Financialization, Intellectual Property Rights, and Global Wealth Chains in the Insulin Market

MSc in International Business and Politics

Master Thesis

May 15, 2023

Supervised by Leonard Seabrooke

Student name: Marianna Irma Sobkiewicz

Student number: S120410

Pages: 61

STU: 100205

Table of Contents

Abstract 4

List of abbreviations 4

1 Introduction 5

2 Literature review 7

2.1 The History of TRIPS 7

2.2 Patents (as assets) 9

2.3 Financialization in the Pharmaceutical Industry 15

2.4 Global Value Chains 15

2.5 Global Wealth Chains 17

2.6 Markets as Politics 18

2.8 Summary of key points 19

3 Methodology 20

3.1 Philosophy of science 20

3.2 Research Design 22

3.2.1 Research strategy 22

3.2.2 Mixed methods approach 23

3.2.3 Data collection 24

3.3 Limitations 25

4 Analysis 26

4.1 Insulin prices in the US 26

4.2 Profit distribution 27

4.3 The United States vs rest of the world 32

4.4 Patents on insulin products 38

4.4.1 Lantus (Sanofi) 39

4.4.2 Patent landscaping 40

4.4.3 Purple Book 42

4.4.4 Insulin's patent landscape 42

4.5 Global Wealth Chains 53

5 Discussion 59

6 Conclusion 62

References 64

List of figures

Figure 1. Average cost of insulin in North American and European countries in 2018 27
Figure 2. Eli Lilly's Net Shareholder Payout vs R&D spending in 2008-2022 28
Figure 3. Novo Nordisk's Net Shareholder Payout vs R&D spending in 2008-2022 29
Figure 4. Sanofi's Net Shareholder Payout vs R&D spending in 2008-2022 30
Figure 5. Big Three's ratios of Net Shareholder Payout to R&D spending in 2008-2022 31
Figure 6. Eli Lilly's ultimately owned subsidiaries by country (only countries with 10+ subsidiaries are shown) 34
Figure 7. Novo Nordisk's ultimately owned subsidiaries by country (only countries with 10+ subsidies are shown) 34
Figure 8. Sanofi's ultimately owned subsidiaries by country (only countries with 10+ subsidies are shown) 35
Figure 9. Eli Lilly's total sales to the US vs rest of the world in 2008-2022 36
Figure 10. Novo Nordisk's total sales to North America vs rest of the world in 2008-2022 37
Figure 11. Sanofi's total sales to North America vs rest of the world in 2008-2022 37
Figure 12. Big Three's insulin-related patents over time 52
Figure 13. Modular GWC governance of insulin manufacturers 55
Figure 14. Big Three's subsidiaries based on their FSI value 58

Abstract

This thesis investigates three leading insulin companies – Eli Lilly, Novo Nordisk, and Sanofi – in the context of financialization, intellectual property rights, and Global Wealth Chains. Through these lenses, it seeks to provide an understanding of the broader political and economic determinants of high drug prices in the United States. Findings show that, although distinctive, the case of insulin prices is representative of a greater issue in global drug markets. Pharmaceutical manufacturers have been incentivized to rely on intellectual property portfolios made up of large quantities of patents to extend and maintain a monopolistic grasp on their markets. Moreover, contemporarily, many pharmaceutical MNCs operate based on highly financialized business models, according to which they are expected to continuously deliver short-term returns to their shareholders. This thesis seeks to contribute to the research agenda that studies pharmaceutical companies' role in the issue of high prescription drug prices in the United States.

List of abbreviations

FDA - Food and Drug Administration

GVC - Global Value Chain

GWC - Global Wealth Chain

IPC - Intellectual Property Committee

IPE - international political economy

IP(R) - Intellectual Property (Right)

MNC - Multinational corporation

OECD – Organisation for Economic Co-operation and Development

R&D – Research & development

TRIPS - Agreement on Trade-Related Aspects of Intellectual Property Rights

TTM – Net Shareholder Payout

USPTO – United States Patent and Trademark Office

USTR - United States Trade Representative

WTO - World Trade Organization

1 Introduction

Prescription drug prices in the United States have soared in the past decades. Pharmaceutical companies face increasing scrutiny but tend to argue that high list prices are a prerequisite for investments in research – required for innovation. The drug pricing crisis in the United States affects millions of patients – compelling many to spend hundreds or thousands of dollars monthly on medication or forcing some to ration. Although certain issues are common to all high-priced prescription drugs, the insulin market faces certain distinctive political, regulatory, and economic challenges. Even though insulin was discovered a century ago, the insulin market remains highly patented, with three companies controlling it almost entirely. Patients living with type 1 diabetes depend on insulin to survive – their bodies do not produce it. Research has shown at as many one in four patients in the United States have rationed insulin because of its high cost (YaleNews, 2018). Thus, the drug pricing crisis has vast socio-economic consequences for the U.S. population.

Between 1999 and 2019 the cost of a vial of Humalog, an insulin produced by Eli Lilly, increased from $21 to $332 - reflecting a price hike of more than 1000 percent (Rajkumar, 2020). Humalog is not an isolated case but indicative of a far broader issue of soaring insulin prices in the US. A recent study shows that insulin list prices increased by 262% in the years 2007-2018 (Hernandez et al., 2020). While the United States comprises only 15 percent of the global insulin market, it accounts for almost 50 percent of insulin-related revenue in the world (Knox, 2020). Although a prime example of modern capitalism dynamics, the problem of high insulin prices is a consequence of the exact opposite of a free market. Three pharmaceutical companies represent 99 percent of the global insulin market[1]. According to a recent report by the Senate Finance Committee, Novo Nordisk repeatedly engaged in a practice known as "shadow pricing", in which it tracked Sanofi's price increases to mirror them "within days or even hours" (Grassley & Wyden, 2022, p. 6).

[1] These three companies collectively represent 99% of the global insulin market by value.

Eli Lilly (United States), Novo Nordisk (Denmark), and Sanofi (France) are sometimes collectively referred to as the "Big Three". All three are multinational corporations (MNCs) that sell their medications across the globe, but the U.S. market bears unique significance to them.

As a rule, when generic drugs enter pharmaceutical markets, producers of branded products experience a decrease in their revenues due to increased competition and thus, downward pressure on prices. However, the Big Three's oligopolistic grasp on the market has prevented competitors from entering the US market for decades. At the same time, list prices of generic drugs also tend to be higher in the US than in other developed countries (RAND Corporation, 2020), thus indicating that the introduction of generics to such a market would not serve as a panacea for high prices.

This thesis seeks to answer the following research questions:

RQ1: How have lead insulin firms distributed their profits in the period 2008-2022?
RQ2: How prominent is the role of U.S. market operations for lead insulin firms?
RQ3: What is the extent of intellectual property protection over the most popular insulins on the market?

The thesis is comprised of six chapters. Following the introduction, the second chapter presents a review of the literature on the history of TRIPS – the most significant international argument on intellectual property rights in relation to trade; patents as assets; financialization of the pharmaceutical industry; Global Value Chains; and finally, Global Wealth Chains. The third chapter outlines the methodology according to which the study has been carried out, including the employed philosophy of science, the research design, and its limitations. Further, the fourth chapter presents the analysis of companies' profit distribution, their embeddedness in the United States jurisdiction, their net sales in the United States, and their intellectual property portfolios. The analysis ends in an operationalization of the GWC governance to understand

how insulin manufacturers create and protect their wealth chains. Chapter five presents the discussion on findings against the background of relevant literature, and the last chapter presents the conclusions and reflections for further research.

2 Literature review

2.1 The History of TRIPS

The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) is an agreement between all member states of the World Trade Organization (WTO) that establishes minimum standards of intellectual property protection. Although TRIPS was largely based on earlier multilateral IPR agreements, it fundamentally altered the intellectual property regime by substantially extending property rights on a global scale (Sell, 2002). Only twelve corporations were primarily responsible for the lobbying efforts behind the agreement. Importantly, TRIPS was not a case of simple lobbying but a sophisticated form of global networking, a product of tireless agency and economic coercion.

The story of TRIPS is largely a story of ideas - of how powerful they can be if disseminated through the right channels. According to Drahos, the agreement was part of a much broader agenda that had been laid out by the OECD in the 1960s and the early 1970s - a time when "a lot of ideas for transforming the world economy were thought about and written about" (Drahos, 2016). The fundamental objective of this agenda was to allow capital to move freely so that firms could obtain the most favorable circumstances possible. To make that possible, processes of deregulation are required. The pharmaceutical industry was the main driving force behind the TRIPS agenda. Pharmaceutical companies understand better than most others how consequential public policy can be for business operations. Drugs are subject to strict regulation by government agencies but at the same time, if already developed, can be imitated easily and inexpensively. Therefore, the growth of pharmaceutical firms depends heavily on them fighting off antitrust enforcement (Drahos, 2003).

In the 1980s, a group of Washington-based policy entrepreneurs thought up the idea that the intellectual property regime could be related to the trade regime. At the time, this was a radical policy proposal with profound implications for national sovereignty over intellectual property rights. Pfizer executives, with CEO Edmund Pratt among them, were some of the leading proponents of this idea. They employed their networks in two distinct ways. Firstly, Pfizer executives used established business networks to "disseminate the idea of a trade-based approach to intellectual property" (Drahos, 2003, p. 3). Secondly, Pratt in particular made use of the interlinking of networks to put himself forward as "someone who could develop US business thinking about trade and economic policy" (Drahos, 2003, p. 4).

In her book "Private Power, Public Law: The Globalization of Intellectual Property Rights" Sell (2003) also gives a detailed account of the lobbying behind TRIPS. The author provides an analysis of the power of multinational corporations in constructing intellectual property law. The main insight that emerges from the book is that power in international politics is increasingly exercised by private actors rather than governmental bodies. Sell highlights that the outcome of TRIPS was a global intellectual property regime that "reaches deep into the domestic regulatory environment of states" (Sell, 2003, p. 1). And perhaps what remains most striking about the history of this agreement is the fact that, as mentioned above, it was orchestrated by a very small group of private actors - the *ad hoc* US-based Intellectual Property Committee (IPC), which consisted of only twelve chief executive officers.

The IPC was set up to develop an international agenda for strengthening IP protection and to find the needed support. The proposal for this global agreement was drafted based on industrialized countries' existing laws. Sell proposes a synthetic approach to analyzing the globalization of IP rights, based on different perspectives. On one level, she suggests, "TRIPS is a 'can do' story about twelve men" who were remarkably effective at pushing their agenda. However, Sell also calls attention to the fact that including intellectual property rules in a multilateral trade regime "made no sense on its face" (Sell, 2010, p. 763). While multilateral

trade policy tends to accelerate trade liberalization by reducing tariffs and other barriers, intellectual property policy is based on the opposite - *rationing* access. By granting temporary monopoly privileges, it effectively obstructs competition.

US policymakers remained skeptical of extending intellectual property protection for most of the twentieth century. However, in the last two decades of the century, they became increasingly concerned with international competitiveness. This, in conjunction with the lobbying work of private actors who advocated for extending IP rights multilaterally, led them to strengthen relevant domestic institutions, in particular the Office of the United States Trade Representative (USTR). Sell (2010) argues that historical institutionalism can provide an understanding of how internal institutional change in the US resulted in the emergence of a global intellectual property regime. Institutional layering can be seen as having given a framework for coalition building to a group of initially disparate private actors. Institutions, including legal norms, are an integral part of the global political economy. TRIPS is an example of policymakers giving private agents access to top-level policymaking.

According to Sell (2017), intellectual property law is one of the most intensely contested and political areas of international law. She also calls the adoption of TRIPS "one of the most dramatic instances of international market regulation in the twentieth century" (Sell, 2010, p. 1). The author highlights the fact that TRIPS resulted in profound distributional consequences in the form of substantial rent transfers from developing markets to OECD-based firms.

2.2 Patents (as assets)

Ideationally, patents should be a means of encouraging innovation and knowledge sharing by providing the inventor with exclusive rights to the patented discovery for a designated period. Importantly, Kang (2020, p. 46) emphasizes that it is "neither new nor surprising that patents serve as mechanisms of generating monopoly rents on innovations". At the same time, criticisms of patents as monopoly rights are valid because they put the underlying principle of the patent system into question. These systems are built on the assumption that a temporary

monopoly promotes innovation. The modern rationale behind the creation of patents rests on two types of temporal postulates. Firstly, that the labor and investment expended should be rewarded (*ex post*). Secondly, it is assumed that the granting of a patent incentivizes further innovation (*ex ante*).

Patents were initially designed to protect innovators from intellectual theft while incentivizing them to disseminate their discoveries – but they are increasingly turned into assets instead. In their book on assetization, Birch and Muniesa (2020) argue that the primary basis of contemporary capitalism is not the commodity but the asset. The authors define an asset as "something that can be owned or controlled, traded, and capitalized as a revenue stream" (Birch & Muniesa, 2020, p. 14). Pharmaceutical companies create intricate patent constructions around their drugs - and through this, they stabilize a value regime that allows them to treat patents as assets rather than merely as a means of intellectual property protection. Bourgeron and Geiger (2022) refer to this process as "bundling". Economist Guy Standing has elaborated on this topic, calling these mechanisms a "winner-takes-all market created by the regulatory apparatus, not market forces" (Standing, 2016).

Kang (2020, p. 52) explains that "the logic of patents as financial assets takes as its object the legal form of *property itself*". A patent is valued based on the future return expected and this financial forecasting seldom accounts for the strength or quality of a patent. Therefore, the property right is treated as a financial vehicle rather than assessed in terms of the potentiality of the invention to its users. Because of this, companies tend to pursue "large quantities of patents as a portfolio" and an individual patent's worth is of less importance (Kang, 2020, p. 54).

Another important term that appears in Bourgeron and Geiger's work is "instability". Importantly, Bourgeron and Geiger (2022, p. 3) argue that the assetization of patents is "by no means an unavoidable or uncontested process". In their paper, the authors highlight the significance of activism against the financialization of business models and pharmaceutical pricing strategies that restrict access to medicines.

Langley (2021) argues that political economists have tended to overlook assetization in their research on contemporary financialized capitalism, especially considering its prevalence. The author sees assets and assetization as an "empirical blind spot". He however argues that they are not a blind spot in the sense that they are entirely neglected, but rather that they are not given the "systematic and sustained analytical attention" that they deserve (Langley, 2021, p. 383). He outlines two principal directions in which financialization research developed following the global financial crisis of 2008. Firstly, researchers have tended to characterize contemporary financialized capitalism as grounded in a financial logic that is fictitious (Haven, 2014, as cited in Langley, 2021), derivative (Li Puma, 2017, as cited in Langley, 2021), and speculative (Adkins, 2018; Konings, 2018, as cited in Langley, 2021). Langley however argues that the post-crisis financial logic is no less "real" than the rationalities of commodity production that it displaced.

Secondly, the author notes that researchers have seen the credit-debt relation as core to financialization and argues that this focus has taken attention away from the role of assetization in the contemporary political economy. Langley highlights the importance of elaborating a research agenda that foregrounds assetization. He also argues that this kind of research could complement wider political debates over wealth inequality, particularly in the Anglo-American context.

An essential insight that emerges from literature, particularly in the perspective of legal scholars, is that the incentive-rationale of patents under the TRIPS regime is "increasingly coming into conflict with investment treaties in which patents are treated as investment assets rather than commodities" (Dreyfuss & Frankel, 2015, as cited in Kang, 2020). Kang argues that the study of patents as instruments of political economy can facilitate an understanding of their "current multiple jurisdictional layers" (Kang, 2020, p. 49). The author highlights the importance of interdisciplinary critique of patent law because formalist patent law scholarship

cannot adequately measure the implications of patent assetization. This is because, from a doctrinal legal perspective, "patents do not give ownership in knowledge" (Kang, 2020, p. 50).

However, according to Kang, patent granting "has become the central legal technique of commodification within the so-called knowledge economy" (Kang, 2020, p. 50). This has raised concern among various scholars because such commodification comes into direct conflict with the nature of knowledge, or at least with how knowledge has been viewed throughout most of history - in which it should not be privately owned but treated as a public good. Recent history shows that commodification through intellectual property has far-reaching consequences – it not only obstructs access to knowledge but also to essential goods, such as medicines.

What further complicates the analysis of above-mentioned practices is still widely understood as an indicator of innovation and thus as contributing to economic growth. This view has been perpetuated for decades and led to patent information becoming "valuable as an economic unit itself" (Kang, 2020, p. 51). Economists have utilized patent data as a quantitative indicator of innovation (Griliches et al., 1987; Griliches, 1990, as cited in Kang, 2020) and as a measurement of the effects of academic research (Jaffe, 1989, as cited in Kang, 2020). However, as Kang highlights, qualitative data presents a more complicated picture, in which incentives for innovation cannot always be equated with monetary gains (European Commission, 2005, as cited in Kang, 2020). Thus, patents are not inherently valuable, but they continue to be regarded as such.

Another key argument in Kang's (2020) work, and one that cannot be separated from the ones outlined above, is that patent assetization does not necessarily align with scientific progress. In fact, financial assetization of intellectual property seems to cause the exact opposite, i.e., halt scientific invention. His argument aligns with Lazonick et al.'s (2017) work, in which they argue that there is a tension between financialization and innovation within pharmaceutical

companies. A key factor contributing to this tension is the extent of share repurchasing that firms engage in.

Kang (2020) highlights that the assetization of patents does not stop at capitalizing on technoscience. The author argues that it has further-reaching implications on law as a knowledge practice, in which "the value of patents as assets rests on the legal fiction of intellectual property" (Kang, 2020, p. 65). He also underscores the abstract entanglements of patents as assets, in which an abstract legal right is granted based on a "inventive essence" (also abstract), and this intangible property right then becomes a financial asset - totaling three levels of abstraction. Kang argues that ultimately, the financialization of the legal system itself is at stake.

Feldman (2018, p. 592) notes that "at a fundamental level, the intellectual property system exudes deep faith in the power of competition". Theoretically, it is a system designed in such a way that after an intellectual property right expires, competitors may enter the market. However, analyses of pharmaceutical markets show a vastly different reality, one that "lies far from the system's theoretical design" (Feldman, 2018, p. 593). Researchers have identified specific strategic behaviors that pharmaceutical companies engage in to prevent competitors from entering their markets. "Evergreening" has been defined as one of the main practices - in which the life of a patent (or other type of IPR) is extended artificially by "obtaining additional protections to extend the monopoly period" (Feldman, 2018, p. 596).

Feldman highlights that although researchers have collected anecdotal evidence that documents such behaviors, literature still lacks a comprehensive empirical view, and he aims to provide it. He aims to identify how pervasive such behaviors are. Only by providing a comprehensive and systematic overview, he argues, can it then be considered what kind of reforms are needed. Feldman (2018, p. 596) also points out that "transparency is not in the industry's interest", and that pharmaceutical companies' strategic behavior tends to be opaque, thus making it a challenge to provide an empirical analysis. This is an important insight that

(at least partly) explains the existence of a literature gap but also simultaneously underscores the importance of filling it.

Feldman's (2018, p. 596) results show "a startling departure from the classic conceptualization of intellectual property for pharmaceuticals". A striking statistic, based on data for the years 2005-2015, is that 78% of the drugs associated with new patents in the Food and Drug Administration's (FDA) records were existing drugs, not new discoveries. Moreover, these practices are particularly pervasive among so-called "blockbuster drugs" - more than 70% of the roughly 100 best-selling drugs in the US had their intellectual property extended at least once. Importantly, research also shows that this issue is becoming more pronounced over time, with the number of drugs being granted extensions rising. Despite these startling results, according to Feldman (2018, p. 597), "much behavior in the pharmaceutical industry remains obscured".

Research also shows that pharmaceutical companies have an immense incentive to delay the entry of generic producers, as even a few months of such a delay can be worth hundreds of millions of dollars for best-selling drugs. In a market with multiple generic competitors, prices of brand drugs can fall by as much as 80-85% (Feldman & Frondorf, 2010). Pharmaceutical producers go as far as applying for patents of questionable validity, knowingly, as they are aware that challenging a patent would be a lengthy and expensive process for generic competitors.

Researchers argue that regulatory processes surrounding intellectual property rights are some of the most complex domains of the US legal system. Arguably, it is inevitable and necessary for the regulation of pharmaceuticals to be complex, as they are complex products that interact with individuals' health and well-being. However, according to Feldman (2018, p. 643), the IP system has become convoluted, thereby giving private actors "endless opportunities" to game it.

2.3 Financialization in the Pharmaceutical Industry

In response to demands for price regulation of drugs by the US government, pharmaceutical corporations have almost invariably argued that higher prices are a prerequisite for investments in R&D. Researchers have shown that this seemingly compelling argument falls apart as soon as one looks at how pharmaceutical MNCs allocate their profits. According to Palladino and Lazonick (2021), between 2010 and 2019 publicly traded companies spent a total of $6.3 trillion on stock buybacks. When firms prioritize using corporate funds for stock buybacks, the funds available for investments (R&D or otherwise) are reduced. An analysis by Lazonick et al. (2017) reveals that the 19 pharmaceutical companies included in the S&P 500 Index as of February 2015 and publicly listed between 2005 and 2014 distributed 97 percent of their profits to shareholders in that time. A total of $226 billion was spent by those companies on buybacks, a number equivalent to 51 percent of their combined R&D expenditures. Collington's (2020) work highlights the issue of financialization in the insulin industry, and the key position of MNC shareholders in determining insulin list price increases.

2.4 Global Value Chains

Literature on Global Value Chains (GVCs) provides insights into the role of intangible assets in the emergence and maintenance of monopoly power. It is argued that monopolization of intellectual property has had such far-reaching implications for global value chains because knowledge is not limited in a physical space. Thus, ownership of knowledge results in "a global monopoly that limits the liberty of many individuals in multiple locations (Pagano, 2014, p. 1413, as cited in Durand & Milberg, 2020). Researchers argue that, as expected based on traditional theory of monopoly, this leads to a slow-down in investment. Although the expansion of GVC trade and the emergence of the international IP regime have been driven by separate factors, both phenomena can be linked to the growing role of intangible assets in production. Moreover, empirical studies support the notion that GVC trade and the strengthening of IP protection are mutually reinforcing (Durand & Milberg, 2020).

Although the expansion of intellectual property protection favors imports of technology-intensive goods, increased IP protection does not benefit economic development. Research shows no evidence of a positive effect of a stricter IP regime on innovation or productivity. In fact, empirical studies demonstrate that the strengthening of IPRs "has at best a nonsignificant effect on economic complexity and most often has a negative effect" (Sweet & Eterovic Maggio, 2015, as cited in Durand & Milberg, 2020). Moreover, patents are overwhelmingly concentrated in developed economies. The US, the EU, and Japan together account for 82.5% of triadic patents in the world - i.e., patents registered at the three major patent offices, which are located in those jurisdictions.

Industrialized countries' receipts of international IP payments were more than 100 times higher than those received by low- and middle-income countries in 2016. Moreover, even within developed economies, receipts concentrate heavily in a handful of countries, with the US accounting for 38.4% of international payments in 2015. This skewed distribution of payments proves the dominance of firms based in high-income countries, which is "both the rationale for, and the result of, their efforts to broaden and tighten IPRs" (Durand & Milberg, 2020, p. 414).

Importantly, the highly skewed distribution of intangible-intensive and tangible-intensive producers limits the ability for "social upgrading" of the latter. As a result, firms in developing economies have obstructed access to improvement in wages and labor standards. Although the distribution of rents from intellectual property is not the sole reason behind this, it should not be overlooked as a driver for such global inequalities. However, as Schwartz (2019) notes, the US political economy also exhibits slow growth and rising income inequality. He argues that firms' "pursuit of monopoly profit through control over IPRs embedded in a vertically disintegrated production chain is the main cause for decreased investment" (Schwartz, 2019, p. 16-17). This, in turn, results in the concentration of profits in the hands of few, thus contributing to rising income inequality in the US. Durand and Milberg (2020) propose a taxonomy of rents related to intangible assets. The authors classify patents on pharmaceuticals

as *legal IP rents*, in which judicial enforcement protects patent owners through artificially rationing the use of protected knowledge.

2.5 Global Wealth Chains

In the recent decades, deregulation has permitted companies to disaggregate activities across numerous jurisdictions to obtain the most favorable market circumstances. Because of this, scholars have even suggested that MNCs could be referred to as "post-national" (Desai, 2008, as cited in Seabrooke & Wigan, 2017). Multiple authors explain how, because of global deregulatory trends, capital has been able to move freely between jurisdictions, thus allowing for a "permanent schism between the location of value creation and the geographical allocation of profits and wealth" (Leyshon & Thrift, 1997, as cited in Seabrooke & Wigan, 2017, p. 2). It is worth noting that the recounts given by these scholars correspond with Drahos' description of the economic tendencies that laid the foundation for TRIPS.

To allow for a more profound understanding of these processes, Seabrooke & Wigan (2017, p. 2) propose a theoretical framework for "Global Wealth Chains", which they define as "transacted forms of capital operating multi-jurisdictionally for the purposes of wealth creation and protection". The authors highlight that capital takes increasingly abstract forms, thus making it difficult to delineate it. They mention intellectual property as one of said abstract forms, which makes their framework relevant for the discussion of patents as assets. In the creation of their theoretical framework, Seabrooke and Wigan (2017) are focused primarily on regulatory liability in terms of distinguishing between types of wealth chains. This is because, as they underline, a lot of GWC activity is guided by the intent to avoid codification by third parties.

The authors define three factors that can be used to analyze GWC governance:

1) The *complexity* of information and knowledge transfer with regard to the product or service being provided by the supplier to meet the client's requirements;

2) The *regulatory liability* involved in transactions and the ease of multi-jurisdictional regulatory intervention;
3) The *capabilities* of suppliers to create solutions to mitigate challenges to the status of the product or service by regulators.

In their typology, Seabrooke and Wigan identify five different types of global wealth chain governance, as demonstrated in the table below.

Table 1. Key determinants of Global Wealth Chain governance

Table 1 Key determinants of Global Wealth Chain governance.

Governance type	Complexity of products and services	Regulatory liability	Capabilities to mitigate uncertainty	Degree of explicit coordination
Market	Low	Low	High	Low
Modular	Low	High	Low	↕
Relational	High	Low	High	
Captive	High	High	High	
Hierarchy	High	Low	High	High

Source: Seabrooke & Wigan (2017), p. 16

2.6 Markets as Politics

Fligstein creates a sociological view of market dynamics by using what he refers to as the "markets as politics" metaphor. He proposes a conceptualization of markets based on three different stages of market development - *formation*, *stability*, and *transformation*. His fundamental argument is that the social structures of markets are best understood as "attempts to mitigate the effects of competition with other firms" (Fligstein, 1996, p. 657). Importantly, the author outlines two potential sources of market instability. Firstly, "the tendency of firms to undercut one another's prices" and secondly, "the problem of keeping the firm together as a political coalition" (Fligstein, 1996, p. 659). The former is particularly relevant to the topic

of this thesis, as it concerns price competition. The author emphasizes that firms are not always successful at sheltering themselves from price competition but rather his argument is that the politics of markets involves such attempts.

The "markets as politics" approach is particularly important in the context of understanding market structures - how they emerge, how they are maintained, and how they may be challenged. The author defines a stable market as one where the hierarchy of firms is known and where firms resemble one another in terms of organizational structure and strategy. Politics in a stable market reproduces the dominant position of incumbent firms. Fligstein offers an argument that incumbent firms only observe the actions of other incumbents. In a stable environment, lead firms tend to ignore challenger organizations because they do not pose a substantial threat to their market positions. Fligstein's approach to markets as social constructions is important as it transcends the view of markets as being governed solely by political and economic forces. This view does not invalidate conventional perspectives but rather serves to unite economic and political themes to better understand them.

2.8 Summary of key points

In this literature review, I aimed to construct a theoretical framework for analyzing the role of IP rights and market stabilization in pharmaceutical markets. Firstly, this review provided an overview of the economic and political determinants and events that led to the linking of intellectual property to trade and to the creation of an international IP regime - largely through the TRIPS agreement signed in 1994. Scholars give detailed accounts of the global networking and lobbying efforts that led to the extension of intellectual property protection on a global scale. In this part of the literature review, I largely drew on the independent works of two scholars - Drahos and Sell - in which many important findings arise but two of them are fundamental. Firstly, that processes of deregulation were a crucial determinant in creating the IP regime and secondly, that pharmaceutical companies were the main driving force behind the TRIPS agenda.

Further, I integrated perspectives from various domains of economics, law, and politics to build an understanding of patents as assets - and what assetization entails for pharmaceutical manufacturers' market position and profits. A fundamental insight that emerges from the literature on patents as assets is that intellectual property rights are still widely regarded as indicators of economic growth - but research has shown that the financial assetization of IPRs causes the exact opposite. Further, I proceeded with a review of academic works on the financialization of companies, mainly by Lazonick, which highlight the fact that many companies prioritize spending corporate funds on stock buybacks over, for instance, investing in R&D. This is particularly important in light of the fact that pharmaceutical companies tend to argue that high prices are a prerequisite for investments in R&D - but research on financialization undermines the credibility of this argument.

Then, I proceeded with an overview of the literature on Global Value Chains (GVCs) and Global Wealth Chains (GWCs), as delineated and recounted by IPE scholars. I drew on the GWC typology by Seabrooke & Wigan (2017), which offers a conceptualization of those forms of capital that are predominantly used for the purpose of wealth creation. The theoretical frameworks of GVC governance and GWC governance provide insights into the role of intangible assets in the global economy and their implications for monopoly power. Durand & Milberg explain that, although driven by separate phenomena, both the expansion of GVC trade and the emergence of the international IP regime can be linked to the increasing role of intangible assets in the global political economy.

3 Methodology

3.1 Philosophy of science

The MSc IBP degree situates business activity within a broader political context, thus emphasizing the entanglement of business within politics - and vice versa. In this thesis I mainly draw on literature from the field of international political economy, which is an

academic field that integrates perspectives from a range of disciplines. Moreover, the case I am studying demonstrates that large-scale business activities are deeply entangled with the social and political dimensions of society and cannot be separated from them. In this thesis I will be employing the paradigm of critical realism. Critical realist thinkers assert that the two paramount objects of knowledge in social sciences are social structures and human beings. This philosophical paradigm treats the global economy as an "open system". Importantly, the paradigm of critical realism assumes that the structures and powers of society are persistent and produce causal mechanisms (López & Potter, 2005).

Bernard Lonergan's thought departs slightly from the frames of traditional critical realism, as outlined by its two most prominent thinkers - Rom Harré and Roy Bhaskar. Lonergan's foremost intention is to develop an integrated view of knowledge, as opposed to the persisting fragmentation emerging from increased specialization across academic disciplines (Walker, 2017). I deem such an approach suitable for my thesis as it concerns a topic that intersects a number of disciplines, such as business, politics, economics, and law. The problem of high prescription drugs in the US cannot be fully analyzed without understanding the domestic and international regulatory environment that defines the systems of intellectual property protection and global trade. At the same time, a business studies perspective is necessary for the analysis of corporate structures, profits, and other measures of firm activity. An integration of these and other perspectives on the case of high drug prices is a prerequisite for capturing its complexity. Thus, the notion of integrating knowledge from various specializations is highly relevant to this research, especially since I predominantly employ literature from the field of international political economy (IPE), which in itself is a study that integrates several broader disciplines, mainly economics, political science, and international relations. As a subfield of economics, IPE relies heavily on placing economic activity in a socio-political context for generating its insights.

Not only are the field of IPE and critical realist thinking both strongly embedded in the notion of integrating perspectives, but they also give prominence to social structures as necessary,

and as entangled in all human activity. Lonergan's distinctive approach to critical realism gives most importance to the notion of *insight*. Walker (2017) highlights that in Lonergan's thought, insight is distinct from conception and definition, and it is always prior to concepts. Lonergan distinguishes between vulnerable and invulnerable insights. According to his view, a vulnerable insight prompts further questions that may either clarify it or change it. On the other hand, an invulnerable one will not require any further inquiry. Lonergan also perceives knowing as a dynamic structure and he sharply distinguishes between sensory experiences, which constitute the first level of cognitional experience, and insights, which are the "supervening act of understanding" (Lonergan, 1992, p. 1). Importantly, he acknowledges that reality is independent of human perception, which demonstrates that however distinctive, his insight-based approach fits squarely within the philosophy of critical realism (López & Potter, 2005).

3.2 Research Design

3.2.1 Research strategy

Rather than employing a solely inductive or deductive approach, in my research process I combine the two in what some scholars refer to as "abductive" reasoning. The abductive approach aligns with Lonergan's insight-based critical realism, in particular his distinction between vulnerable and invulnerable insights. According to his view, research, especially in its early stages, is commonly characterized by insights that solicit further answers - thus creating follow-up questions.

Sæther (1998) argues that the dualism between the inductive and deductive approaches can be transgressed through a *retroductive* research process. Retroduction is characterized by back-and-forth interactions with theories and empirics, thus being a "continually evolving, dynamic process" (Sæther, 1998, p. 245). Therefore, retroduction allows for making adjustments to the theories, methods, and perspectives being employed, as new insights are generated by the researcher over time. A retroductive process also shields the researcher from relying too

heavily on preconceived notions of the research trajectory, which may sometimes be inaccurate.

This thesis aims to answer a set of three research questions:

RQ1: How have lead insulin firms distributed their profits in the period 2008-2022?
RQ2: How prominent is the role of U.S. market operations for lead insulin firms?
RQ3: What is the extent of intellectual property protection over the most popular insulins on the market?

The method employed is that of a case study. The intention is to understand insulin companies' corporate strategies related to their extending of and maintaining monopoly in the insulin market (dependent variable) against the contemporary legal environment (independent variable). In the first section of the analysis, a comparison between U.S. insulin prices and prices in other countries is presented to introduce the context of how the United States differ from other countries in this regard. Then, to answer RQ1, an analysis of each company's profit distribution is presented for the period 2008-2022. Further, an overview of companies' subsidiaries and data on their net sales to the United States is provided to analyze the role of U.S. operations for each company and to offer an understanding of their embeddedness in the U.S. jurisdiction. The next section focuses on the companies' intellectual property portfolios in relation to insulin products – an analysis that rests on secondary data. Finally, the theoretical framework of GWC governance is employed to offer an understanding of insulin companies' interactions with the U.S. legal system and the extent of opaqueness in their IP-related operations.

3.2.2 Mixed methods approach

This thesis draws on a mixed methods approach to data collection and analysis, in which quantitative and qualitative insights are combined. I employ this approach due to the

entanglement of many disciplines in the topic, which include but are not limited to economics, political science, and law. Across these disciplines, quantitative and qualitative models are used to varying degrees, also depending on their subfields. Therefore, I believe that it would be more difficult to capture the multi-dimensionality of the issue if relying solely on one type of data. While the quantitative data presented in this thesis does provide valuable insights on its own, qualitative findings complement it and allow for a more detailed and nuanced analysis.

The academic literature I engaged in prior to data collection also played a key role in my decision to employ a mixed methods approach. Across the papers I read that dealt with the broader themes relevant to this thesis, I have observed a wide variety of methods and models, with some scholars relying on either quantitative or qualitative analysis, and some engaging in a mix of both. Moreover, I have noticed several authors made references to the fact that a mixed methods approach to a given set of data yielded a more complete picture. Thus, I concluded that the topic of my thesis can benefit from both types of data. Finally, especially for the purpose of Global Wealth Chain analysis, qualitative insights are crucial in understanding the nature of the relationships between relevant actors. Simultaneously, the analysis necessitates quantitative insights, e.g., in relation to profit distribution, net sales, or patent quantities in IP portfolios.

3.2.3 Data collection

This research rests predominantly on secondary data collected in the Orbis database and in companies' annual reports. Orbis is deployed to collect data on:

- Corporate ownership structures (companies' subsidiaries based on their geographical location)
- Intellectual property portfolios (insulin-related patents)

To map each company's insulin patent portfolios, I used data offered by the Orbis database and delimited the search to active patents: ones that had been granted and still active. To identify the relevant patents, I searched for the following keywords:

- “Insulin”
- International non-proprietary names (e.g., “insulin aspart”)
- Brand names of the companies’ drugs (e.g., “Fiasp”)
- Names of devices used for insulin delivery (e.g., “insulin pen”)

Data collection on companies’ insulin patent protection is complemented by statements from the insulin manufacturers’ annual reports for 2022. The study is also supported by complementary data in the form of expert reports on insulin patents and patent search methodologies.

3.3 Limitations

Most significant limitations of this study lie in the complexity of intellectual property rights as assets. Patents are much better understood in legal terms than they are in the economic and financial realm. Intellectual property has legal, scientific, and financial dimensions but this study preliminarily focuses on IP rights as intangible assets, thus limiting the perspective. As an IBP student, I am inclined to focus more firmly on the economic nature of intellectual property. Patents’ inherent complexity makes it difficult for any one researcher to grasp their quality in all realms. Furthermore, it has been argued that generalizing from a single case study may pose a challenge (Yin, 2015). Although certain determinants are common across pharmaceutical markets, a single case study of the insulin market can only provide limited generalizable conclusions about the wider issue of pharmaceutical monopolies and patent assetization. Finally, in retrospect, this study’s results could have been made more detailed and profound by collecting primary data, e.g., through expert interviews.

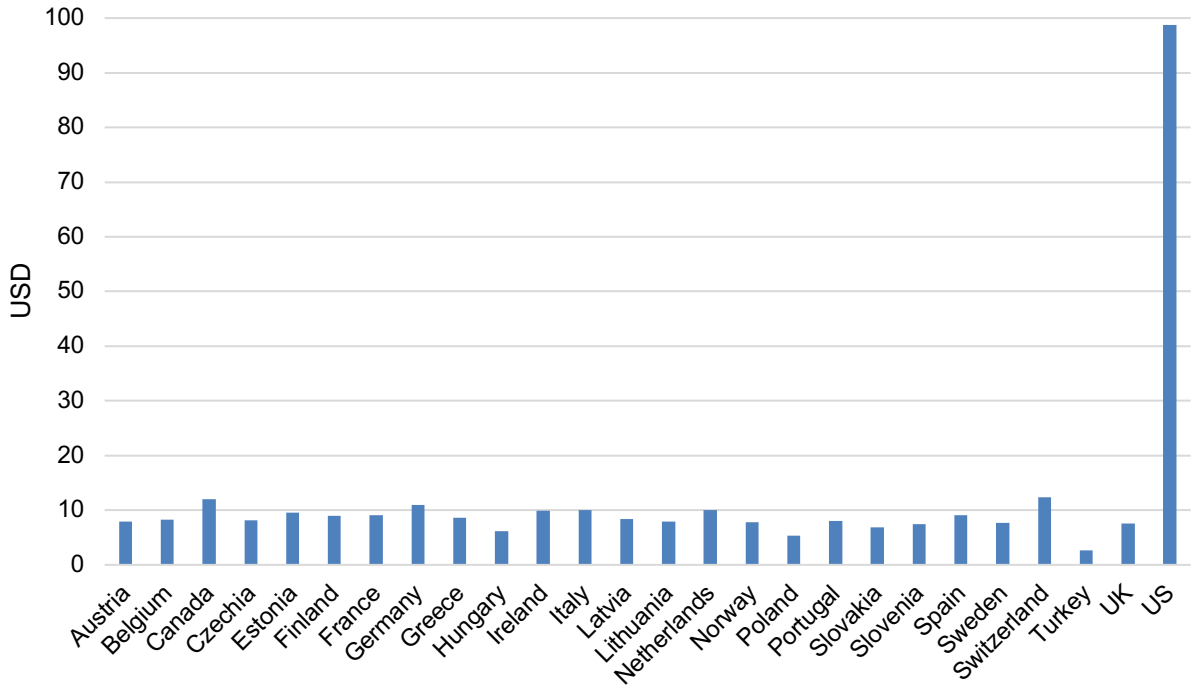
4 Analysis

4.1 Insulin prices in the US

The United States has long been an outlier with regard to prescription drug prices, and prices in the country continually rank among the highest globally. Moreover, the magnitude of discrepancy between prices in the United States and other countries is substantial. According to a report by RAND Corporation (2021), U.S. prices across all drugs equate to 256 percent of those in 32 OECD countries selected by the authors for comparison. The cost of insulin is emblematic of the larger drug pricing problem in the United States and a remarkable amount of legislative action has been devoted solely to capping the price of insulin at both state and federal level, a notable example of which is the Affordable Insulin Now Act that was passed by the House of Representatives and introduced in the Senate in 2022 (Affordable Insulin Now Act, 2022).

Insulin prices have increased more substantially than overall drug prices in the United States. According to RAND Corporation (2020), an American market basket of insulins is 8.1 times more expensive than in all non-U.S. OECD countries combined. Figure 1 presented below demonstrates the discrepancy in the average cost of insulin in 2018 in the United States in comparison with Canada and most European countries. Although prices between the comparison countries also vary, the differences are slight in contrast to the United States, which is a clear outlier.

Figure 1. Average cost of insulin in North American and European countries in 2018



Source: RAND Corporation

Researchers from RAND Corporation (2020) note that prices vary depending on the insulin category, with prices being higher for analog insulins compared to human insulins. The former are the newest generation of insulin, with a more predictable duration of action, which generally leads to better health results and a higher quality of life for patients with diabetes. Insulin analogs are now the standard of care in developed countries, and they are also becoming more commonly available globally (*Types of insulin*, n.d.). Eli Lilly, Novo Nordisk, and Sanofi have all long argued that as a biologic, insulin analogs are more expensive to manufacture than other medications and that their high prices are thus justified.

4.2 Profit distribution

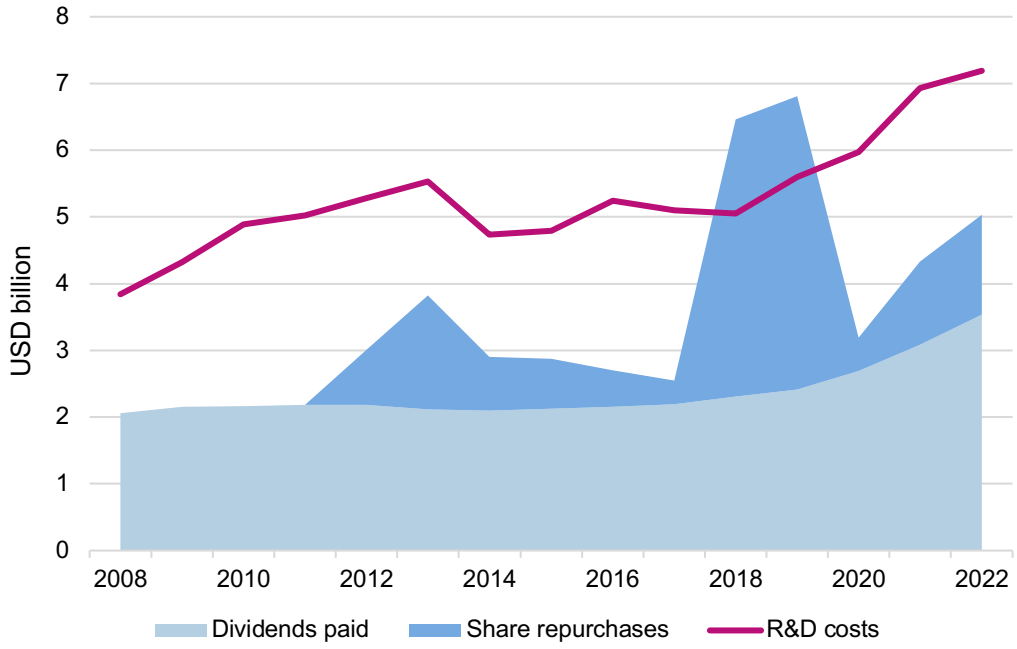
A fundamental argument provided by the insulin companies is that they need to maintain high prices to be able to reinvest their profits in innovation research. To gain information about how

the three major insulin manufacturers (Eli Lilly, Novo Nordisk, and Sanofi) allocate their profits, I turned to cash flows for the years 2008-2022 to compare their Net Shareholder Payout (TTM) vis-à-vis their spending on research & development. To obtain the values of TTM for each company, I analyzed the value of cash dividends distributed to shareholders and the value of share repurchases for each year, according to the following formula:

Net Shareholder Payout (TTM) = Dividends paid + Share repurchases

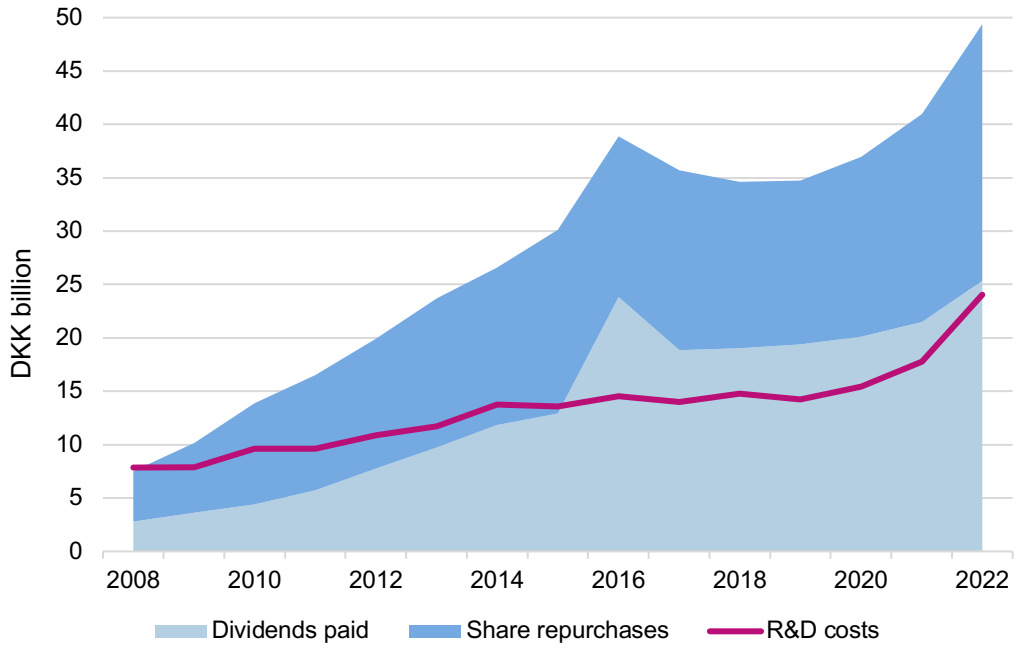
The three figures below present each company's Net Shareholder Payout compared to their R&D spending each year between 2008 and 2022.

Figure 2. Eli Lilly's Net Shareholder Payout vs R&D spending in 2008-2022



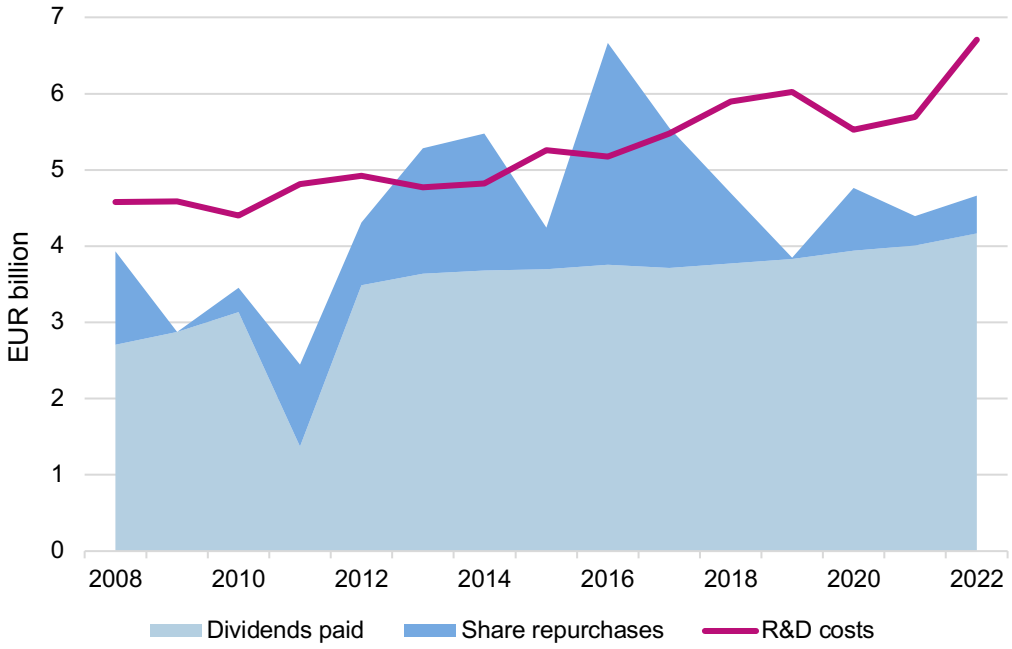
Source: Eli Lilly's annual reports

Figure 3. Novo Nordisk's Net Shareholder Payout vs R&D spending in 2008-2022



Source: Novo Nordisk's annual reports

Figure 4. Sanofi's Net Shareholder Payout vs R&D spending in 2008-2022



Source: Sanofi's annual reports

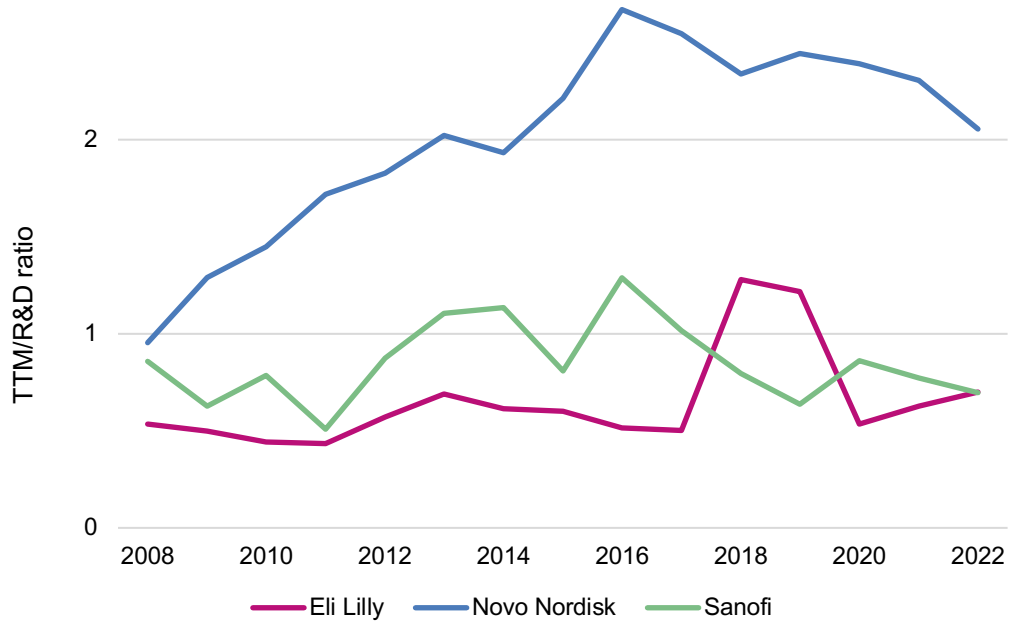
The figures above demonstrate significant differences in how the three companies distributed their profits. For Eli Lilly, Net Shareholder Payout outweighed spending on R&D only in the years 2018 and 2019. In every other year analyzed, R&D spending was significantly higher than payouts to the company's shareholders. For Sanofi, Net Shareholder Payout was higher than R&D spending in the years: 2013, 2014, 2016, and 2017.

Novo Nordisk provides a substantially different case from the other two insulin companies. The company's Net Shareholder Payout was higher than spending on R&D in every year analyzed except for 2008. Moreover, Novo Nordisk's payouts to shareholders have increased starkly in the 15-year period. Since the company's R&D spending has increased steadily but modestly in the period analyzed, TTM has far outweighed it in the past decade.

To provide a transparent comparison between how each of three insulin manufacturers distributed their profits in the analyzed period, for each year and for each company I calculated their Net Shareholder Payout to R&D spending ratio. The higher the ratio, the higher the payouts to shareholders in relationship to R&D spending, and a value above 1 indicates that shareholder payouts outweigh the company's research spending.

Figure 5 below presents the results of said calculations and demonstrates clear differences between the three companies' profit distribution. For Eli Lilly and Sanofi, the ratio has varied across the period analyzed but is in some years comparable between the two and the variance has been moderate. For Novo Nordisk, however, it was similar to the other two companies in 2008 but has since increased substantially. Despite a moderate decrease in the last five years, Novo Nordisk's TTM to R&D ratio has remained 2-3 times higher than Eli Lilly's and Sanofi's ratios.

Figure 5. Big Three's ratios of Net Shareholder Payout to R&D spending in 2008-2022



Source: Company annual reports

The table below presents the three insulin companies' Net Shareholder Payout to R&D ratios for each year in the past decade.

Table 2. Big Three's Net Shareholder Payout to R&D ratios in 2013-2022

	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022
Eli Lilly	0.7	0.6	0.6	0.5	0.5	1.3	1.2	0.5	0.6	0.7
Novo Nordisk	2	1.9	2.2	2.7	2.5	2.3	2.4	2.4	2.3	2.1
Sanofi	1.1	1.1	0.8	1.3	1	0.8	0.6	0.9	0.8	0.7

The relationship between the amount of profits that the companies distributed to their shareholders in the form of cash dividends and share repurchases varies substantially and each company presents a different case. For Eli Lilly and Sanofi, their average TTM to R&D ratio for the analyzed period amounts to 0.65 and 0.85, respectively. For Novo Nordisk, however, the average ratio equals 2, thus in the past 15 years the company has on average distributed to their shareholders double the amount of profits it spent on research & development. Thus, in this aspect, Novo Nordisk differs significantly from its two competitors.

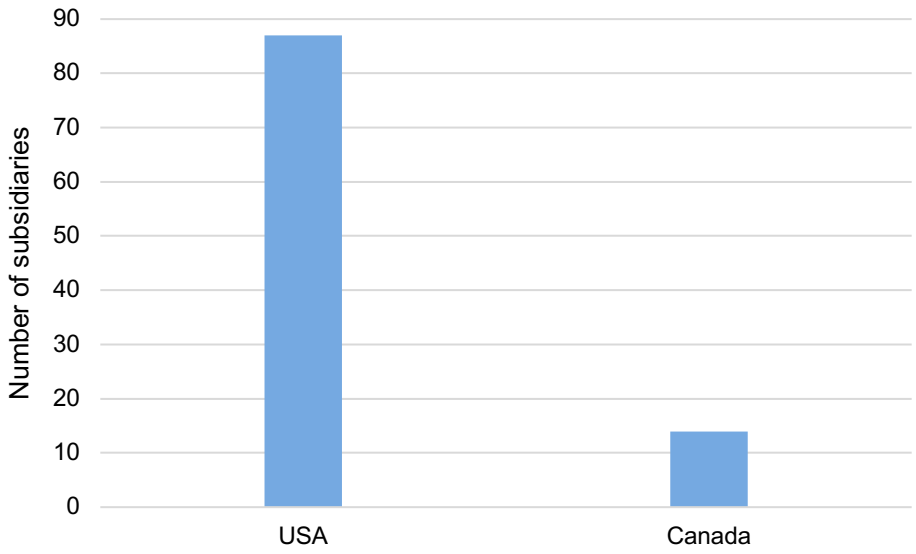
4.3 The United States vs rest of the world

All three leading insulin companies are multinational corporations that reach many of the world's markets. According to the firms' most recent annual reports, Eli Lilly sells their products in approximately 110 countries, Novo Nordisk in 168 countries, and Sanofi reaches an astonishing number of 180 countries with their products. The three leading insulin manufacturers – Eli Lilly, Novo Nordisk, and Sanofi – represent 99 percent of the global insulin market value. Although the United States comprises only 15 percent of the insulin market, it accounts for almost half of the global insulin-related revenue (Knox, 2020). These numbers indicate that the U.S. market bears extraordinary significance.

According to Novo Nordisk's most recent annual report (Novo Nordisk, 2022), the company had a 44.6% value share in the global insulin market in 2022. Insulin has always been the company's core competency – it was founded in 1923 by August Krogh, a Danish Nobel laureate, only two years after insulin was discovered. Although in its century of operation it has extended into other areas (wider diabetes care and more recently, rare diseases), the manufacturing and sale of insulin remains fundamental to the company. Insulin bears higher significance to Novo Nordisk than it does to its competitors – Eli Lilly and Sanofi – who have much more diverse drug portfolios. However, the company's insulin focus is not only a product of its 100-year long history but has also long been a corporate strategy. In 2011, Lars Rebien Sørensen, then-Chief Executive Officer at Novo Nordisk, said in an interview that he "took a calculated risk" by shutting down the company's research into diabetes pills and focusing more resources on insulin instead, as he expected that segment to grow (Langreth, 2011).

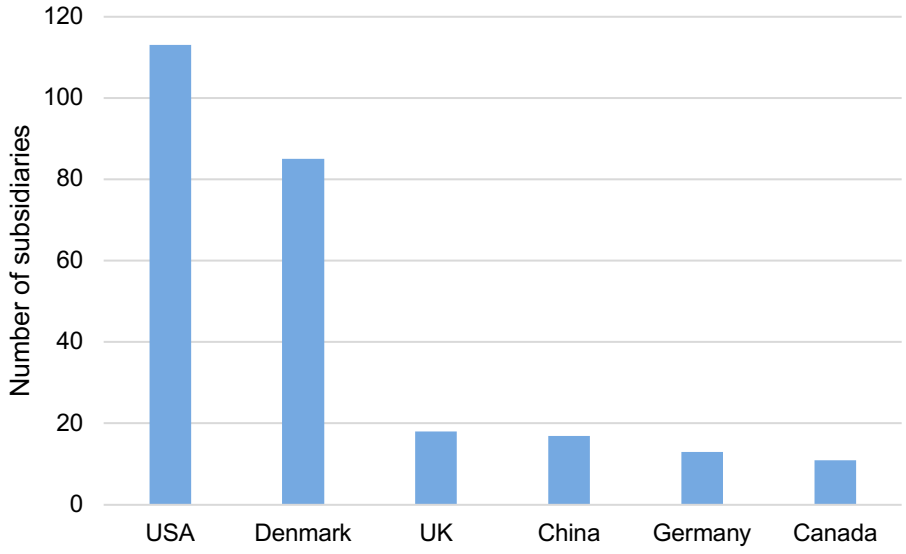
To gain insights about the geographical aspect of the companies' corporate ownership structures, I deployed the Orbis database to gather data about each firm's subsidiaries. Jurisdictions where companies set up entities give information about where they choose to locate both their value-creating and wealth-creating structures. The objective of this stage of the research was to create an overview of where the companies have set up a significant number of subsidiaries – the three figures below present data on where each company has created or obtained 10 or more subsidiaries.

Figure 6. Eli Lilly's ultimately owned subsidiaries by country (only countries with 10+ subsidiaries are shown)



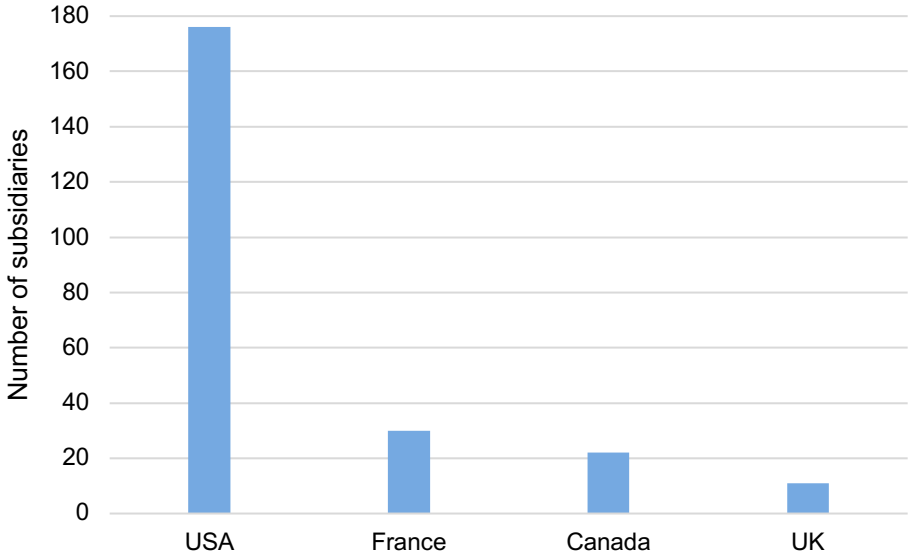
Source: Orbis

Figure 7. Novo Nordisk's ultimately owned subsidiaries by country (only countries with 10+ subsidies are shown)



Source: Orbis

Figure 8. Sanofi's ultimately owned subsidiaries by country (only countries with 10+ subsidies are shown)



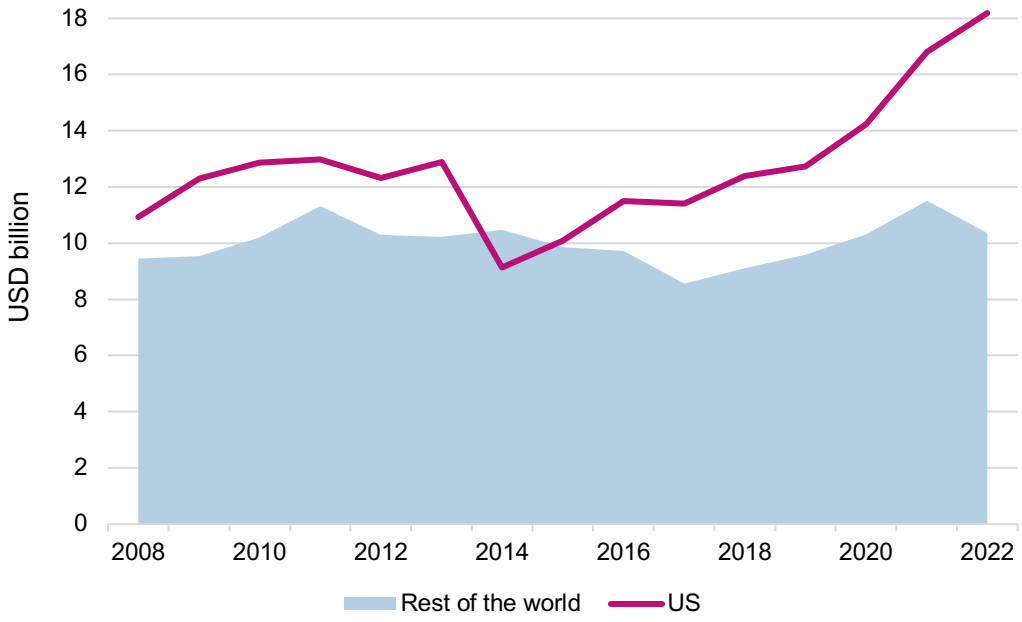
Source: Orbis

The figures demonstrate that all three MNCs each have set up most subsidiaries in the United States – even Novo Nordisk and Sanofi, which are not headquartered there. Although a globalized company like the other two, the data for Eli Lilly shows that it is the least internationalized out of the three, with most (87) subsidiaries located in its native country and 11 in Canada – a neighboring one. For companies that are not U.S.-based, Novo Nordisk and Sanofi have a remarkable embeddedness in the United States jurisdiction. Sanofi has more than five times more subsidiaries in the United States than it does in France – where it is headquartered. The difference between Novo Nordisk's U.S. and Danish subsidiaries is not as stark but still significant.

To gain insights about each companies' sales to the US vis-à-vis sales to the rest of the world, I analyzed sales data for the years 2008-2022. For Novo Nordisk and Sanofi, U.S. sales data was not available for the entire 15-year period, so data for North American sales is provided instead. Conversely, for Eli Lilly, North American sales data was not available for every year,

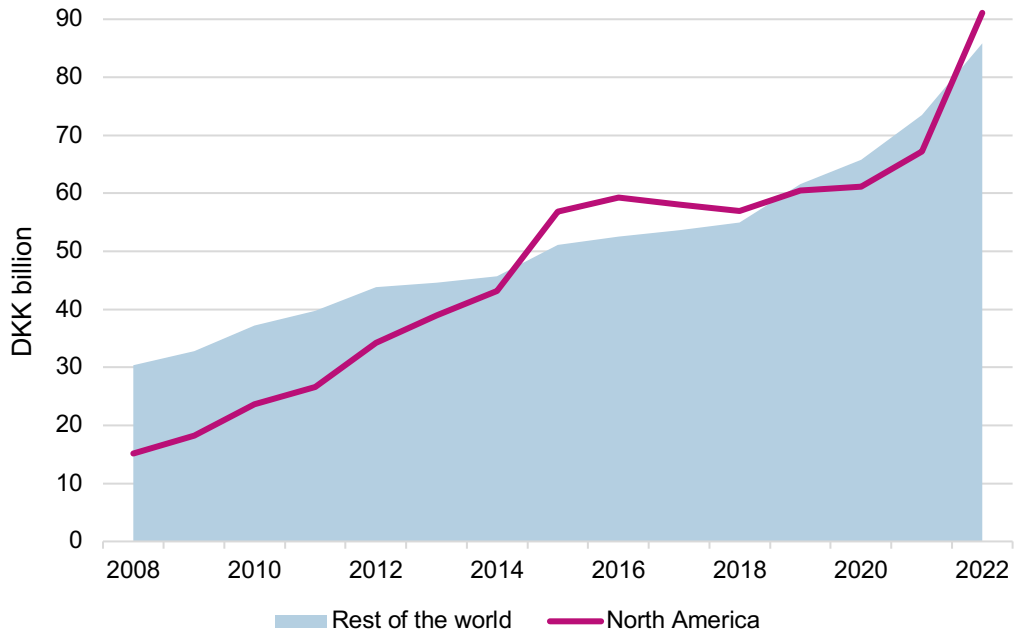
so neither one of the two could be chosen for all three analyses. However, in the years where U.S. sales data was available, the United States consistently accounted for over 90 percent of both Novo Nordisk's and Sanofi's North American sales.

Figure 9. Eli Lilly's total sales to the US vs rest of the world in 2008-2022



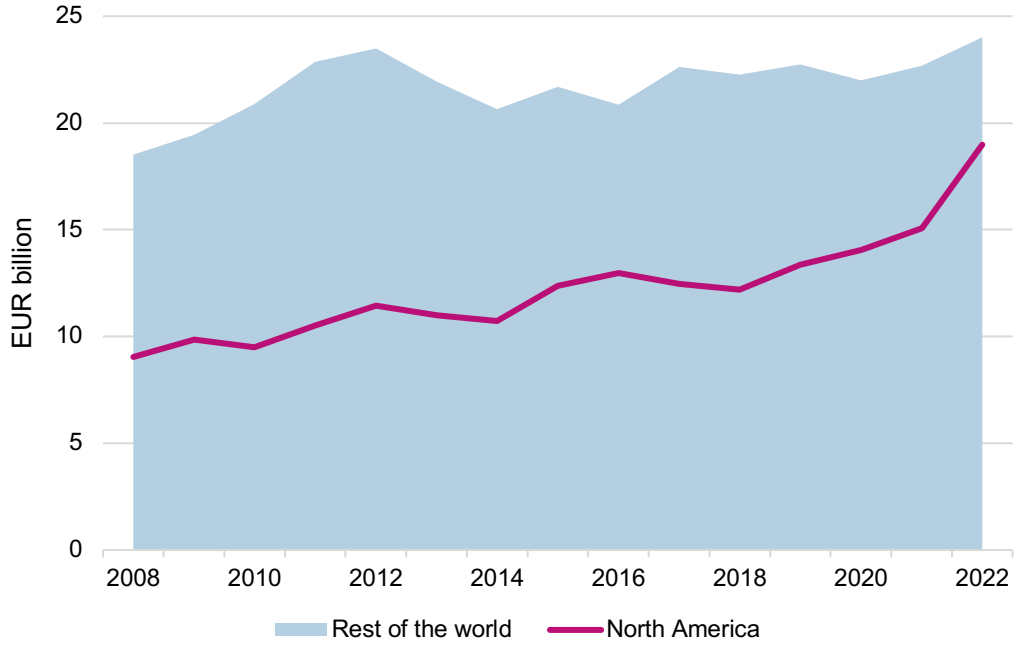
Source: Eli Lilly's annual reports 2008-2022

Figure 10. Novo Nordisk's total sales to North America vs rest of the world in 2008-2022



Source: Novo Nordisk's annual reports 2008-2022

Figure 11. Sanofi's total sales to North America vs rest of the world in 2008-2022



Source: Sanofi's annual reports 2008-2022

The three figures above demonstrate the comparison between each company's U.S./North American sales and their sales to the rest of the world. For Eli Lilly, U.S. sales exceed sales to the rest of the world in almost every year between 2008-2022. Considering that Eli Lilly is a U.S. company, and although highly globalized but not as much as its two competitors, this is not a surprising finding. For Novo Nordisk, North American sales are well below sales to the rest of the world in 2008 but increase steadily until 2015, when North American sales first exceed those to the rest of the world. From then on, North American sales are either almost equal to or greater than sales to the rest of the world. For a Danish company that sells their drugs to 168 of the world's countries, the numbers are striking. For Sanofi, sales to the rest of the world far exceed those in North America over the entire period of 15 years. For a French-origin, hyper-global company that sells their products in a total of 180 countries, this is expected. Therefore, a comparison between Novo Nordisk and Sanofi, two non-U.S. highly globalized MNCs demonstrates that the former is much more dependent for its sales to the U.S. market than the latter.

Moreover, Eli Lilly and Novo Nordisk have experienced a much steeper rate of growth in their U.S./North American sales than Sanofi, whose North American sales growth resembles its overall sales growth. However, while Eli Lilly's international sales have remained reasonably steady over the 15-year period, for Novo Nordisk both the North American and global sales growth has been steep.

4.4 Patents on insulin products

In the literature I reviewed that relates directly or indirectly to the issue of drug pricing in the United States, authors frequently refer to the role of intellectual property in the pharmaceutical sector. Moreover, much of the work that analyzes pharmaceutical companies through the

lenses of law or international political economy refers to patent-related strategies that companies utilize to create, protect, and extend monopolies and extract (larger) profits.

4.4.1 Lantus (Sanofi)

I-MAK is a leading non-governmental organization in the field of research on pharmaceutical patents and has created a database that covers the ten top selling drugs in the United States as of 2021[2]. No insulins are among the ten medications listed in the database, but the organization has published a report on Lantus (Lantus (insulin glargine), 2018), which is an insulin sold by Sanofi. The researchers provide critical insights about the intellectual property behind the drug, which potentially apply to other patented insulins on the market.

Firstly, findings reveal that 95 percent of all patent applications on Lantus in the United States were filed by Sanofi after the drug was first approved by the FDA and already on the market. The company filed its first application for a patent on Lantus and the insulin was given approval in 2000. Had Sanofi not filed any additional applications, the primary patent would have secured it 15 years of monopoly protection for Lantus in the United States. However, until 2018 (when the report was published) the company had filed a total of 74 applications and had been granted a total of 47 patents on the drug.

These findings demonstrate that Sanofi engaged in the practice of patent evergreening – one that is often referred to by authors in the literature on intellectual property in pharmaceutical markets and that is defined by the company obtaining multiple patents on various features of the same product to extend its monopoly on it, not rarely over several decades. More broadly, this provides evidence that Sanofi created what researchers refer to as a "patent thicket" – a web of overlapping intellectual property rights on a single medication, which not only extends the duration of a company's monopoly but also makes it more strenuous for competitors to introduce their own drug into the market. According to I-MAK's report, as of 2018 Sanofi had

[2] https://drugpatentbook.i-mak.org/

secured a monopoly over Lantus until at least 2031. Importantly, data also demonstrates that secondary drug patents often lead to "litigation initiated by the patent holder and settlements that delay competitors entering the marketplace" (Lantus (insulin glargine), 2018, p. 4). Sanofi initiated litigation with two potential competitors, including one that had already received FDA approval on their version of the drug.

4.4.2 Patent landscaping

Although the I-MAK database does not list any insulin products and therefore its content does not align with the topic of this thesis, I-MAK's patent search methodology, published by the organization along with the database, provides valuable insights into the issue of mapping patent portfolios for individual drugs. In literature authors repeatedly refer to the fact that multinational companies' intellectual portfolios are opaque in the sense that matching patents to individual drugs is difficult. Patents are not straightforward – if a patent protects a certain drug, its information will not necessarily state that. In their methodology report, researchers from I-MAK provide a list of pharmaceutical patent types, as demonstrated in the table below.

Table 3. Patent types

Patent type	Definition
Biomarker	Method to measure the actions of a drug
Crystalline	Crystal structures inherent within the main compound
Derivative	Structural variations of the main compound
Device	Used for delivering a drug (e.g., syringe, insulin pen)
Enantiomer / Stereoisomer	Molecular forms of the main compound
Formulation / Combination	Pharmaceutical preparations, including ingredients, to help deliver the drug into the human body

Kit	A kit for administering the drug for a period of time according to a specific regimen
Main compound	Covers the active substance used in a small molecule drug
Method of Delivery	Method of controlling the distribution of a drug to patients, including information for at-risk patient groups and how pharmacies fill prescriptions
Method of Diagnosis	Method to identify patients that are most likely to respond to treatment
Method of Production / Process	Method or process for manufacturing a biological product or small molecule compound
Method of Treatment	Specific indications (diseases) that can be treated with a biologic or small molecule drug alone, or in combination with another drug(s)
Packaging	Packaging and containers used for the pharmaceutical product or device
Product	Covers the antibody, antibody fusion proteins, and vectors for delivery to the relevant site in the human body
Salt Form	The pairing of a small molecule compound (main compound) with a counterion (ion) to create a salt version of the compound to improve the bioavailability, stability, manufacture, and patient compliance

Source: I-MAK

The above table illustrates the multiplicity and complexity of pharmaceutical patents. It becomes evident that if patents do not necessarily contain the information about what specific drug they protect, and if so many aspects and parts of a drug can be granted patent protection, creating a patent landscape for individual medications is a strenuous task. Moreover, it is apparent that doing so requires specialized knowledge of pharmaceuticals – to be able to connect individual patents to a specific drug. Researchers from I-MAK provide their methodologies for each drug contained in the database, in which they outline each type of search they carried out. For every medication, the authors searched for: either the drug's compound structure or antibody sequence, keywords, in some cases chemical names, and for every drug they cross checked patents with either the Orange Book or the Purple Book, and sometimes with patents asserted in litigation.

4.4.3 Purple Book

The U.S. Food and Drug Administration publishes information about all drug products and biological products that have been approved for use in the United States. Insulin is a biologic – unlike drugs that are chemically synthesized, biologics are isolated from natural sources, e.g., humans, animals, or microorganisms. Therefore, insulin products are listed in the Purple Book. In 2020, the U.S. Congress passed the Consolidated Appropriations Act. Its section on Biological Product Patent Transparency requires reference product sponsors to provide to the FDA the list of patents and corresponding expiry dates. The FDA began publishing said information in the Purple Book 180 days after the enactment of the law (June 25, 2021) and intends to revise the published list monthly (FAQs – FDA Purple Book, n.d.).

I searched the Purple Book's Patent List for insulins but as of May 2023 no patent information on any insulins had been published. Its database does, however, provide information about insulin products approved and available for the U.S. market. I collected that data and cross checked with the insulin companies' website information to identify how many insulin products are available on the U.S. market and who manufactures them. I provide the information in the tables below, but I decided to summarize it by only distinguishing between insulins based on their international non-proprietary name (INN), which facilitates the identification of pharmaceutical substances or pharmaceutical active ingredients in the drug. Eli Lilly, Novo Nordisk, and Sanofi all offer a wide range of insulin products but often they contain the exact same INN but in a different dosage or in a different packaging (e.g., in either a pre-filled insulin pen or in a vial). Therefore, two or more products offered can have the exact same therapeutic impact but a different method of delivery or a different concentration.

4.4.4 Insulin's patent landscape

Searches in the Purple Book revealed that all but three (out of 31) of the insulin products available on the U.S. market are manufactured by either Eli Lilly, Novo Nordisk, or Sanofi.

All three of the companies offer both analog and human insulins for sale in the United States. However, according to a 2016 study by Health Action International, there are no active patents on any formulations of human insulin anymore. Therefore, as this part of my research concerns the issue of intellectual property rights on insulin products, in the tables below I only present the insulin analogs each company offers, categorized by their international non-proprietary name.

Table 4. Eli Lilly's insulin products by international non-proprietary name

Product name	International non-proprietary name (INN)	Type of insulin
Humalog	Insulin lispro	Fast-acting insulin
Basaglar	Insulin glargine	Long-acting insulin
Humalog Mix	Insulin lispro protamine/insulin lispro	Premix insulin

Source: Eli Lilly's website[3]

Table 5. Novo Nordisk's insulin products by international non-proprietary name

Product name	International non-proprietary name (INN)	Type of insulin
Fiasp, NovoRapid (NovoLog in the US)	Insulin aspart	Fast-acting insulin
Tresiba	Insulin degludec	Long-acting insulin
Levemir	Insulin detemir	Long-acting insulin
NovoMix	(Biphasic) insulin aspart	Premix insulin
Ryzodeg	Insulin degludec/insulin aspart	Premix insulin

[3] https://www.lilly.com/our-medicines/current-medicines

Source: Novo Nordisk website[4]

Table 6. Sanofi's insulin products by international non-proprietary name

Product name	International non-proprietary name (INN)	Type of insulin
Admelog	Insulin lispro	Fast-acting insulin
Apidra	Insulin glulisine	Fast-acting insulin
Lantus, Toujeo	Insulin glargine	Long-acting insulin
Soliqua	Insulin glargine/lixisenatide	Premix insulin

Source: Sanofi's website[5]

My data research based on I-MAK sources made it evident that it is unrealistic to conduct a thorough patent landscaping for an individual drug without in-depth knowledge of pharmaceuticals – their compounds, how they work, and other aspects, such as method of delivery. Researchers from I-MAK, who created the patent database for the ten top selling drugs in the United States, and who have an interdisciplinary team of experts and much more substantial resources than I do for this thesis, themselves note that:

"Wherever possible, I-MAK has attempted to identify all relevant patents related to the drugs included in the database through its patent search methodology described above. However, due to the nature of pharmaceutical patents and the various terminologies that companies can use to describe the same invention, it is possible that our patent searches may not have captured all relevant patents on a drug."

I-MAK's Patent Methodology report, 2022

[4] https://www.novonordisk.com/our-products/our-medicines.html
[5] https://www.sanofi.us/en/products-and-resources/prescription-products

Therefore, the patent landscaping I conducted for each of three insulin manufacturers had the underlying assumption that it was unlikely for me to identify all insulin patents owned by the companies, and that limitation must be acknowledged. Moreover, the intent was not to match patents to individual drugs but to provide insights into each company's insulin patent landscape as a whole. It must be made clear that the objective of the data collection was not to present a complete list of the companies' insulin patents and the lists below should not be treated as such.

My search for an appropriate approach to collect the data, one that would ensure a sufficient degree of validity, was an extensive and retroductive process. I went back-and-forth between different patent databases and conducted preliminary searches to obtain an understanding of the kind of information patents provide and how it is presented. I ended up deciding on using the Orbis database as my source, as it provides each company's intellectual property portfolio, thus making the process more straightforward than other databases I encountered (e.g., the USPTO's patent database).

Table 7. Overview of each company's patents

	Granted patents	Pending patents	Expired patents	All patents
Eli Lilly	34277	15903	70307	92216
Novo Nordisk	10918	9901	22430	35932
Sanofi	138739	53148	271809	344184

Source: Orbis

Table 7 provides an overview of each company's patent portfolio. In the Orbis database, the category "Granted patents" also includes some but, as the numbers show, not all expired patents, so it is not possible to get the exact number of granted active patents for each company. It also must be noted that the numbers provided above include patents filed and granted

anywhere in the world, thus some patents are multiple-counted, as companies often file applications for the same innovation at multiple patent offices globally. However, these numbers still demonstrate that each company's patent portfolio is significant in size and the number of both granted and pending patents for each company is large.

To map each company's insulin-related patents, I used their intellectual property portfolio as presented in the Orbis database and delimited the search to active patents: ones that had been granted and still active. To identify the relevant patents, I searched for the following keywords:

- "Insulin"
- International non-proprietary names (e.g., "insulin aspart")
- Brand names of the companies' drugs (e.g., "Fiasp")
- Names of devices used for insulin delivery (e.g., "insulin pen")

I also delimited my search to patents granted in the United States to avoid double-entry for the same patents that had been filed elsewhere. The three tables below present all insulin-related patents that I could identify for each company.

Table 8. Eli Lilly's active insulin-related patents

Patent number	Patent name	Filed	Granted	Expires
US8075525B2	Sheet for guiding location of insulin injection	2010	2011	2029
US8637458B2	Insulin with a stable basal release profile	2010	2014	2030
US9381247B2	Magnesium compositions for modulating the pharmacokinetics and pharmacodynamics of insulin and insulin analogs, and injection site pain	2013	2016	2032
US8933023B2	Rapid acting injectable insulin compositions	2014	2015	2024
US9399065B2	Magnesium compositions for modulating the pharmacokinetics and injection site pain of insulin	2014	2016	2032
US9439952B2	Rapid-acting insulin compositions	2015	2016	2034

US9993555B2	Rapid-acting insulin compositions	2015	2018	2034
US11052133B2	Glucose responsive insulins	2016	2021	2035
US9901623B2	Rapid-acting insulin compositions	2016	2018	2035
US10172922B2	Rapid-acting insulin compositions	2016	2019	2034
US11045601B2	Infusion set with components comprising a polymeric sorbent to reduce the concentration of m-cresol in insulin	2017	2021	2036
US10925931B2	Rapid-acting insulin compositions	2018	2021	2035
US11123406B2	Rapid-acting insulin compositions	2018	2021	2034
US10400021B2	Acylated insulin compound	2018	2019	2037
US11207384B2	Rapid-acting insulin compositions	2018	2021	2037
US11510967B2	Pharmaceutical combinations comprising insulin and at least an agent selected from meloxicam, bromfenac sodium, acetylsalicylic acid, salicylic acid and paracetamol	2018	2022	2037
US10597436B2	Acylated insulin compound	2019	2020	2037

Source: Orbis

Table 9. Novo Nordisk's active insulin-related patents

Patent number	Patent name	Filed	Granted	Expires
US7615532B2	Insulin derivatives	2006	2009	2025
US8796205B2	Insulin derivative	2007	2014	2026
US9018161B2	Protease resistant insulin analogues	2007	2015	2026
US8518668B2	Method for making maturated insulin polypeptides	2007	2013	2026
US8937042B2	Pharmaceutical compositions comprising GLP-1 peptides or extendin-4 and a basal insulin peptide	2008	2015	2027
US9034818B2	Pharmaceutical formulations comprising an insulin derivative	2008	2015	2027

US8691759B2	Protease stabilized, acylated insulin analogues	2009	2014	2028
US8324156B2	Oral insulin therapies and protocol	2009	2012	2023
US8828923B2	Insulin derivatives	2009	2014	2023
US8476228B2	Insulin derivatives	2011	2013	2025
US8324157B2	Preparation comprising insulin, nicotinamide and an amino acid	2011	2012	2029
US9481721B2	Insulin formulations	2013	2016	2032
US9045560B2	Protease stabilized, acylated insulin analogues	2013	2015	2028
US8962554B2	Oral insulin therapies and protocol	2014	2015	2023
US11167035B2	Insulin compositions and methods of making a composition	2014	2021	2025
US9035020B1	Insulins with an acyl moiety comprising repeating units of alkylene glycol containing amino acids	2015	2015	2027
US10040839B2	Insulin derivatives and the medical uses hereof	2015	2018	2034
US9688737B2	Protease stabilized acylated insulin analogues	2015	2017	2028
US10259856B2	Protease stabilized acylated insulin analogues	2015	2019	2028
US11208452B2	Insulins with polar recombinant extensions	2016	2021	2035
US11352406B2	Insulin derivatives and the medical uses hereof	2016	2022	2035
US11195606B2	Systems and methods for the determination of insulin sensitivity	2017	2021	2036
US11562816B2	Systems and methods for analysis of insulin regimen adherence data	2017	2023	2036
US10930382B2	Systems and methods for analysis of insulin regimen adherence data	2017	2021	2036
US11464447B2	Regimen adherence measure for insulin treatment based on glucose measurements and insulin pen data	2017	2022	2036
US11521730B2	Systems and methods for the determination of insulin sensitivity	2017	2022	2036
US11462313B2	Systems and methods for adjusting a basal/bolus ratio in an insulin regimen	2017	2022	2036
US11282598B2	Starter kit for basal insulin titration	2017	2022	2036

US10914728B2	Bioassay for insulin formulations	2017	2021	2036
US10596229B2	Method of treating diabetes mellitus by administration, at specifically defined intervals, of a derivative of a naturally occurring insulin or insulin analogue, the derivative having a prolonged profile of action	2017	2020	2030
US11278596B2	Insulin degludec in cardiovascular conditions	2017	2022	2036
US11471537B2	Oligomer extended insulin-Fc conjugates	2018	2022	2037
US10335464B1	Device for titrating basal insulin	2018	2019	2038
US10265385B2	Insulin containing pharmaceutical compositions	2018	2019	2036
US10919949B2	Acylated insulin analogues and uses thereof	2018	2021	2037
US10596231B2	Insulin containing pharmaceutical compositions	2019	2020	2036
US11498951B2	Insulin analogues and uses thereof	2020	2022	2040

Source: Orbis

Table 10. Sanofi's active insulin-related patents

Patent number	Patent name	Filed	Granted	Expires
US8017350B2	Glimepiride- and insulin-induced glycosylphosphatidylinositol-specific phospholipase C regulation	2006	2011	2024
US7659363B2	Process for the preparation of insulin or an insulin derivative in the presence of oxygen	2006	2010	2024
US8048854B2	Amidated insulin glargine	2009	2011	2026
US9526764B2	Combination of an insulin and a GLP-1-agonist	2009	2016	2028
US8633156B2	Insulin derivatives having an extremely delayed time-action profile	2010	2014	2028
US9138462B2	Prodrugs comprising an insulin linker conjugate	2010	2015	2029
US9265723B2	Long acting insulin composition	2010	2016	2029

US10029011B2	Pharmaceutical composition comprising a GLP-1 agonist, an insulin and methionine	2010	2018	2029
US9821032B2	Pharmaceutical combination for improving glycemic control as add-on therapy to basal insulin	2012	2017	2031
US9839675B2	Stabilized pharmaceutical formulations of insulin analogues and/or insulin derivatives	2014	2017	2033
US9345750B2	Long-acting formulations of insulin	2014	2016	2030
US10092513B2	Treatment of diabetes mellitus by long-acting formulations of insulins	2014	2018	2033
US9839692B2	Stabilized pharmaceutical formulations of insulin analogues and/or insulin derivatives	2015	2017	2034
US9895423B2	Stabilized pharmaceutical formulations of insulin aspart	2015	2018	2034
US9895424B2	Stabilized pharmaceutical formulations of insulin analogues and/or insulin derivatives	2015	2018	2034
US9457066B2	Prodrugs comprising an insulin linker conjugate	2015	2016	2029
US11017891B2	Titration of basal insulin with two modes	2015	2021	2034
US9950039B2	Insulin glargine/lixisenatide fixed ratio formulation	2015	2018	2034
US10117909B2	Combination of an insulin and a GLP-1 agonist	2016	2018	2028
US11396534B2	Insulin analogs with reduced affinity to insulin receptor and use thereof	2017	2022	2036
US10610595B2	Stabilized pharmaceutical formulations of insulin analogues and/or insulin derivatives	2017	2020	2034
US11026999B2	Insulin glargine/lixisenatide fixed ratio formulation	2019	2021	2033
US11191722B2	Treatment of diabetes mellitus by long-acting formulations of insulins	2019	2021	2033
US11098102B2	Insulin conjugates	2019	2021	2038

Source: Orbis

In my search of the companies' intellectual property portfolios, I identified the following numbers of insulin-related patents for each company:

1) Eli Lilly – 17
2) Novo Nordisk – 37
3) Sanofi – 24

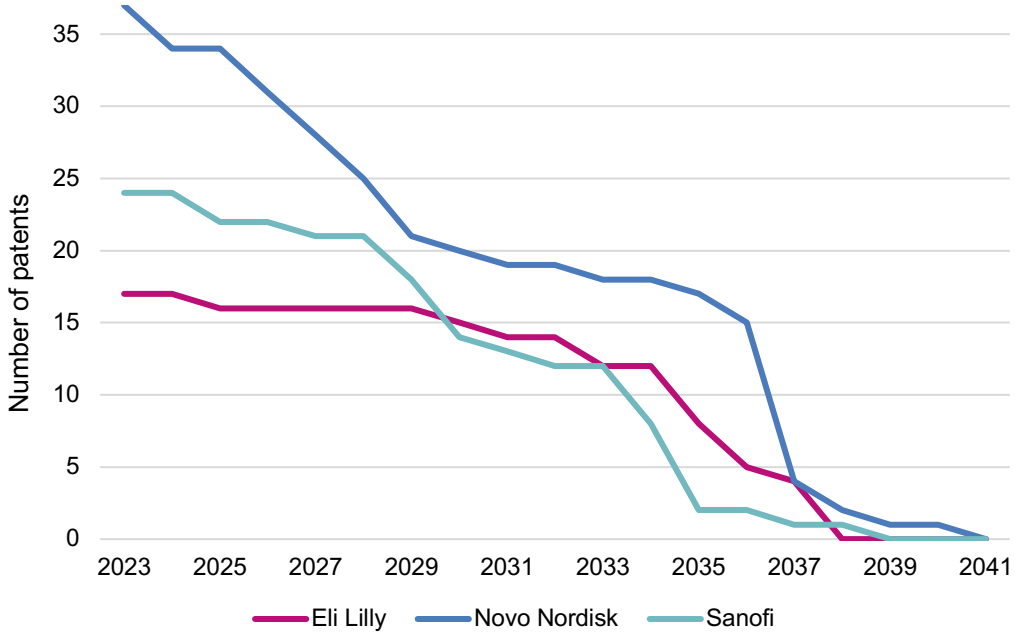
I also obtained information from the companies' most recent annual reports (for year 2022) to provide complementary insights about patent protection on their insulins. Eli Lilly's annual report did not contain information about any insulins in their summary of "most relevant U.S. patent protection or data protection and associated expiry dates for [Eli Lilly's] major or recently launched patent-protected marketed products" (Eli Lilly, 2022). Table 11 below summarizes said data from Novo Nordisk and Sanofi:

Table 11. Patent coverage on Novo Nordisk and Sanofi insulins

Novo Nordisk	
Tresiba	Patent coverage until 2029
Ryzodeg	Patent coverage until 2029
Xultophy	Patent coverage until 2029
Fiasp	Patent coverage until 2030
Sanofi	
Lantus	Patent coverage until April 2033
Toujeo	Patent coverage until May 2031

Source: Novo Nordisk 2022 annual report; Sanofi 2022 annual report

Figure 12. Big Three's insulin-related patents over time



Source: Orbis; Company annual reports

Figure 12 above presents the duration of each company's patents, with the last one expiring in 2040. Conclusions from the data presented above must be drawn with utmost consideration, as the above-presented patent landscape most likely does not account for all insulin-related patents owned by each company. Moreover, I could not match individual patents with specific drugs. It is reasonable to assume that some of these patents, especially the newer ones, relate to ongoing research into innovations that have not yet been approved for use in patients and it is not yet known whether they will be. However, my research provides two main findings.

Firstly, it is evident that overall, each company's intellectual property portfolio contains tens of thousands of patents, thus indicating that each manufacturer's firm value largely depends on them as assets. The insulin manufacturers are also transparent about this importance in their annual reports:

"We depend on products with intellectual property protection for most of our revenues, cash flows, and earnings; the loss of effective intellectual property protection for certain of our products has

resulted, and in the future is likely to continue to result, in rapid and severe declines in revenues for those products."

Eli Lilly 2022 Annual report

"Among our flagship products, Lantus, Lovenox and Plavix already face generic competition on the market. Lantus[6] is particularly important; it was one of Sanofi's leading products in 2022 with net sales of €2,259 million. […] More generally, an expiration of effective intellectual property protections for our products typically results in the market entry of one or more lower-priced generic competitors, often leading to a rapid and significant decline in revenues on those products."

Sanofi 2022 annual report

The companies' insulin-related active patents indicate that their oligopolistic grasp over the insulin market may prevail for years to come. Secondly, but perhaps more importantly, findings reveal that the extent of opaqueness in the companies' intellectual property portfolio is substantial. Even the most advanced methodologies used by researchers for patent landscaping are limited and cannot provide a definite answer as to how many patents protect a single given drug.

4.5 Global Wealth Chains

The theoretical framework of GWC governance created by Seabrooke and Wigan (2017) can provide an understanding of the relationships and mechanisms that enable lead firms in the insulin market to create and protect their intellectual property-based wealth chains. Importantly, the authors emphasize that the five types of GWCs that they distinguish between "are not "silos" but can interact with each other" (Seabrooke & Wigan, 2017, p. 10).

[6] Sanofi's best-selling insulin

Moreover, especially in the case of MNCs, firms may have more than one type of wealth chain (e.g., off the shelf tax products, intellectual property rights, etc.). Thus, depending on the type of wealth being protected, one firm's wealth chains may be analyzed from more than one perspective, and potentially fit multiple types of GWC governance. For this thesis, I will analyze the insulin firms' wealth chains in the context of their intellectual property rights. It should be noted that this is not the only context these companies' GWC governance may be analyzed in and that its other wealth chains may not necessarily fit the characteristics of their IP assets.

As described already in the Literature Review section, Seabrooke and Wigan name three types of actors in their theory: the Client, the Supplier, and the Regulator. In this case, in the context of insulin companies and their intellectual property, the "Big Three" insulin manufacturers are the Clients, the United States Patent and Trademark Office is their Supplier, and any relevant regulatory bodies who have the mandate to regulate them constitute the Regulator.

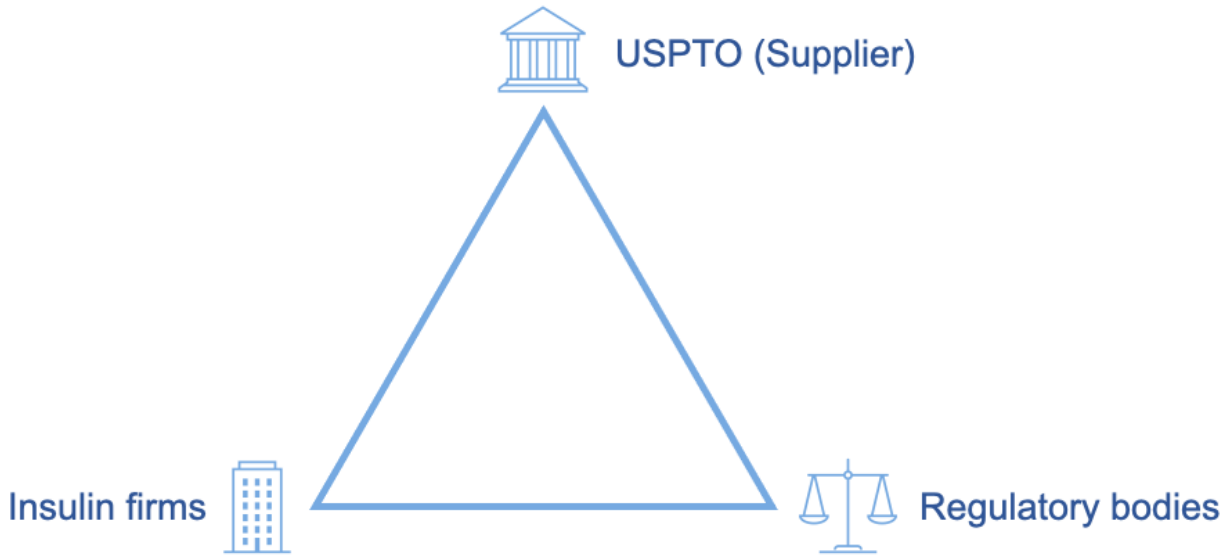
In the theoretical framework of GWC governance, the Modular type is characterized by low information asymmetry between the three types of actors. Modular forms should not be difficult to trace, in principle. This is, in fact, the case for lead insulin firms' intellectual property rights. It may seem counter-intuitive to state so, having emphasized the opaqueness of the three companies' intellectual property portfolios. However, that lack of transparency concerns the difficulty in matching patents to individual drugs, while the information is out there. Here, in the analysis of GWC governance, the perspective is broader and concerns the firms' intangible assets as a whole. Of course, that is not to diminish the significance of the opaqueness surrounding it, but it also cannot be said that there is a high degree of information asymmetry in this case.

If one considers the companies' IP portfolios from this wider perspective, information asymmetry is low between all three actors. The USPTO grants patents to the insulin firms within the framework of the U.S. legal system and none of the activity is illicit. Information is thus available to the Regulator. Although the granting of patents is entirely legal, a range of

actors deems it exploitative of the patent system or has the opinion that the U.S. patent system should be changed to prevent overpatenting of drugs. These actors include nongovernmental organizations (e.g., previously mentioned I-MAK) and the Regulator themselves. In February 2023, the Senate Judiciary Committee passed legislation aimed at preventing pharmaceutical companies' anti-competitive behavior through making changes to the patent system, one of the solutions being to improve cooperation between the FDA and the USPTO (Wilkerson, 2023). As the authors point out, in the Modular form it is the lack of political will that allows for this type of governance. Despite some actions on the part of legislators to initiate reform in the patent system, this is a demanding challenge that will require significant political momentum.

Figure 13 below illustrates the degree of information asymmetry between the three actors.

Figure 13. Modular GWC governance of insulin manufacturers



At the same time, the case of insulin MNCs and their IP rights exhibits some characteristics of the Hierarchy form of GWC governance. Authors of the GWC governance framework explain that in this form, the Client and the Supplier have a collective dominant position in the market" that allows them to increase "the pace of financial and legal innovation" (Seabrooke & Wigan, 2017, p. 16). Moreover, the authors point out that the Regulator has "little capacity to keep pace with innovations" (Seabrooke & Wigan, 2017, p. 16). These characteristics mostly apply to the insulin MNCs. Eli Lilly, Novo Nordisk, and Sanofi themselves have a dominant position in the market – they collectively control around 99 percent of its value. They also each have a substantial share of it, with Novo Nordisk controlling 44.6% percent of the value. The USPTO – the Supplier – is a highly influential actor, with full control over who patents are granted to.

Furthermore, it is a challenge for the regulators to keep up with pharmaceutical companies' legal innovations pertaining patent strategies, such as: patent evergreening, patent thickets, and patent litigation. These are all actions that the insulin firms do legally, but they have proven to be anti-competitive, thus posing a challenge for the regulators – any significant reform will require a lot of political will and a lot of knowledge about the legal innovations that this concerns, likely more than the Regulator has gathered thus far.

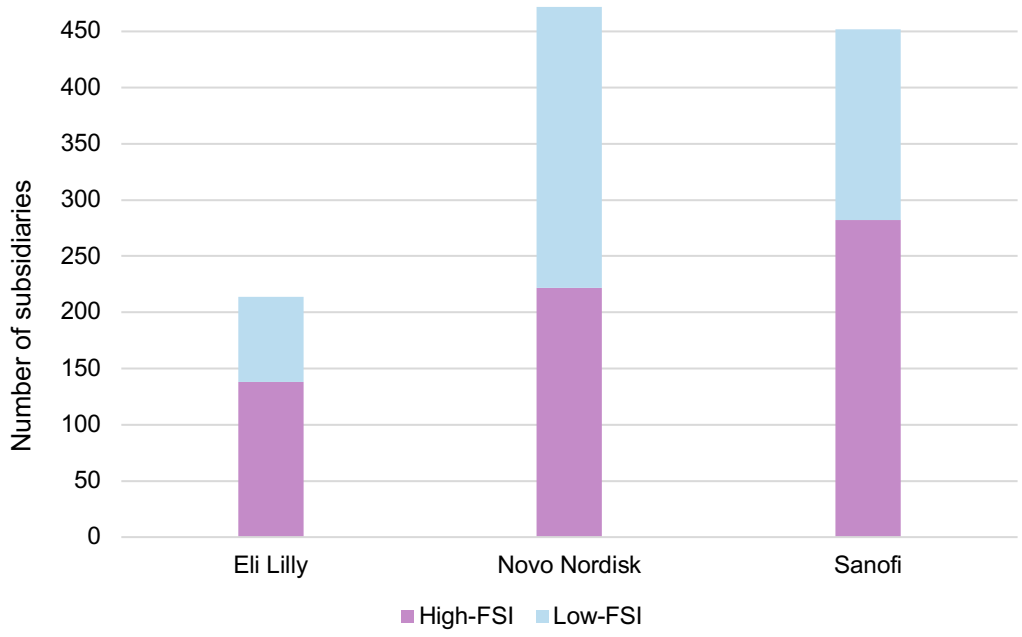
Only a closer and detailed investigation into the individual subsidiaries of each firm could provide an overview of value-creating vs wealth-creating entities (Dahl, 2022). Although I do not carry out such a detailed analysis in this thesis, as this study is focused more on intellectual property portfolios than corporate network mapping. I conducted preliminary searches on some of the subsidiaries that were listed for each company in the Orbis database. My search revealed that some entities were dormant, some were R&D facilities, and for some of them it was difficult to obtain information about their purpose of business. Among U.S.-based entities, multiple were located in Delaware – by many experts labeled a "tax haven". The Delaware state does not tax intangible assets, which encourages businesses to set up entities in the jurisdiction (Semuels, 2016). No firm conclusions can be drawn from this preliminary finding, as I did not carry out a detailed analysis on how many entities each firm has set up in Delaware, but this is worthy of further investigation. The United States is a large and developed economy,

thus it is likely that a significant number of the firms' U.S. subsidiaries are value-creating entities (e.g., R&D facilities or production plants). However, especially for Novo Nordisk and Sanofi which are not U.S.-based, their remarkable embeddedness in this one jurisdiction is striking.

I also deployed the Orbis database to analyze each company's subsidiaries based on the Tax Justice Network's Financial Secrecy Index for each jurisdiction. The FSI is a ranking based on an investigation into the level of financial secrecy that each jurisdiction allows for in their laws (Financial Secrecy Index 2022, n.d.). If a country has a score above 60, it is likely that entities located in it serve wealth-maximizing objectives rather than value creation (Seabrooke & Wigan, 2016). The Tax Justice Network evaluates "secrecy" based on four dimensions: ownership registration, legal entity transparency, integrity of tax and financial regulation, and international standards and cooperation (Secrecy Indicators, n.d.).

The figure below provides an overview of the three firms' subsidiaries based on the FSI value of each jurisdiction that the company has set up entities in. Subsidiaries are classified as low-FSI if they have a score up to 60 on the ranking, and as high-FSI it the score is above 60.

Figure 14. Big Three's subsidiaries based on their FSI value



Source: Orbis; Tax Justice Network

The findings demonstrate that each MNC has a substantial number of entities located in high-FSI jurisdictions. For Eli Lilly and Sanofi, they constitute more than half of all subsidiaries. As demonstrated in a previous section the analysis, all companies have a large number of U.S.-based subsidiaries. The United States has a FSI score of 67 and makes for a significant percentage of each company's high-FSI entities. However, each company still has many high-FSI entities that are not located in the United States – common locations are Singapore, Switzerland, or the Cayman Islands. These findings demonstrate a strong likelihood that among the 100+ (for Eli Lilly) and 200+ (for Novo Nordisk and Sanofi) high-FSI entities that each company owns, there are multiple that serve wealth-maximizing objectives. Without a further investigation, the case is more ambiguous for Eli Lilly, as 87 out of its high-FSI subsidiaries are located in the United States which is its native country, thus it is expected for the company to have set up many entities in that jurisdiction.

5 Discussion

This thesis has sought to better understand the broader political, legal, and economic determinants of high insulin list prices. It has largely focused on the aspect of intellectual property as contributing to the monopolization of the insulin market – which is almost entirely controlled by three MNCs. This study has also consisted of an analysis of the three lead firms' profit distribution. Further, each company's subsidiaries and sales have been analyzed to provide a (mainly quantitative) understanding of the firms' embeddedness in the U.S. jurisdiction. Moreover, profit distribution was investigated to understand the extent of each company's financialization. Lastly, the theoretical framework of GWC governance was employed to provide a more conceptual understanding of insulin companies' wealth-related activity, particularly in the context of their relationships with the U.S. regulatory bodies.

Firstly, findings have demonstrated that each company operates based on a somewhat financialized business model – with all three insulin manufacturers reporting multi-billion shareholder payouts yearly. However, findings suggest that Novo Nordisk is the most financialized out of the three – with a significantly higher spending on dividends and share buybacks in relation to spending on R&D. A comparison between the companies' TTM to R&D ratios has shown that they differ substantially – in some years, Novo Nordisk's ratio was even five times higher than Eli Lilly's, and typically 2-3 times higher than Sanofi's. Ranging between 1.9 and 2.7 in the past decade (2013-2022), Novo Nordisk has routinely spent the equivalent of double or more of its R&D spending on shareholder payouts.

These findings echo Lazonick et al.'s (2017) argument that in pharmaceutical companies there is a tension between financialization and innovation, and that a key factor that contributes to said tension is the extent of share repurchasing that pharmaceutical MNCs engage in. In their research, Palladino and Lazonick (2021) analyze pharmaceutical companies' spending on stock buyback against the firms' routine argument that high drug prices are a prerequisite for investment in R&D. Based on Eli Lilly's high spending on R&D in relation to its shareholder

payouts, this argument may have some truth to it. For Sanofi, this is more ambiguous, as their Net Shareholder Payout is in many years close to or equivalent to their spending on R&D. For Novo Nordisk, however, data on profit distribution clearly demonstrates that the company has in the past 15 years prioritized using corporate funds for stock buybacks and dividend payouts. Thus, due to the tension between the two, its R&D expenditure has been relatively reduced.

Data on the insulin companies' subsidiaries has demonstrated that Novo Nordisk and Sanofi display a remarkable embeddedness in the U.S. jurisdiction, despite them being headquartered in Denmark and France, respectively. The two companies exemplify the "post-national or decentered multinational corporation" that Seabrooke and Wigan (2017, p. 1) refer to in their work on GWC governance. Novo Nordisk and Sanofi produce a substantial share of their products in countries other than the United States (Novo Nordisk Kalundborg, n.d.; Sanofi, 2021), yet each firm has set up more entities in that jurisdiction than anywhere else. Simultaneously, for both companies, a significant portion of their research and development activities are still carried out in their native countries. Therefore, the two MNCs rely on their home countries' resources (e.g., their highly skilled employees) for a substantial share of their value-creating activities. Further, in the case of Novo Nordisk, the company's sales to North America (most of which account for the United States) equal to about half of its global net sales, as evidenced by the findings. Thus, there is a significant disjuncture between where the firm extracts its wealth and where its value is created.

Birch and Muniesa (2020) contend that the primary basis of contemporary capitalism is not the commodity but the asset. The authors define an asset as "something that can be owned or controlled, traded, and capitalized as a revenue stream" (Birch & Muniesa, 2020, p. 14). This perspective on assets is well-reflected in the insulin lead firms' treatment of their intellectual property portfolios. Findings from the companies' annual reports show that the companies' revenues greatly depend on patent protection of their drugs – especially the best-selling ones. The companies report openly that the loss of intellectual property protection over their most popular drugs would likely result in "rapid and severe declines in revenue".

As Kang (2020) notes, contemporarily, patents are often valued based on future expected returns they may bring, while financial forecasting rarely accounts for the genuine quality of a patent in its scientific realm. Because of this, MNCs have been incentivized to pursue intellectual property portfolios made up of large quantities of patents. Researchers often refer to the lack of transparency in firms' IP portfolios, and the fact that the assetization of patents constitutes an empirical blind spot. Data analyzed in this study has echoed these statements. Even leading researchers studying drug patents face this limitation and note that pharmaceutical companies often use terms in patent documentation that obfuscate the claimed invention. Feldman (2018, p. 596) notes that "transparency is not in the industry's interest". Although, as presented in the analysis, insulin companies operate within the realm of legal systems, their patent strategies tend to be opaque to prevent competition. Findings have shown that insulin manufacturers also resort to patent litigation to halt potential biosimilars from entering the market.

This study has provided insights about the companies' insulin-related patents. Although likely the analysis has not accounted for all of them, it has demonstrated that each company's portfolio is made up of multiple (or in the case of Novo Nordisk and Sanofi – dozens) of insulin-related patents. Although compounds of most insulin analogs on the market are no longer patent-protected – each insulin manufacturer has extended its monopoly by filing additional patents that may refer to, for instance, the method of delivery. Because insulin companies often employ this strategy of "patent evergreening", individual patents lose their value but become wealth-creation devices.

Ideationally, the intellectual property system rests on the assumption that patent protection incentivizes innovation. However, pharmaceutical companies' have been employing strategies that circumvent this assumption. Moreover, the high degree of financialization that Novo Nordisk demonstrates leads to an opposite effect – in which shareholder payouts outweigh R&D spending, thus halting innovation rather than promoting it.

Intellectual property assets are intangible, thus hard to value but easy to move (Lochhead, 2012). The theoretical framework of GWC governance offers an understanding of how the three insulin firms' dominant position in the market has enabled them to utilize patent strategies to maintain monopoly and simultaneously obfuscate said activity. Although the degree of information asymmetry between actors is low to moderate, the intrinsic complexity of intellectual property makes it difficult to link individual patents to individual drugs. Assetization of patents has made them abstract forms of capital, where a substantial disjuncture emerges between their financial value and their scientific quality.

Findings have shown significant differences between the three insulin companies – both in the degree of financialization and in their IP portfolios. Novo Nordisk is most distinctive – it displays the highest degree of financialization in their profit distribution and has the largest number of insulin-related patents. Novo Nordisk also has a relatively narrow drug portfolio compared to its two competitors and thus is most reliant on insulin sales for its revenues. The Danish company makes about half of its net sales in the United States and therefore depends heavily on prices there. For the leading insulin firms, profits would not be experiencing such substantial increases over the past 15 years were it not for their ability to hold so many patents, thereby ensuring oligopolistic market conditions. This study holds important insights about the interactions between the legal system of IP rights protection and the financialized model of corporate governance employed by the three companies.

6 Conclusion

This thesis has further developed the present understanding of the interrelatedness of pharmaceutical monopolies, financialization, and intellectual property rights protection. Although distinctive, the case of insulin prices is representative of a greater issue. Pharmaceutical manufacturers have been incentivized to rely on intellectual property

portfolios made up of large quantities of patents to extend and maintain a monopolistic grasp on their markets. Moreover, contemporarily, many pharmaceutical MNCs operate based on highly financialized business models, according to which they are expected to continuously deliver short-term returns to their shareholders. Both determinants lead to upward pressure on drug prices. At the same time, or as a result, pharmaceutical companies lack incentive to conduct long-term research – which carries higher risks but is critically needed for significant therapeutic advances. Investments in R&D should be one of the driving forces behind public health but are increasingly made at its cost.

The complexity of legal and financial structures within corporations has made it difficult to keep up with the pace of evolving corporate strategies aimed at halting competition in drug markets. Certain empirical blind spots persist but the literature already offers critical findings that suggest that intellectual property systems require a reform. In further research, existing theories of international political economy and related fields could support a more in-depth and detailed understanding of the complexities of profits, innovation, and access in the pharmaceutical industry. However, while researchers may continue to refine their methodologies and to seek further findings, there is a need for greater transparency. While U.S. legislators have taken steps in this direction, the urgence of the drug pricing crisis calls for definitive action. While many therapeutic advances remain needed and undiscovered, access to existing ones also remains a challenge. Thus, public policy that supports innovation while ensuring access to existing therapies is required, especially to protect the most vulnerable.

References

Affordable Insulin Now Act, S.3700, 117th Cong. (2021-2022). https://www.congress.gov/bill/117th-congress/senate-bill/3700

Birch, K., Muniesa, F. (2020). Introduction: Assetization and Technoscientific Capitalism. In K. Birch & F. Muniesa (Eds.), *Assetization: Turning Things into Assets in Technoscientific Capitalism*. The MIT Press.

Bourgeron, T., Geiger, S. (2022). (De-)assetizing pharmaceutical patents: Patent contestations behind a blockbuster drug. *Economy and Society, 51*(1), 23-45. https://doi.org/10.1080/03085147.2022.1987752

Collington, R. (2020, March). *Profits, Innovation and Financialization in the Insulin Industry*. (Working Paper No. 120). Institute for New Economic Thinking. https://www.ineteconomics.org/uploads/papers/WP_120-Collington-The-insulin-industry.pdf

Dahl, M. H. (2022). Beer and Pharmaceuticals. In L. Seabrooke & D. Wigan (Eds.), *Global Wealth Chains*. Oxford University Press. DOI: 10.1093/oso/9780198832379.003.0007

Drahos, P. (2003, November 30). *Expanding Intellectual Property's Empire: the Role of FTAs*. GRAIN. https://www.grain.org/media/W1siZiIsIjIwMTEvMDcvMjUvMDZfMjhfMjRfNzUxX2RyYWhvc19mdGFfMjAwM19lbi5wZGYiXV0

Drahos, P. (2016). *A Philosophy of Intellectual Property*. Taylor & Francis Ltd.

Durand, C., & Milberg, W. (2020). Intellectual monopoly in global value chains. *Review of International Political Economy, 27*(2), 404-429. https://www.tandfonline.com/doi/full/10.1080/09692290.2019.1660703

FDA Purplebook. (n.d.). https://purplebooksearch.fda.gov/faqs

Feldman, R. (2018). May your drug price be evergreen. *Journal of Law and the Biosciences*, *5*(3), 590–647. https://doi.org/10.1093/jlb/lsy022

Financial Secrecy Index 2022. (n.d.). https://fsi.taxjustice.net/

Fligstein, N. (1996). Markets as Politics: A Political-Cultural Approach to Market Institutions. *American Sociological Review, 61*(4), 656-673. https://doi.org/10.2307/2096398

Gereffi, G., Humphrey, J., & Sturgeon, T. (2005). The governance of global value chains. *Review of International Political Economy, 12*(1). 78-104. https://www.tandfonline.com/doi/abs/10.1080/09692290500049805

Grassley, C. E., Wyden, R. (2022). *Insulin: Examining the Factors Driving the Rising Cost of a Century Old Drug*. United States Senate Finance Committee. https://www.finance.senate.gov/imo/media/doc/Grassley-Wyden%20Insulin%20Report%20(FINAL%201).pdf

Health Action International. (2016). *Insulin Patent Profile*. https://haiweb.org/wp-content/uploads/2015/05/HAI_ACCISS_factsheet_insulinpatent.pdf

Hernandez, I., San-Juan-Rodriguez, A., Good, C.B., Gellad, W.F. (2020). Changes in List Prices, Net Prices, and Discounts for Branded Drugs in the US, 2007-2018. *JAMA 323*(9), 854–862. https://doi.org/10.1001/jama.2020.1012

I-MAK. (2018). *Lantus (insulin glargine)*. http://www.i-mak.org/wp-content/uploads/2018/10/I-MAK-Lantus-Report-2018-10-30F.pdf

I-MAK. (2022). *Patent Search Methodology*. https://www.i-mak.org/wp-content/uploads/2022/09/Overpatented-Patent-Methodology-2022-09-08.pdf

Kang, H. Y. (2020). Patents as Assets: Intellectual Property Rights as Market Subjects and Objects. In K. Birch & F. Muniesa (Eds.), *Assetization: Turning Things into Assets in Technoscientific Capitalism*. The MIT Press.

Knox, R. (2020). Insulin insulated: barriers to competition and affordability in the United States insulin market. *Journal of Law and the Biosciences*, 1-25. https://doi.org/10.1093/jlb/lsaa061

Langley, P. C. (2021). Assets and assetization in financialized capitalism. *Review of International Political Economy*, *28*(2), 382–393. https://doi.org/10.1080/09692290.2020.1830828

Langreth, R. (2011, February 9). Novo Nordisk's Medical Miracle. *Forbes*. https://www.forbes.com/forbes/2011/0228/features-lars-sorensen-novo-nordisk-medical-miracle.html?sh=5d134ab2291f

Lazonick, W., Hopkins, M., Jacobson, K., Sakinç, M. E., Tulum, Ö. (2017, July). *US Pharma's Financialized Business Model*. (Working Paper No. 60). Institute for New Economic Thinking. https://www.ineteconomics.org/uploads/papers/WP_60-Lazonick-et-al-US-Pharma-Business-Model.pdf

Lonergan, B. (1992). *Insight: A Study of Human Understanding* (Vol. 3). University of Toronto Press.

López, J., & Potter, G. (2005). After Postmodernism: An Introduction to Critical Realism. Bloomsbury Publishing.

Mulcahy, A. W. (2020, October 6). *Comparing Insulin Prices in the United States to Other Countries: Results from a Price Index Analysis*. RAND. https://www.rand.org/pubs/research_reports/RRA788-1.html

Mulcahy, A. W. (2021, January 28). *International Prescription Drug Price Comparisons: Current Empirical Estimates and Comparisons with Previous Studies*. RAND. https://www.rand.org/pubs/research_reports/RR2956.html

Novo Nordisk Kalundborg. (n.d.). https://www.novonordisk.com/careers/career-areas/manufacturing/novo-nordisk-kalundborg.html

One in four patients say they've skimped on insulin because of high. (2018, December 3). YaleNews. https://news.yale.edu/2018/12/03/one-four-patients-say-theyve-skimped-insulin-because-high-cost

Palladino, L., Lazonick, W. (2021, May). *Regulating Stock Buybacks: The $6.3 Trillion Question*. (Working Paper). Roosevelt Institute. https://rooseveltinstitute.org/wp-content/uploads/2021/04/RI_Stock-Buybacks_Working-Paper_202105.pdf

Rajkumar, S. V. (2020). *The High Cost of Insulin in the United States: An Urgent Call to Action.* Mayo Clinic. https://www.mayoclinicproceedings.org/article/S0025-6196(19)31008-0/pdf

Sanofi. (2021). *Excellence in Manufacturing and Supply*. https://integrated-report.sanofi.com/strategy/committed-to-excellence-in-manufacturing-and-supply/

Sæther, B. (1998). Retroduction: An alternative research strategy? *Business Strategy and the Environment*, *7*, 245–249. https://doi.org/10.7748/ns.6.28.54.s53

Schwartz, H. M. (2019). Mo' Patents, Mo' Problems: Corporate strategy, structure and profitability in America's political economy. University of Virginia. https://uva.theopenscholar.com/files/hermanschwartz/files/mo-patents.pdf

Seabrooke, L., Wigan, D. (2016). Powering ideas through expertise: Professionals in global tax battles. *Journal of European Public Policy, 23*(3), 357-374. https://doi.org/10.1080/13501763.2015.1115536

Seabrooke, L., Wigan, D. (2017). The governance of global wealth chains. *Review of International Political Economy, 24*(1). 1-29. https://www.tandfonline.com/doi/full/10.1080/09692290.2016.1268189

Secrecy Indicators. (n.d.). https://fsi.taxjustice.net/secrecy-indicators/

Sell, S. K. (2002). Intellectual Property Rights. In A. McGrew & D. Held (Eds.), *Governing Globalization: Power, Authority and Global Governance*. Wiley.

Sell, S. K. (2003). *Private Power, Public Law: The Globalization of Intellectual Property Rights*. Cambridge University Press.

Sell, S. K. (2010). The rise and rule of a trade-based strategy: Historical institutionalism and the international regulation of intellectual property. *Review of International Political Economy*, *17*(4), 762–790. https://doi.org/10.1080/09692291003723722

Sell, S. K. (2017). The Politics of International Intellectual Property Law. In W. Sandholtz, J. A. McCone, & C. A. Whytock (Eds.), *Research Handbook on the Politics of International Law*. Edward Elgar Publishing.

Semuels, A. (2016, October 11). Delaware as a Tax Haven. *The Atlantic*. https://www.theatlantic.com/business/archive/2016/10/dont-blame-delaware/502904/

Standing, G. (2016, September 5). *The left must combat rentier capitalism*. openDemocracy. https://www.opendemocracy.net/en/opendemocracyuk/we-must-combat-rentier-capitalism/

Types of Insulin. (n.d.). https://dtc.ucsf.edu/types-of-diabetes/type2/treatment-of-type-2-diabetes/medications-and-therapies/type-2-insulin-rx/types-of-insulin/

Walker, T. (2017). Approaches to Critical Realism: Bhaskar and Lonergan, *Journal of Critical Realism*, *16*(2), 111-127. https://doi.org/10.1080/14767430.2017.1288062

Wilkerson, J. (2023, February 9). Senate panel passes drug patent reforms, but not without dissent. *STAT*. https://www.statnews.com/2023/02/09/senate-panel-passes-drug-patent-reforms/

Yin, R. K. (2015). Case Studies. In J. D. Wright (Eds.), *International Encyclopedia of the Social & Behavioral Sciences* (pp. 194-201). Elsevier. https://doi.org/10.1016/B978-0-08-097086-8.10507-0