instead, suggests any other mitigation actions that Novo Nordisk can perform to avoid the patent cliff risk impact on its pipeline, despite the second-mitigation strategy that it is already applied in the quantitative assessment.

5.1 Key findings and final considerations

The model developed in this thesis has not to be considered as a tool to verify if Novo Nordisk's strategy is appropriate or effective, rather it gives an understanding of the company's performance based on the strategy that it is planning to achieve in the next years.

It is important to state that the forecasting of the future sales of a pharmaceutical product is very difficult to perform, because of the infinite number of variables to take into account in planning; however, every forecasting tool is difficult to build, especially when it takes into account human behaviors.

The scope of the thesis is to give an overview of the complexity of the pharmaceutical market; an industry that is continuously expanding through different ways and that is keeping facing several challenges due to the constantly increasing prices (especially in US) and increasing costs. Novo Nordisk is a stable company that is seeking for improvements and expansion after a downturn period, therefore the firm's sales of its main product (Victoza®) together with its newly developed product (Saxenda®) are expected to growth a lot in the next years. The tool presented in this thesis aims at identifying, monitoring and quantifying the impact of one of the

key risks of Novo Nordisk's sales and operating profit. The patent cliff risk that will affect the two products in scope (and the rest of Novo Nordisk's pipeline) is a challenge that has always been a reason of struggle for pharmaceutical companies and it will always be, because of the particular nature of the industry.

On the other hand, the profitability of the sector makes companies still willing to invest in products' research and development, which benefits also the whole world population.

The analysis reveals the primary role of patents as a key variable to produce high sales for pharmaceutical companies; the quantitative assessment also shows how the patent itself can be a source of losses when its expiration date comes, forcing firms to actively prevent that, even many years before. Indeed, some of the main challenges for pharmaceuticals are firstly, the creation of a clinically effective product, secondly the prediction and planning of future sales of the new drug.

It shall be noticed that this paper reveals useful information to measure the sensitivity of sales value to the impact of losing patents' protection of a product, however - for the reasons explained above - a future prediction of sales is hard to perform when it takes into account human behavior, and especially how this behavior can influence illnesses trends.

Moreover, an ERM assessment can include even more risks, quantifying the combined impact of those on relevant metrics; rather the focus of this thesis is narrowed down to the study of one risk, which yet generates by itself a large impact on the company's sales.

The ERM tool provided also identifies the key role of demographics trends to develop a scenario analysis of medicines' sales; the population affected by diabetes and obesity is projected to disproportionately growth, even in few years from now, reflecting the need to keep investing in their treatment. From the developed tool, it is also clear how with an increase in those trends, it is projected a steady increase in sales of the medicines able to cure those illness-, in fact, future sales are calculated taking into consideration those demographic changes, thanks to the information available from Diabetes International Association and IMS Health.

Recalling that the metric used for the analysis is operating profit in year 2022, the mitigation actions put in place by Novo Nordisk aims at increasing this value.

Rather, when performing an ERM assessment which use as metric the company value, the increase in revenues, does not always corresponds to an increase in cash flow; moreover,

mitigation actions usually aims at decreasing the risk exposure, consequently downsizing the company value. Therefore, it is not possible to state that the strategy applied by Novo Nordisk is effective or not; in fact, it really depends on the company's risk propensity, as well as changing financial conditions that leads Novo Nordisk's future decisions: moreover, the firm's pipeline can change a lot in the next years, depending on state of approval from FDA of current products.

In conclusion, even with possible limitation of the model developed, the value based ERM approach provides a solid and practical method to determine the risk exposure on relevant metrics and for sure, it provides useful information on the sensitivity of Novo Nordisk's sales to the patent cliff risk.

5.2 Other mitigation actions

The second-generation strategy that Novo Nordisk applies is one of the most common strategies used from pharmaceuticals to contrast the patent cliff risk. From the model, though, it is resulted that the second-generation strategy is actually ineffective when applied on Saxenda® later than the expiration date of the main product's patent; Saxenda®'s losses are not covered by the strategy put in place, however Saxenda®'s sales combined with Victoza®'s reflects how the company is actually able to reduce the risk impact, even with inevitable sales losses.

The constant presence of a rich pipeline is a robust measure of a pharmaceutical company's strength, although this means significant costs which are recovered just after years from the investment. At the same time, a rich pipeline does not mean a superior ability of the company to overcome the patent cliff risk; indeed, the sales forecast of a product is not a "always true" measure. Even though it is possible to forecast sales based on historical data and population trends, predicting customer's reactions to a new product and their future needs is impossible. Therefore, Novo Nordisk must provide other initiatives to contrast the patent cliff risk. The company has just been through a crush period because of the increasing intensity of rivalry and prices challenged by the US government, so it can face a downturn period like the one just passed, in few years from now.

Other preventive actions that Novo Nordisk can take to avoid those risks are:

- Investing in other business segments
- Externalisation of late-stage pipeline

The first option that Novo Nordisk has is investing in other business segments; this means targeting other customers and creating a completely different new market. Novo Nordisk is the leading company in diabetes care, however the competitive scenario is changing very fast and the diabetes sector will be challenged even more in the next years. Novo Nordisk already started its customers' diversification introducing Saxenda®, the first product in the obesity market; however, obesity and diabetes illnesses are very much connected, since from obesity usually derives diabetes type 2. This means that it was quite obvious for Novo Nordisk to target obesity, indeed, it could have started investing in this sector even earlier. What pushed Novo Nordisk to invest in obesity is the fact that Saxenda® comes from a collateral effect of Victoza®, in fact the product is also injectable and not in form of tablet (like competitors).

The risk occurring from patent losses can be better faced with a differentiated portfolio of products, such that customers cannot influence each other.

Novo Nordisk's investments in growth hormone therapy reflect the strength of the business; Novo Nordisk is leader also in this sector, which is keeping expanding. The hemophilia segment, instead, is very small, considering the rare illness, meaning also that it is not so much profitable for Novo Nordisk even though it reaches almost all the people affected by hemophilia.

A diversified portfolio leads to a new market, but it is important to recall that the increase in competition do not encourages Novo Nordisk in investing in something different; moreover, often the return of investment of a biopharmaceutical company does not even cover its cost of capital. Indeed, there are actually more efficient strategies to avoid large R&D investments.

The second option that Novo Nordisk has is the externalisation of late-stage pipeline.

This approach aims at increasing the number of products in the pipeline, but increasing in less proportion the development costs related to them.

Pharmaceuticals already use traditional ways of reducing the risk of investing in new products through licensing, acquisitions or partnerships, however new models of partnership allow the

firms to divide the financial investment and the operational (and executional) control, to obtain the maximum return, sharing and reducing the upfront risk.

One of the options of externalisation is to Join Venture, however this raises many issues in terms of IPR protection and IP appropriation can be a large source of losses for a company; however, there are some strategies that can be put in place to avoid this risk. Firstly, there are two basic “rules” to apply when creating a JV:

- Including a “no-guarantee agreement”, that basically explains that there is no guarantee that the partnership will lead to the results intended by the JV;

- Make a “non-disclosure agreement” (more common) or a “Joint development agreement”, which is more effective because it states that the creation and use of intellectual property is made as part of the JV, it explains how the people involved in the agreement should bear the financial risk related to IP, and finally it recap which are the rights and obligations that arise from the termination of the contract, which also includes IP protection.

Besides the legal aspect, some other practicalities can be used from a firm that wants to protect its IP in partnerships:

- Talking about the logistic aspect of protecting the kind of equipment used in the products’ development, a company can use IT and machineries which do not include design descriptions, but that, instead, are ready to be used. Of course, this means also a high cost of providing the equipment, but it still guarantees technology’s protection;

- Talking about the manufacturing process, it is also possible to separate the steps of the pipeline (whenever chemically and physically conceivable for a medicine), leaving the critical ones protected and isolated from the partners.

Taking into consideration the risks coming from it, the externalisation can be done in several ways, depending on the company’s capacity and financial assessment. For instance, a company like Novo Nordisk that currently has limited capital but enough late-stage development capacity, can make an insurance contract to hedge the pipeline risk.

Hedging the pipeline means paying a premium that allows the company to get a reimburse of the costs sustained for the development of the hedge product, if it fails during the late-stages phases. With this strategy, Novo Nordisk can drastically reduce the risk of losses only when the

early-stage R&D costs of the product have already been paid for it; however, it is unlikely that insurers want to share the potential costs of a product failing at the beginning of its development. In this type of contract the risk should be measured based on recent statistics on clinical trials on the product's category and type of treatment.

Novo Nordisk can utilise this strategy as an alternative on the logistic externalisation of the late-stage production, because doing that, it can lose the credibility on its high quality standards.

Indeed, with tight capacity, outsourcing can be the best option to reduce the investment costs; for instance, Eli Lilly created a risk-sharing partnership where other companies (for instance Indian or Chinese pharmaceutical companies) take over part of the product's development for a low price. Novo Nordisk did not take any step forward these mitigation strategies, however, the company just started its growth after a crisis and it will take time before implementing new and different actions to offset the patent cliff risk.

Empirical evidences⁵⁸ show that there is a classification of the most used mitigation strategies on patent cliff risk and their effects in terms of annual revenues losses in US; some of the most used strategies have been mentioned in Paragraph 1.3.2 Patent cliff escaping strategies.

The strategy most used in pharmaceuticals is the Pediatric Exclusivity, which consist in guarantee that a treatment is not only effective in adults, but also on pediatric population; this allows companies to extend the exclusivity period on a different customers' segment; the second most used strategy is the Authorised Generic, which is part of the adaptation strategy and allows a branded company to launch a product under private label, like a generic one, at generic prices. The third most used strategy is the re-formulation of the product, which can be either seen as part of prevention or innovation strategies, depending on the degree to which an existing product's composition is altered to provide improvements. Another used, but less spread approach is to sell a product OTC (this approach is part of the innovation strategy).

Given the most common used strategies to mitigate the patent cliff risk, from the Rutgers Research, it is also stated that, even though some mitigation actions are more used or spread

⁵⁸ Patent cliff mitigation strategies: analysis of current trends and implications, by Brian Lee, PharmD; Amanda White, PharmD, MBA; Dhaval Patel, PharmD; Manish Patel, PharmD; Michael Toscani, PharmD Rutgers Pharmaceutical Industry Fellowship, Rutgers University, Piscataway, NJ P show the mostly utilised mitigation strategies over patent risk, as well as their impact on annual revenues in the US

than others, they all have a similar effect on revenues, decreasing the annual global impact (on average) by 29,4%, in a range that goes from a 19% to 40% revenues change comparing pre and post-mitigation revenues. The annual global impact on sales in the present analysis is changed by 36%, giving a result that is in between the range showed by the Rutgers Research.1.3 To conclude, it is important to state that the effectiveness of a strategy strictly depends on the unique characteristics of a company and its capacity, in terms of equipment, IT, human resources and capital.

Conclusion

This thesis is an interesting implementation of the Value-Based Enterprise Risk Management approach on the financial performances of a big pharmaceutical company like Novo Nordisk A/S.

The tool developed gives an understanding of the complexity of the pharmaceutical industry, as well as the impact that one single risk can have on the sales performance of Novo Nordisk; it is interesting to see how just two of the products manufactured by a single company can actually determine a large portion of revenues.

When the patent cliff risk materialises it is very difficult – even for a financially stable firm – to take actions against it; when talking about pharmaceuticals, it is, indeed, very important to plan the strategy to be used to tackle the patent cliff risk, long time ahead.

The first two chapters of this thesis explains the unique characteristics of the pharmaceutical industry: if on one hand, most of the large pharmaceutical companies established a monopoly (or duopoly) on the market thanks to the possibility to determine the price of manufactured medicines, on the other hand, research and development costs are very high and they are repaid just after 15-20 years from the product manufacture.

The product pipeline lasts, in fact, between 15 and 20 years; in the meantime, companies must overcome many milestones to get the approval from the authorities to put the product on the market.

Because of these reasons, incentives from the governments are crucial to stimulate companies to keep investing in the pharmaceutical business, and IPR is one of it. Patents give the right to exclusively sell a product, set high prices and avoid competition for quite a long time.

The benefits of patents last until its expiration, when the company has to deal with several threats: rivalry increasing exponentially from existing competitors and from generic drugs firms, drop in prices and loss of market share.

All these factors combined generate a significant negative financial impact, that the author estimates through the ERM assessment on Novo Nordisk; to begin with, the impact on Victoza® - which represents 25% of US sales - is much larger than the impact generated by Saxenda®.

Through the ERM tool created, it is quantified the severity of the impact on the two products' sales combined, net of COGS and also and the Operating Profit of Novo Nordisk, obtained subtracting R&D and SG&A costs.. The transmission channels used to develop the assessment shows the relevance of social and demographic trends on pharmaceutical companies, which are high dependent on “extraordinary factors” difficult to predict and assess.

Indeed, while it is quite easy to rely on data coming from official sources about people historically affected by illnesses like diabetes and obesity, it is very difficult to predict how those trends will change with the evolution of human behaviour.

The choice to analyse the patent cliff risk comes from a qualitative risk assessment (performed in Chapter 3) that provides a comprehensive view of some of the major risks for Novo Nordisk, classifying them into several risks categories and sub-categories. The qualitative risk assessment aims at identify the root causes of the risks and therefore, the classification of the risks that can mostly impact the company's financial performances.

The patent cliff risk is considered the main cause of sales drop and loss of profit margin and it is taken into consideration for the quantitative risk assessment, because of both high likelihood and severity of the impact.

It is known that an ERM model it is useful also to assess the combined impact of two or more risks together, however, for the reasons explained above, the patent cliff risk deserves an individual analysis because of the extremely high impact that it has even on a single product, which for a pharmaceutical company can also represents a great part of the business.

Despite the limitation that the ERM model can have, it is important to highlight its benefits.

Firstly, the model shows all the sub-components of sales of Victoza® and Saxenda®. The analysis, in fact, incorporates the main driver of sales: population affected and diagnosed by diabetes and obesity; market share captured by Novo Nordisk in US, among the specific medical treatment of Victoza® and Saxenda® respectively; and finally, the selling price applied. Each of those three variables directly impacts Novo Nordisk's net revenues to a different extent; through the risk scenarios created it is possible to quantify the severity of this impact considering the optimistic and pessimistic cases, in which the patent cliff risk's effect on net sales is lower or higher than the baseline. The net sales value is later broken further down into EBIT or

Operating profit, which is obtained subtracting the main costs that Novo Nordisk sustain, which are R&D costs and SG&A costs.

Secondly, the ERM model quantifies the individual risk exposure on the operating profit given by Victoza® and Saxenda®, either on the pre-mitigation results and on the post-mitigation results; the baseline value achieved after putting in place mitigation action is 36% higher than the pre-mitigation value, showing that the strategy analysed to offset the patent cliff risk is meaningful and useful to sustain the sales value resulted after the patents expiration.

The mitigation actions are a fundamental part of an ERM assessment, since they explain how to tackle a risk that will eventually materialise, considering the current resources that a company can use.

In the model created, the strategy that Novo Nordisk is planning to achieve is the so-called second generation strategy. An analysis of other pharmaceutical companies that used the same strategy in the past, is made to quantify the potential impact of the patent cliff risk and to use it as a proxy on Novo Nordisk.

Finally, the post-mitigation actions results show the degree to which Novo Nordisk's strategy offsets the risk effect and it shows the volatility caused by the strategy itself. One can argue that the standard deviation from the baseline value is high, even though positive. In fact, the purpose of this assessment is to actually show the results that Novo Nordisk can obtain applying the second generation strategy, and not its effectiveness.

Another benefit of the ERM assessment, indeed, is the practicality of the model, which provides a robust approach to assess the risk exposure and a comprehensive view of the strategy to apply.

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SUMMARY

THE IMPACT OF PATENT CLIFF RISK ON NOVO NORDISK A/S: AN ERM ASSESSMENT WITH FOCUS ON TWO MAIN PRODUCTS IN THE US MARKET

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INTRODUCTION

Large pharmaceutical companies drive innovation through investments in research and development activities for the creation of a new drug product that could represent a milestone for the whole world.

The worldwide pharmaceutical revenues amount to more than 1 trillion US Dollars and the industry is “responsible for the development, production and marketing of medications”⁵⁹, meaning that the sector has a broad and significant social scope, besides the monetary value.

Although the pharmaceutical industry is heavily regulated and with high barriers to entry, the competition in this market increased exponentially over recent years, given the high number of small pharmaceutical start-ups and biopharmaceutical products firms that try to enter the market, as well as the generic competition that arises with patents expirations.

The risk that a pharmaceutical company faces when the patent of a drug is about to expire, with consequent possible entrance from generic products firms and fall of revenues, is called patent cliff. This thesis analyses the consequences of the patent cliff risk on a large pharmaceutical company, named Novo Nordisk A/S, which has its headquarter in Denmark and that sells in more 200 Countries, with \$16.61 Billion of revenues in 2016. The core business of Novo Nordisk is diabetes treatment, but the company is now expanding its business also in obesity treatment. The purpose of the present paper is to identify and describe the impact of patent cliff risk on two main products of Novo Nordisk - Victoza® and Saxenda® - focusing only on the US market, which is the biggest for the company.

The US population is the most affected by those kinds of diseases, with a total adult population with diabetes of 30.2 million, in 2015. Only in the first half of 2017, the new cases of diabetes were 1.5 million, reflecting the fast growth of an unhealthy life style.

The business value of Novo Nordisk is highly dependent on social factors and trends, indeed the investment in diabetes and obesity sector became extremely profitable over the last five years, and this fact is reflected on the company’s net sales, which increased by a CAGR of 11%, between 2010 and 2016.

⁵⁹ The Statistics portal, Global Pharmaceutical Industry – Statistics & Facts

The thesis is made up of five Chapters: Chapter 1 provides a broad understanding of the pharmaceutical industry, as well as property rights as driver of innovation in the industry.

Chapter 2 provides a deep analysis of the company in scope from a strategic point of view, with the identification of the firm's segments and products, its position in the market and the strategy that Novo Nordisk is following to increase the company value, in the future.

Chapter 3 represents the Risk Identification process in the ERM assessment; in fact, it consists of the identification of the main risks that can affect Novo Nordisk and their classifications, with the patent cliff risk representing the most impactful risk based on likelihood and severity of the impact. In Chapter 4, instead, the author analyses the financial impact of the patent cliff risk on net sales and operating profit, together with the mitigation actions put in place by Novo Nordisk, to diversify and reduce the impact of the risk in scope. Finally, in the last Chapter of the present thesis gives an understanding of limitations and strengths of the firm in scope and the possible business changes that could be adopted by the firm's Risk Governance, to enable the patent cliff risk to be anticipated early, but also to be proactively responded in order to minimise its bearing on financials, assets and reputation.

CHAPTER I - PHARMACEUTICAL INDUSTRY OVERVIEW

The pharmaceutical industry is characterised by high innovation costs, but low marginal costs, therefore intellectual property rights - especially patents - are very important to cover those initial costs. Patents give the opportunity to create a monopolisation of the market, where a specific product is unique and can be sold at a high price, with zero-bargaining power for customers. Of course, on one hand, the state is willing to give incentives to businesses to innovate and to guarantee the development of the society and the economy; on the other hand, the state must guarantee welfare gains and let competition increase to reduce drug prices. Indeed, Regulatory Authorities introduced the Hatch-Waxman Act, which allows companies to submit an ANDA, or Abbreviated New Drug Application, and avoid the performance of clinical trials, ensuring that the product is bioequivalent to the branded one. Usually, in order to launch a new product on the market, it is mandatory to refer to the Food and Drug Administration (or

European Medicines Agency) and submit an NDA, New Drug Application (MA, Marketing Authorisation, in Europe). With the introduction of the Act, the number of generic drug products manufacturers increased exponentially, reducing consistently the market share of branded drug companies; in fact, nowadays almost every drug faces generic copies.

Intellectual property rights should be the engine of welfare maximisation, since the application of those rights is different among countries and it depends very much on dissimilarities in income and on the elasticity of demand on prices.

The impact of IPR on pharmaceutical companies is on market competition and innovation; market competition is supposed to be low thanks to the exclusivity – and basically the monopoly – of a drug manufacturing, selling and pricing. The other impact is on a company's innovation capability, which should be incentivised by the opportunity of exclusivity and by the possibility to cover research and development costs, with also high profit margins.

The pharmaceutical industry is unfortunately threatened by the pressure from rising in research and development costs, together with the general decrease in the patent life, usually challenged by generic companies. On top of that, when generics launch their products, the price difference with the branded ones is very much visible, meaning that the price of drug products is meant to be high when patent protection occurs. Patents protection is necessary to ensure the competitive advantage of a company; in fact, a survey on the impact of patents on R&D expenses⁶⁰ shows that if there was no secure exclusivity protection of a product, research and development investments would be much less – about 50% - than the current value.

The patent cliff phenomenon is defined also as the revenues-cliff and one of the major risk for large pharmaceuticals because the innovator firm cannot avoid the entrance of generics on the market when patents expire. The traditional business model of the pharmaceutical firms is such that the company focus on the development of a single drug for a wide target of customers; it is not a guaranteed that the company will succeed in covering the high R&D costs, thus if on one hand, this business model leads to important innovations and advances in the pharmaceutical industry, on the other hand, it is not always profitable and it is becoming outdated with the evolution of the market.

⁶⁰ The impact of patents on R&D, Taylor and Silberston (1973)

According to the current business model, new patented products must replace losses caused by patent expiration of the previous products, but the cost of bringing new products to the market is becoming higher and the approval process is becoming longer, therefore pharmaceutical companies are now challenged by developing products which are more effective than those already on the market. Moreover, healthcare regulatory authorities are favoring the entrance of generics, changing the average price of products. Companies must reinvent new business models and abandon the traditional one. Among the new strategies that branded companies can adopt to fight competition, there is the one that Novo Nordisk is using: the so-called second-generation strategy (part of prevention strategy category), which aims at creating important and meaningful improvements on a product, selling to the same customers' segment.

CHAPTER II - NOVO NORDISK COMPANY OVERVIEW

Novo Nordisk is a leader in four main sectors and it has a global diabetes care value market share of about 27%: diabetes care, obesity, hemophilia and growth disorders

According to the 2016 sales report, the amount of sales in that year is DKK 11.8 billion. Diabetes and obesity care account for 80% of 2016 sales and Hemophilia accounts for 9% of sales.

In order to get a good picture of the company in scope, three strategic analysis are conducted: The 3C framework, the Porter's Five Forces Analysis and the SWOT analysis.

With the 3C framework it is developed an analysis of customers, competitors and the company itself. Firstly, Novo Nordisk's customers are patients, therefore another company that sells the similar, but likely effective drug that patients need, may be mistrusted at the beginning; however, when generic firms sell equivalent products at much lower prices, customers are willing to switch toward those. Secondly, competition affected the company a lot in the past five years, meaning that Novo Nordisk suffered big losses and the last year, it had to declare a considerable amount of people to lay off. Competition is expected to growth in the next years and this fact goes hand in hand with the increase in the number of patients affected by diabetes and obesity. Talking about the company, it is important to mention its strategy: <Driving change

to defeat diabetes and other serious chronic conditions⁶¹. Given the current economic condition of the pharmaceutical industry, Novo Nordisk has decided to adopt a different investment strategy from the past; in fact, with the increase in R&D costs and with payers less willing to pay for innovation, the investment projects must be better selected and scrutinised before arriving at the latest stages of the pipeline. The recent drawback pushed Novo Nordisk to a new defensive strategy to reduce the risk of patents expirations and new coming competitors; Novo Nordisk is indeed converging toward new markets in strong expansion, hence, it is focusing on reaching a new customers segment, expanding its leadership especially within the diabetes and obesity area.

Porter's Five Forces Analysis focuses on: threat of new entrants, power of suppliers, bargaining power of buyers, availability of substitutes and intensity of rivalry.

The threat of new entrants is relatively low in the pharma industry, except for generic pharmaceutical companies, but they must wait until branded products' patents expiration date to have access to the market. Yet, they represent one of the biggest threat, because they can take over a big portion of the market share. The power of suppliers is very low, as well as the bargaining power of buyers. The lack of power regarding pricing is due to the fact that, only the insurance companies that acquire drug products from the pharma companies can somehow regulate the price of distributors, but they have no power with manufacturers' decisions. Also, professionals do not profit from the selling of drugs, on the other hand, pharmacies and medical institutions that accomplish patients' prescriptions have a margin of negotiations, but they are not incentivised to lower prices to customers. Therefore, patients who represent the last step of the value chain, are in a very disadvantaged position, in which they have zero-negotiating power because of their need of being cured and having access to the drug products that they require.

The availability of substitutes is quite high either in the diabetes and obesity sector. Finally, the competitive rivalry is influenced by the lack of public information, because non-disclosure agreements and non-compete clauses represent a huge obstacle for competitors, that in such way, are not able to deeply analyse the industry and create substitutes.

⁶¹ Novo Nordisk Annual Report 2016

Finally, from the SWOT analysis, it results that among the strengths of Novo Nordisk there are: its expertise and worldwide presence, the company increasing market portfolio and it has also experienced business units and a good diversity in senior management, which calls for new and different perspectives and opportunities for improvements. Novo Nordisk recently reduced its labor costs to align with expected future revenues and it also increased its growth rate. Talking about weaknesses, Novo Nordisk has huge R&D costs, as well as distribution costs, due to its worldwide presence. Moreover, the long time and the high cost to approve a product in its different development phases represent a big slowdown of the company performances, competition is increasing very fast and Novo Nordisk does not have a big portfolio of products, meaning that it is not differentiated to mitigate the risk of generic entrants on the market. On the other hand, Novo Nordisk has lots of opportunities to potentially exploit: the population affected by diabetes and obesity diseases will increase in a disproportionate amount in the next years, giving pharmaceutical companies the opportunity to increase revenues and profit margins; together with that, there are the increase of urbanisation and average life expectancy, the rise in the access to healthcare, the presence of many products in the firm's pipeline and the willingness to expand the business in developing countries. Among the threats that Novo Nordisk is facing, there are those regarding the changing government regulations (especially in the US). For instance, the risk of rebates in the US, together with the risk of reducing drug prices for patients, increasing in interest rates, taxes and costs of raw materials, might reduce the margin of the company. Besides that, there is also the risk of bioequivalent products which are sold at a lower price and the threat of patent pending, or the risk of losing time and money during the patent's approval process.

CHAPTER III - RISK IDENTIFICATION AND QUALITATIVE RISK ASSESSMENT

The process-step ERM assessment includes the risk categorization and definition, to create a comprehensive list of the main risks that affect a company. The risks taken into scope for the qualitative assessment are the following: Competition and global market, biosimilar competition, loss of intellectual property rights, risk of rebates, legal and compliance risk,

compromised operational quality and delay, breach of information technology and currency impact. After assigning likelihood and severity for each risk, through the qualitative scoring criteria, the risk of intellectual property rights loss and patent cliff phenomenon result as the major risk to deep dive in. The patents' permission is necessary to avoid generics from taking over the market and to recover the research and development costs that the company faces when producing a new drug. Considering also the fact that returns from R&D investments are visible just in the long term, pharmaceutical products must be protected to ensure a proper financial return; in the short term, the loss of exclusivity of a product causes financial losses and decrease in market share.

The IPR risk analysis shows that two main products of diabetes and obesity care segment- Victoza® and Saxenda® - will expire in 2022, exposing Novo Nordisk to the risk just mentioned. In particular, in Novo Nordisk the patent cliff threat is likely to materialise especially in the years between 2021 and 2024, even though the products that Novo Nordisk is about to launch, or that are now during the last clinical phases will expire in around 15-20 years.

Historically, Victoza® has been the driver of sales and Saxenda® was launched later on the market has an “equally profitable” product. Given the fact that patent expiration can't be avoided, it is very difficult for Novo Nordisk to exploit efficient mitigation actions. The company continuously monitor and analyse its competitors and make internal controls that aim to minimise its vulnerability to other players. After taking mitigation actions, Novo Nordisk can alleviate the impact on profit of new generics entering the market or anticipate existing competitors' move. Therefore, the next step of the risk assessment process is to analyse the impact of this risk. For the purpose of this theses, the focus is limited to the impact on sales of Victoza® and Saxenda® in US, that is most profitable market of Novo Nordisk.

CHAPTER IV - IPR LOSS RISK AND PATENT CLIFF QUANTIFICATION

The baseline company value is defined as the operating profit of Novo Nordisk, that comes from the evaluation of the long-term growth of sales of two main products, Victoza® and Saxenda®, based on current expectations. Sales amount is one of the relevant metric used for the

quantification of the shocks, which are described as changes to the expected value or as any deviation from the baseline. Revenues are given by *Number of unit sold * Sales price*, however an increase or decrease in revenues is either caused by a change in volume of unit sold, or by a change in price.

Those sub-components of revenues may vary for many reasons, however the variable that mostly influence the sales' value is the social and demographic trend; more specifically, the US' population growth and the spread of diabetes and obesity illnesses.

Victoza® and Saxenda® are analysed separately, however there are three important variables used for the evaluation of the products' sales: Number of people affected by the illness and people treated, price per unit sold, per person and market share of the company.

After defining the relevant metric to use for the construction of the ERM model, the second step consist in identifying how the sub-components of sales vary to evaluate the sales' long-term growth, which give the current baseline-value of the model before subtracting operating costs. Once known the baseline sales value, the next step is to evaluate the risk impact; in order to do so, it is made an analysis of competitors which already have experienced the patent cliff risk and its impact on some main products' sales. The competitors are taken in scope because they implemented the same strategy that Novo Nordisk will apply to contrast the risk impact: the second-generation strategy. From the competitors' analysis, it is possible to take out two key findings:

- The average sales loss at the patent's expiration year of the first product introduced is -29.42%; while its loss one year after the expiration date is -58.09%. After that, the sales loss is assumed to be -100%;
- Since a decline in sales is inevitable, it is reasonable to state that the second generation strategy is effective if the combined sales level after the expiration date of the first product is maintained at least close to the sales of the product prior patent's expiration and before the introduction of its substitute⁶².

The next step is attributing the impact of the risk on the products' sales in the baseline-case scenario pre-mitigation actions. Considering fixed COGS of 15% of revenues, the combined net

⁶² Approach developed by Henriette, A.C. van Looveren in her Master Thesis, Pharmaceutical companies and their patent expiries, what do pharmaceuticals do to maintain their sales value?

sales value of Victoza® and Saxenda® is \$1.921 in 2022. The main costs to subtract to get the operating profit is given by SG&A costs, which in year 2022 are expected to account for 34,70% of sales, while R&D costs are expected to take 15,34% of the sales portion. Finally, the operating profit in the baseline scenario is \$960, while the EBIT Ratio - which is the operating profit as percentage of Gross sales – is 42,47%.

Once assessed the gross impact of the risk on the baseline value, the different assumptions on the *Pessimistic* and *Optimistic* scenarios are applied to the same variables used for the calculation of net sales, as well as for the calculation of the main costs of the company: inflation, market shares, R&D costs and SG&A costs.

In an ERM assessment process it is very important to identify the mitigation actions to put in place to contrast the risk: as anticipated, the strategy that Novo Nordisk is using to offset the sales loss of Victoza® and Saxenda® is called second generation strategy. More specifically, the company is planning to launch two similar products for the same segment of customers.

The substitute of Victoza® is called Semaglutide NN9535 and it currently is in the last phase of development⁶³ and expected to be launched in year 2020. Regarding Saxenda®, a substitute of this product is currently in Novo Nordisk's pipeline and it is called Semaglutide NASH 9931, however the product is just in phase II development; thus, it is expected that – if the product overcomes positively all clinical trials – it will be launched in year 2024.

For the substitute of Victoza®, considering that it is assumed to be launched in 2020, in order to calculate the net impact on sales post-mitigation actions, some assumptions are made to establish the future sales value of the new product: the future market share of Semaglutide NN9535 will grow at the same pace as Victoza®'s and considering that is exactly the same clinical treatment as Trulicity® (manufactured by Eli Lilly), to estimate the potential price applied to this product, Trulicity®'s prices⁶⁴ (from its launch in 2015 to year 2017) are taken as a proxy for the sales projection. The next step in the assessment is the calculation of net sales and operating profit post-mitigation actions, The net sales amount is \$2.619. Even though the strategy applied for Saxenda® does not work, its sales value is so minimal that does not

⁶³ Novo Nordisk Pipeline, Novonordisk.com

⁶⁴ Medicaid USA Drug Prices, prices are reported per Mg. Since Trulicity® is sold in a pack with 1,5Mg/0,5MI pen for a once-weekly use, the price per year, per patient is calculated just multiplying by 48 (weeks)

influence that much the sales level in year 2022. Indeed, the sales drop at the expiration date of the two products is -13.8%, compared to -29.4% without mitigation actions. After calculating the net sales value, the operating costs are applied to get the operating profit, which amount is expected to be \$1.309 in year 2022.

The last step in the analysis is the calculation of the Individual Risk Exposure, as the “quantification of multiple deterministic scenarios for the key risk, in terms of its potential impact on the baseline value” (Segal, 2011) and the Summary Statistics related to it.

Table 36-Individual risk exposure

Individual Risk Exposure (USD million)		Pre-Mitigation Actions		Post-Mitigation Actions	
<i>Scenarios description</i>	Probability	EBIT 2022	Delta from Baseline	EBIT 2022	Delta from Baseline
<i>Pessimistic</i>	15,0%	720	-239	918	-390
<i>Baseline</i>	75,0%	960	0	1.309	0
<i>Optimistic</i>	10,0%	1.395	435	1.901	593

Table 37-Summary statistics: Individual risk exposure

<i>Summary Statistics</i>	Pre-Mitigation	Post-Mitigation	Delta from pre-mitigation	% delta from pre-mitigation
<i>Baseline</i>	960	1.309	349	36%
<i>Expected Value</i>	967	1.309	342	35%
<i>Std dev. from Baseline</i>	166	241	75	45%
<i>Std dev. from Exp. Val.</i>	166	241	75	45%
<i>Range</i>	674	983	309	46%

Looking at the table above and going through the summary statistics what is possible to understand is that:

-The post-mitigation baseline value is to considered high enough to efficiently offset the patent cliff risk. The baseline value is 36% higher when implementing the mitigation actions, even though these covers just one of the two products in scope;

-The post-mitigation expected value is 35% higher than the pre-mitigation expected value. This means that the mitigation decision increases Novo Nordisk's sales even though the introduction of a new product raises the total COGS, R&D and SG&A costs and it is considered risky;

-The standard deviation from the baseline and from the expected value shows the degree to which the pre and post mitigation results are considered risky. The value obtained from both (45%) shows that the second-generation strategy is very risky; indeed, with a higher amount of operating profit there is also a higher risk connected to the investment in a new product, which is reflected in raising of R&D and SG&A costs. When the standard deviation is a positive value it is called "upside volatility", meaning that the company is producing results that exceed its strategic plan, however even upside volatility means a high degree of instability and uncertainty of the mitigation actions put in place, as well as a high dispersion of values from the baseline operating profit;

-The range confirms the statements just above, in fact the range of values from the optimistic to the pessimistic scenarios with post-mitigation actions is higher compared to the value with pre-mitigation, this means a number that goes from \$674 to \$983.

It is important to mention that, when applying the same summary statistics on the Net sales value, the standard deviation from the baseline is 53%, meaning 800 bps higher than using as a metric the operating profit. The reason is that, limiting the analysis on the net sales value, the risk is to overestimate the actual value added to the balance sheet, because it does not take into account the costs occurring from the new strategy put in place by the company.

CHAPTER V – WRAP-UP

The model developed in this thesis has not to be considered as a tool to verify if Novo Nordisk's strategy is appropriate or effective, rather it gives an understanding of the company's performance based on the strategy that it is planning to achieve in the next years.

The tool presented in this thesis aims at identifying, monitoring and quantifying the impact of one of the key risks of Novo Nordisk's sales and operating profit. The patent cliff risk that will affect the two products in scope (and the rest of Novo Nordisk's pipeline) is a challenge that has

always been a reason of struggle for pharmaceutical companies and it will always be, because of the particular nature of the industry. The analysis reveals the primary role of patents as a key variable to produce high sales for pharmaceutical companies; the quantitative assessment also shows how the patent itself can be a source of losses when its expiration date comes, forcing firms to actively prevent that, even many years before. Indeed, some of the main challenges for pharmaceuticals are firstly, the creation of a clinically effective product, secondly the prediction and planning of future sales of the new drug.

It shall be noticed that this paper reveals useful information to measure the sensitivity of sales value to the impact of losing patents' protection of a product, however - for the reasons explained above – a future prediction of sales is hard to perform when it takes into account human behavior, and especially how this behavior can influence illnesses trends. The ERM tool provided also identifies the key role of demographics trends to develop a scenario analysis of medicines' sales; the population affected by diabetes and obesity is projected to disproportionately growth, even in few years from now, reflecting the need to keep investing in their treatment. From the developed tool, it is also clear how with an increase in those trends, it is projected a steady increase in sales of the medicines able to cure those illness-, in fact, future sales are calculated taking into consideration those demographic changes, thanks to the information available from Diabetes International Association and IMS Health. The second-generation strategy that Novo Nordisk applies is one of the most common strategies used from pharmaceuticals to contrast the patent cliff risk. From the model, though, it is resulted that the second-generation strategy is actually ineffective when applied on Saxenda® later than the expiration date of the main product's patent; Saxenda®'s losses are not covered by the strategy put in place, however Saxenda®'s sales combined with Victoza®'s reflects how the company is actually able to reduce the risk impact, even with inevitable sales losses.

The constant presence of a rich pipeline is a robust measure of a pharmaceutical company's strength, although this means significant costs which are recovered just after years from the investment. At the same time, a rich pipeline does not mean a superior ability of the company to overcome the patent cliff risk; therefore, Novo Nordisk must provide other initiatives to contrast the patent cliff risk. Other preventive actions that Novo Nordisk can take to avoid those risks are:

- Investing in other business segments
- Externalisation of late-stage pipeline

The first option that Novo Nordisk has is investing in other business segments; this means targeting other customers and creating a completely different new market; the risk occurring from patent losses can be better faced with a differentiated portfolio of products, such that customers cannot influence each other. A diversified portfolio leads to a new market, but it is important to recall that the increase in competition do not encourages Novo Nordisk in investing in something different; moreover, often the return of investment of a biopharmaceutical company does not even cover its cost of capital. Indeed, there are actually more efficient strategies to avoid large R&D investments.

The second option that Novo Nordisk has is the externalisation of late-stage pipeline. This approach aims at increasing the number of products in the pipeline, but increasing in less proportion the development costs related to them.

Pharmaceuticals already use traditional ways of reducing the risk of investing in new products through licensing, acquisitions or partnerships, however new models of partnership allow the firms to divide the financial investment and the operational (and executional) control, to obtain the maximum return, sharing and reducing the upfront risk.

One of the options of externalisation is to Join Venture, however this raises many issues in terms of IPR protection and IP appropriation can be a large source of losses for a company; however, there are some strategies that can be put in place to avoid this risk (legal and logistic).

Taking into consideration the risks coming from it, the externalisation can be done in several ways, depending on the company's capacity and financial assessment. For instance, a company like Novo Nordisk that currently has limited capital but enough late-stage development capacity, can make an insurance contract to hedge the pipeline risk. Hedging the pipeline means paying a premium that allows the company to get a reimburse of the costs sustained for the development of the hedge product, if it fails during the late-stages phases. With this strategy, Novo Nordisk can drastically reduce the risk of losses only when the early-stage R&D costs of the product have already been paid for it; however, it is unlikely that insurers want to share the potential costs of a product failing at the beginning of its development.

Empirical evidences⁶⁵ show that there is a classification of the most used mitigation strategies on patent cliff risk and their effects in terms of annual revenues losses in US; some of the most used strategies have been mentioned in Paragraph 1.3.2 Patent cliff escaping strategies.

The strategy most used in pharmaceuticals is the Pediatric Exclusivity, which consist in guarantee that a treatment is not only effective in adults, but also on pediatric population; this allows companies to extend the exclusivity period on a different customers' segment; the second most used strategy is the Authorised Generic, which is part of the adaptation strategy and allows a branded company to launch a product under private label, like a generic one, at generic prices. The third most used strategy is the re-formulation of the product, which can be either seen as part of prevention or innovation strategies, depending on the degree to which an existing product's composition is altered to provide improvements. Another used, but less spread approach is to sell a product OTC (this approach is part of the innovation strategy).

Given the most common used strategies to mitigate the patent cliff risk, from the Rutgers Research, it is also stated that, even though some mitigation actions are more used or spread than others, they all have a similar effect on revenues, decreasing the annual global impact (on average) by 29,4%, in a range that goes from a 19% to 40% revenues change comparing pre and post-mitigation revenues. The annual global impact on sales in the present analysis is changed by 36%, giving a result that is in between the range showed by the Rutgers Research. The analysis shows that the second-generation strategy used by Novo Nordisk actually has a meaningful effect in avoid the sales cliff; 1.3To conclude, it is important to state that the effectiveness of a strategy strictly depends on the unique characteristics of a company and its capacity, in terms of equipment, IT, human resources and capital.

⁶⁵ Patent cliff mitigation strategies: analysis of current trends and implications, by Brian Lee, PharmD; Amanda White, PharmD, MBA; Dhaval Patel, PharmD; Manish Patel, PharmD; Michael Toscani, PharmD Rutgers Pharmaceutical Industry Fellowship, Rutgers University, Piscataway, NJ P show the mostly utilised mitigation strategies over patent risk, as well as their impact on annual revenues in the US

CONCLUSION

This thesis is an interesting implementation of the Value-Based Enterprise Risk Management approach on the financial performances of a big pharmaceutical company like Novo Nordisk A/S.

The tool developed gives an understanding of the complexity of the pharmaceutical industry, as well as the impact that one single risk can have on the sales performance of Novo Nordisk; it is interesting to see how just two of the products manufactured by a single company can actually determine a large portion of revenues. When the patent cliff risk materialises it is very difficult – even for a financially stable firm – to take actions against it; when talking about pharmaceuticals, it is, indeed, very important to plan the strategy to be used to tackle the patent cliff risk, long time ahead.

The first two chapters of this thesis explains the unique characteristics of the pharmaceutical industry: if on one hand, most of the large pharmaceutical companies established a monopoly (or duopoly) on the market thanks to the possibility to determine the price of manufactured medicines, on the other hand, research and development costs are very high and they are repaid just after 15-20 years from the product manufacture. The benefits of patents last until its expiration, when the company has to deal with several threats: rivalry increasing exponentially from existing competitors and from generic drugs firms, drop in prices and loss of market share. All these factors combined generate a significant negative financial impact, that the author estimates through the ERM assessment on Novo Nordisk; to begin with, the impact on Victoza® - which represents 25% of US sales - is much larger than the impact generated by Saxenda®. Through the ERM tool created, it is quantified the severity of the impact on the two products' sales combined, net of COGS and also and the Operating Profit of Novo Nordisk, obtained subtracting R&D and SG&A costs. The transmission channels used to develop the assessment shows the relevance of social and demographic trends on pharmaceutical companies, which are high dependent on “extraordinary factors” difficult to predict and assess.

The choice to analyse the patent cliff risk comes from a qualitative risk assessment (performed in Chapter 3) that provides a comprehensive view of some of the major risks for Novo Nordisk, classifying them into several risks categories and sub-categories. The qualitative risk assessment

aims at identify the root causes of the risks and therefore, the classification of the risks that can mostly impact the company's financial performances.

Through the risk scenarios created it is possible to quantify the severity of this impact considering the optimistic and pessimistic cases, in which the patent cliff risk's effect on net sales and operating profit is lower or higher than the baseline. After that, the ERM model quantifies the individual risk exposure on the operating profit given by Victoza® and Saxenda®, either on the pre-mitigation results and on the post-mitigation results; the baseline value achieved after putting in place mitigation action is 36% higher than the pre-mitigation value, showing that the strategy analysed to offset the patent cliff risk is meaningful and useful to sustain the sales value resulted after the patents expiration.

The mitigation actions are a fundamental part of an ERM assessment, since they explain how to tackle a risk that will eventually materialise, considering the current resources that a company can use.

In the model created, the strategy that Novo Nordisk is planning to achieve is the so-called second generation strategy. An analysis of other pharmaceutical companies that used the same strategy in the past, is made to quantify the potential impact of the patent cliff risk and to use it as a proxy on Novo Nordisk.

Finally, the post-mitigation actions results show the degree to which Novo Nordisk's strategy offsets the risk effect and they also show the volatility caused by the strategy itself. One can argue that the standard deviation from the baseline value is high, even though positive. In fact, the purpose of this assessment is to actually show the results that Novo Nordisk can obtain applying the second generation strategy, and not its effectiveness.

Another benefit of the ERM assessment, indeed, is the practicality of the model, which provides a robust approach to assess the risk exposure and a comprehensive view of the strategy to apply.